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# Pharmaceutical services for patients in methadone treatment in Ireland and the introduction of the Methadone Protocol Scheme

Being submitted for the Degree of Doctor of Philosophy at
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by

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## **Declaration**

I declare that this thesis has not been submitted as an exercise for a degree at this or any other university and that it is my own work except where acknowledged.

I agree that Trinity College may lend or copy this thesis upon request.

Síle O'Connor

## **Acknowledgements**

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## **Summary**

Methadone is a long-acting opiate commonly used in substitution therapy for heroin addiction. In Ireland, prior to 1998, people requiring treatment for opiate addiction could either attend the National Drug Treatment Centre, where low dose, short-term methadone treatment was available, or they could attend a limited number of private general practitioners (GPs), who were prepared to prescribe methadone linctus (Physeptone®). In 1998, the Misuse of Drugs Act (Supervision of Prescription and Supply of Methadone) Regulations were introduced and resulted in the implementation of the Methadone Protocol Scheme (MPS). Under the MPS only methadone 1mg/ml could be prescribed for the treatment of opiate addiction and free prescribing and dispensing services were made available to all.

This research project set out to examine, for the first time, the extent and nature of pharmaceutical services for patients in methadone treatment in Ireland before and after the introduction of the MPS. It examines this aspect of the MPS from the perspective of both service providers and service users, using both quantitative and qualitative research techniques.

A postal survey undertaken among all community pharmacies in the southern sectors of the EHB region eight months prior to the introduction of the MPS showed that 29% of respondents were dispensing methadone (either methadone 1mg/ml, Physeptone® or both). In addition, 22% of these pharmacists were supervising the on-site consumption of methadone at that time. This survey also identified a number of barriers to service provision among non-participating pharmacies.

A second postal survey of community pharmacies who dispensed methadone 1mg/ml, which was undertaken two months before the introduction of the MPS, showed that 36% of all community pharmacies dispensing methadone 1mg/ml in Ireland were supervising dose consumption on-site. Dispensing methods were not always in accordance with Pharmaceutical Society of Ireland best practice guidelines (1996), with child-resistant containers and pharmaceutical measures being used inconsistently. Community

pharmacists participating in the MPS were positive about their own ability to contribute to patient care, and 49% reported that they found it satisfying working with drug misusers. This was offset by the majority of pharmacists (54%) reporting that they found it difficult to cope with abusive patients and 65% said that they had fears that on-site supervision could damage their business interests.

A third postal survey among community pharmacies participating in the MPS six months after its introduction found on-site supervision in 48% of responding pharmacies. This survey also found that the Pharmaceutical Society of Ireland's dispensing guidelines for "take-home" methadone doses were still not uniformly applied, although there had been a statistically significant increase in the supply of pharmaceutical measures with multidose methadone dispensings compared to the earlier survey prior to the introduction of the MPS. Thirty-eight percent of respondents reported that they had experienced problems with patients on methadone, problems with which they needed external support. They also reported that the liaison pharmacists had had some success in providing support for them. Pharmacists' attitudes included a "confidence" in their professional ability to manage patients on methadone and a need to "control" their patients, arising from their personal fears and concerns.

A longitudinal analysis of the responses of those involved in the multiple community pharmacy surveys showed a fall in the mean number of patients per pharmacy following the introduction of the MPS and an increase in the provision of on-site supervision. It also indicated an increase in the use of pharmacy/patient contracts.

A retrospective study of the queries handled by the liaison pharmacy service in the two southern sectors of the EHB region over a one-year period encompassing the introduction of the MPS showed that the service was widely utilised, managing queries from a number of disciplines on a variety of diverse issues. The primary sources of enquiry were EHB Addiction Service's doctors and community pharmacists. Most enquiries related to the organisation of community based methadone dispensing services but a considerable proportion related to the provision of specialist advice or peer support for the community pharmacists who dispensed methadone.

A quantitative survey of 217 patients in treatment in the MPS was carried out at the same time as the third survey of community pharmacies. Approximately half of those surveyed were attending community pharmacies while the remainder were in DTC pharmacies. The survey reported high frequency attendance and supervision regimens, particularly among patients in DTC pharmacies. Given a choice, 60% of respondents would have chosen to attend their methadone dispensing services on a once weekly basis while 11% would choose to attend at least four days each week. Three- quarters of those surveyed were currently drinking methadone under supervision and 87% had previously done so. Given a choice, seventy percent of respondents would have preferred not to drink methadone under supervision but 24% would self-select to drink at least some doses on-site. Most patients expressed a preference for attending community pharmacies, as opposed to DTC pharmacies.

As found in the concurrent survey of community pharmacies, patients also reported poor compliance with the Pharmaceutical Society of Ireland's guidelines in relation to the supply of "take-home" methadone doses. Most patients reported being "happy" with their current dispensing regimens and having "good relationships" with the pharmacists who dispensed their methadone. In addition, most reported short waiting times for their methadone to be dispensed and the majority of those who had been affected by the introduction of the MPS reported that it had had a positive impact on them. Side effects were commonly associated with taking methadone, with many patients reporting that these side effects continued throughout treatment.

The first ever qualitative investigation of Irish users' views of pharmaceutical services under the MPS was carried out two years after this survey of patients' views. Its findings also indicated that patients recognised the value of on-site supervision in some circumstances, but emphasised the importance of providing adequate privacy throughout the supervision process, particularly in the community pharmacy setting. Respondents described individualised dosing routines and identified a number of difficulties associated with taking their methadone at home.

Contrary to the earlier survey of patients' views, where the majority expressed a preference for attending a community pharmacy, participants in this study believed that

both community pharmacies and DTC pharmacies were useful in the treatment of opiate addicts. Community pharmacies were more convenient and had longer opening hours while DTC pharmacies offered more support services. Respondents described an underlying tension in the pharmacist/patient relationship, which was characterised by the use of unduly strict pharmacy/patient contracts in community pharmacies. They also outlined an absence of mutual trust, which could result in conflict and resentment in the community pharmacy.

Respondents described a number of limitations to the exclusive use of methadone 1mg/ml in the treatment of opiate addiction. As in the earlier survey, there were reports of side effects associated with methadone and much discussion around the importance of methadone's formulation, with methadone 1mg/ml being perceived as less effective than Physeptone®.

The results of these studies provide unique insight into pharmaceutical services under the MPS, which will be invaluable for both policy makers and practitioners in the development of future treatment initiatives for Irish opiate addicts.

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## **Abbreviations**

CDTL Central Drug Treatment List

DOHC Department of Health & Children

DTC Drug Treatment Centre

EHB Eastern Health Board

ERHA Eastern Region Health Authority

GA General Assistant

GP General Medical Practitioner

ICGP Irish College of General Practitioners

IPU Irish Pharmaceutical Union

MPP Methadone Pilot Project

MPS Methadone Protocol Scheme

MV Missing values

Phy Physeptone®

PSI Pharmaceutical Society of Ireland

# **CHAPTER 1**

# Introduction

#### 1.1. OPIATE ADDICTION & SUBSTITUTION THERAPY WORLD-WIDE

By the 1990's the misuse of opiates, namely heroin, was recognised as a serious social problem in Ireland (Butler 1991, O'Farrell et al 2001). On a world-wide scale, heroin misuse was associated with raised mortality rates (Janssen et al 1989) and misusers were at high risk from infectious disease due to unsafe injecting and sexual practices and concurrent involvement in prostitution (Walger et al 1989, Gossop et al 1993 & 1995). In addition, untreated heroin misuse resulted in substantial costs for the criminal justice and healthcare systems (Healey et al 1998), with many heroin misusers also experiencing psychological problems resulting in contact with mental healthcare services (Gossop et al 1998).

The treatment of heroin addiction has been addressed in a number of ways, one of which involves using alternative opiates as substitutes for heroin. These substitution programmes reduce the harm associated with opiate addiction by offering patients a legal alternative to illicit heroin, an alternative which is usually orally active and has a longer half-life than heroin, thereby facilitating less frequent dosing via the oral route. The benefits of such programmes are described by Gronbladh and colleagues (1990), Pottieger and colleagues (1992), Caplehorn and colleagues (1996), Gossop and colleagues (2001) and Petitjean and colleagues (2001).

The nature of the substitution treatment provided for opiate addicts is dependent on a number of factors including the local political and economic climate. It can vary in philosophy from abstinence orientated treatment which aims for drug-free living, to harm reduction treatment which accepts that some people may continue to use drugs and aims to create an environment where they can do so as safely as possible. Substitution treatment can also vary its service delivery mechanisms, with some treatment programmes being delivered within primary care, others by tertiary (i.e. specialist) drug treatment services or by a combination of both primary and tertiary carers. Substitution treatment can also differ in the opiate that is prescribed as an alternative to heroin.

There are positive and negative aspects to any treatment modality adopted. For example, some studies suggest that the provision of community-based services may diminish some of the negative aspects of methadone treatment by reducing patients'

contact with active drug misusers and the drug scene (O'Connor et al 1996) and that patients may do at least as well in community-based compared to tertiary treatment services (Lewis & Bellis 2001). One study suggests that patients may do even better in primary compared to tertiary care, if their carers have positive attitudes towards them (Gabbay et al 1996). But conflicting paradigms such as the traditional "patient/doctor" relationship with emphasis on continuity of care versus substance abuse treatment models that employ limit-setting methods and behavioural consequences can result in tension when methadone treatment is provided in the primary care setting (Herman & Gourevitch 1997).

Methadone is commonly used in substitution therapy for the treatment of heroin addiction in many European countries, in Australia and in the US, but some recent studies have focussed on alternative opiates such as buprenorphine and levo-alpha-acetylmethadol (LAAM) (Pani et al 2000, Ling et al 2001, Petitjean et al 2001). LAAM has recently been associated with clinically significant side effects, so that it is no longer recommended for first line use (FDA 2001). However, although it is not currently recommended for the treatment of opiate addiction in Ireland, buprenorphine is commonly prescribed as an alternative to methadone in the treatment of heroin addiction elsewhere in Europe (EMCDDA 2000a, Duburcq et al 2000) and has been shown to yield treatment outcomes similar to those of methadone (particularly in terms of illlicit opiate use) both in Europe (Fischer et al 1999b) and in the US (Schottenfeld et al 1997).

#### 1.2. THE VALUE OF METHADONE IN THE TREATMENT OF OPIATE ADDICTION

The usefulness of methadone in the treatment of opiate addiction has been well established and is broadly accepted (Gronbladh et al 1990, Ball & Ross 1991, Pottieger et al 1992, Caplehorn et al 1996). Continuous methadone maintenance treatment has been shown to eliminate or reduce illicit drug use (Bianchi et al 1992, Condelli & Dunteman 1993). Even one month of methadone treatment has been shown to reduce the amount and frequency of illicit heroin and cocaine use in a sample of London patients, with an additional reduction in injecting behaviour (Strang et al 1997). Methadone treatment has also been associated with reduced mortality among opiate addicts (NIH 1998) and with a reduction in involvement in acquisitive crime and

significant improvements in both physical and psychological health (Strang et al 1997). One study reported that patients 'feel better in themselves' - better able to cope, more in control and more self-confident when they are on methadone (Neale 1998).

More recent research also supports these findings: methadone maintenance has been shown to be cost effective in terms of life-years gained for those in treatment (Barnett 1999) and for non drug-misusing members of the population in terms of a reduction in the transmission of HIV (Zaric et al 2000). Recent research has also shown that the substitution of heroin with the longer acting methadone reduces the use of illicit drugs (Borg et al 1999, Dore et al 1999, Fischer et al 1999a, Gossop et al 2000a & 2000b, Bell & Zador 2000): reduces mortality among opiate misusers (Ward et al 1999, Caplehorn & Drummer 1999, Dore et al 1999): reduces the incidence of crimes and incarcerations (Gossop et al 1999b, Dore et al 1999, Keen et al 2000): reduces illicit drug market activity (Fischer et al 1999a) and helps patients to feel and function better (Gossop et al 1999b, Fischer et al 1999a, Dore et al 1999, Royse et al 2000).

While some service providers augment methadone treatment with on-site psychosocial supports, others offer relatively basic methadone prescribing and dispensing services. There is considerable argument in the literature, where some suggest that the ancillary services are the most important feature of any methadone treatment programme (e.g. Avants et al 1999) while other studies indicate that there is little additional benefit associated with the provision of ancillary services during methadone treatment (Yancovitz et al 1991).

While the various merits of methadone treatment are well-accepted, its value in substitution therapy is compromised by a number of negative outcomes. Risks associated with methadone treatment include an increased risk of death during induction into treatment (Caplehorn & Drummer 1999) and the risk of accidental death associated with the diversion of dispensed methadone (Bentley & Busuttil 1996). Critics of methadone treatment also point to the dangers associated with maintaining people in an addicted lifestyle (Larkin 2002).

On a practical level, the literature also associates methadone use with a number of physical and psychological side effects, including damage to teeth, weight changes,

stiffness and soreness, hallucinations, constipation, sweating, sleeping problems and tiredness (Preston 1996). Scottish patients involved in one qualitative study reported that methadone could alter people's personalities, making them violent and aggressive (Neale 1998). A survey of 45 males in methadone treatment found that they experienced an increased frequency of impotence and sexual retardation (Mintz et al 1974). While some of these negative effects have been scientifically shown to be caused by methadone, other adverse effects are incorrectly linked to its use. For example, methadone is commonly blamed for tooth decay among those in treatment, but whilst it may be a contributory factor, a study undertaken on 86 women in methadone maintenance showed a high sugar dietary intake, which may also have contributed to the high prevalence of dental caries found in the study sample (Zador et al 1996).

Despite their incidence, research has shown that the adverse effects from methadone itself rarely result in negative attitudes towards its use (Zule & Desmond 1998). In addition, specific adverse effects are often associated with one formulation of methadone (Steels et al 1992, Silver & Shaffer 1996), so that patient intolerance of one formulation may be linked to other factors such as injectability or taste. Nine out of 80 patients surveyed in Scotland said there were important differences between the methadone mixtures dispensed at different community pharmacies (Neale 1998).

As well as the negative outcomes associated with methadone treatment, its involvement in fatal and non-fatal overdose cannot be ignored, particularly when related to continued polydrug use (Oppenheimer et al 1994, Cullen et al 2000, Heinemann 2000, Ward & Barry 2001, Byrne 2001). More recently, methadone "take-home" doses have also been linked to an increased risk of death among those not in treatment and the number of methadone-related deaths was significantly higher in Edinburgh than in Glasgow (in Glasgow patients were obliged to drink their methadone on-site at community pharmacies for the first year of treatment) (Weinrich & Stuart 2000). Other research from Scotland also identified the consumption of another person's prescribed methadone as one primary cause of non-fatal overdose resulting in hospital admission (Neale 2000) and an Irish publication has suggests that supplies of "take-home" methadone have been involved in incidences of fatal overdose in children (Harkin et al 1999).

However, research has also identified multiple factors involved in determining the extent to which methadone is implicated in fatal overdose. These factors include the extent to which substitution services succeed in attracting the more insidious or "hardcore" drug misusers into treatment (Neale 2000); expansion in the addict population (Neeleman & Farrell 1997); increases in the provision of methadone services (Kaa 1992, Obafunwa & Busuttil 1994, Scott et al 1999); local variations in treatment programmes e.g. the extent of supervised dosing, (Bentley & Busuttil 1996, Scott et al 1999); polydrug and alcohol misuse (Ward & Barry 2001, Byrne 2001) and the incidence of unfavourable discharge or drop-out from treatment (Davolì et al 1993, Fugelstad et al 1995, Zanìs & Woody 1998).

# 1.3. THE IMPORTANCE OF SERVICE SITE IN METHADONE TREATMENT PROGRAMMES

While research supports the cost-effectiveness, safety and efficacy of methadone maintenance (Darke et al 1990, Des Jarlais 1992, Caplehorn et al 1996), the choice between the provision of tertiary and community-based care continues to be a dilemma. There are two aspects to patients' methadone treatment service location: their prescribing site and their methadone dispensing site. Research has shown little difference in overall treatment outcomes between patients attending prescribers in tertiary services whose methadone is dispensed by community pharmacists versus those who attend methadone prescribers and pharmacies within the tertiary treatment service setting (Gossop et al 1999a).

In terms of overall treatment, little research has been undertaken to investigate the relative value of community-based and tertiary service sites, although the work that has been carried out suggests that both have intrinsic advantages and disadvantages. Community-based methadone treatment is low profile, accessible and relatively inexpensive (Harrison 1994) and a study done in the US suggested that treatment in the community setting may result in better methadone maintenance retention rates at 6 and 12 months (MacGowan et al 1996). In addition, research has identified a patient preference for community-based methadone treatment, although it related this

preference to the prescribing rather than the dispensing site involved (Bennett & Wright 1986, Hindler et al 1995).

While community-based methadone treatment has advantages, many patients are unsuitable for management in that setting due, for example, to multiple drug addictions, alcohol problems, outstanding legal issues and psychiatric or behavioural problems. One study found that over 60% of patients in methadone treatment were unsuitable for transfer to the community (De Vries et al 1997). In addition, one Scottish study also showed that shortcomings in clinical care could be identified in the methadone-related deaths of many patients who were attending GPs (Scott et al 1999).

Tertiary drug treatment services are particularly useful in the initial and stabilisation stages of methadone treatment and have value in treating more difficult patients, who cannot be managed in the community. For example, hostility among female patients has been shown to be a predictor of early treatment termination (Petry & Bickel 2000) but the provision of tertiary drug services may facilitate their management, thereby improving retention rates. Additionally, some patients require psychological or medical services that are not available in the community. For example, the provision of women's groups for female patients in a tertiary drug service improved their self-esteem and knowledge and was associated with longer retention in treatment (Bartholomew et al 1994).

Other research has shown better treatment outcomes among patients in tertiary care. For example, one study from Leeds showed that the incidence of illicit drug use, and particularly, opiate misuse, was significantly reduced among patients attending a tertiary methadone treatment centre compared to those attending community-based programmes (Wolff et al 1996).

Conversely, where drug treatment takes place in a tertiary base, it has been suggested that the inclusion of on-site primary care and mental health services might increase the accessibility of these services (Friedmann et al 1999).

# 1.4. THE ROLE OF THE PHARMACIST IN THE PROVISION OF METHADONE TREATMENT PROGRAMMES

The pharmacist can play an important part in the delivery of methadone treatment for opiate misusers both at primary and tertiary level. The role of the pharmacist in tertiary drug treatment services is well established (Levine & Kabat 1975, Ball et al 1986, Haynes 1988, Ives & Stults 1990), and the importance of pharmacy involvement in community-based methadone treatment has also been broadly recognised (Glanz et al 1989, Scott & McNulty 1996, Sheridan et al 1996). One Australian study suggested that the nature of the pharmacy service provided affected patient retention in methadone maintenance (Gaughwin et al 1998). Widespread pharmacy participation in methadone dispensing is necessary due to the needs of individual patients (e.g. childcare issues, work commitments, personal or public transport) and of the pharmacies (e.g. opening hours, clinical specialities, security concerns) and because pharmacists need to be able to develop a rapport with their patients (Roberts 1992).

Community pharmacies represent an network of treatment outlets for drug misusers, a network that has been long involved in the provision of methadone in the UK, and has been increasingly utilised in recent years (Glanz et al 1989, Sheridan et al 1996). Community pharmacists have been dispensing methadone in Hamburg since 1988 and research shows that the services they provide are both flexible and user-friendly (Kalke 1997). More recently, data from south west France showed 80% of community pharmacists agreed with the provision of a daily dispensing service for patients in buprenorphine maintenance treatment there (Jeantaud et al 1999).

Community pharmacists also have an important role in minimising the impact of methadone treatment programmes on the community in general by supervising the consumption of methadone doses on-site at their pharmacies. On-site supervision has traditionally been provided by Australian community pharmacists (Ezard et al 1999) and almost two fifths of community pharmacists in England and Wales said they felt that supervising the consumption of methadone was an appropriate role for them (Sheridan et al 1997). In Scotland community pharmacists overwhelmingly supported the supply and supervised administration of methadone and were willing to provide any other services required by drug misusers (Anon 1995, Kayne 1996).

However, one research study found that while community pharmacists believed they had a professional role to play in the provision of services for opiate misusers, they also held negative personal views on opiate misusers, which had been associated with stigmatisation (Sheridan & Barber 1997).

Several studies have identified a number of the issues involved in a community pharmacist's decision to participate in methadone treatment programmes. Early work indicated that these issues were complex, and were open to external political, social and professional influences (Myers et al 1996) and a later study indicated that the safety of pharmacy staff was of paramount importance (Myers et al 1998). This study also found male community pharmacists were more in favour of methadone dispensing than females, while females were more positive about their role in preventative care (e.g. advice and counselling for at risk groups). Studies have also indicated that education, training, role support and collaboration with methadone prescribers and the community can positively influence community pharmacists' attitudes towards the provision of methadone dispensing services (Myers et al 1996, Sheridan et al 1997, Caplehorn et al 1998a, Matheson et al 1999b).

Research from Canada suggested that remuneration was not a major determinant in community pharmacists' decision to provide services for IV drug misusers (Myers et al 1998), but one Australian study suggested that the dispensing fees associated with the supply of methadone were inadequate (Muhleisen 1998).

Where methadone was dispensed more frequently than once weekly, the introduction of the Methadone Protocol Scheme (MPS) reduced the remuneration for community pharmacists compared to the private arrangements previously in place. In addition, no fee was directly associated with the supervision of methadone doses in the community pharmacy. In other words, community pharmacists who dispensed methadone on a daily basis or offered on-site supervision services were paid less following the introduction of the MPS. Nevertheless, the availability of one-off grants from the Department of Health & Children (DOHC) to fund modifications to community pharmacies to create private areas for on-site supervision may have encouraged some pharmacists to become involved in the provision of pharmaceutical services for opiate misusers (Jackson 2001).

### 1.5. THE VALUE OF PATIENTS' VIEWS

Patients' views have been shown to be of great value in determining the structure and content of healthcare services (Ball & Ross 1991, Powell et al 1993, Krook et al 1995). A number of studies have recorded patients' views on their methadone treatment programmes (Jones et al 1994, Hagman 1995, Lovejoy et al 1995, Maddux et al 1995, Sheridan & Barber 1996, Matheson 1998a, 1998b & 1998c, Neale 1998, Ezard et al 1999) and research also suggests that they should be taken into account in determining good pharmacy practice in this area (Matheson 1998b).

Many service providers acknowledge the need to communicate fully with their patients, provide them with full information regarding their health status and treatment options and respect their input in the decision-making process (Gadow 1981, Lewis 1994, Jarman 1995, Kerridge et al 1998). Similarly, patients have expressed the need for better communication with their doctors and more thorough information about their conditions and their treatment options (Chappell 1992).

Research has identified both positive and negative patient views on methadone treatment programmes and the implications of these views on recruitment and retention in methadone treatment cannot be ignored. One study described how patients in methadone treatment reported a loss of identity and diminished feelings of self-worth, and how they believed that they had failed by "selling out" and entering methadone treatment (Hunt et al 1985). Another showed that negative attitudes to methadone treatment were associated with general societal disapproval of methadone, previous experience of abstinence-orientated treatment, previous obligatory prison-based rapid detoxification using methadone and witnessing peers on methadone who continued to use other drugs (Zule & Desmond 1998). But the same study showed that positive attitudes to methadone were associated with prior success in methadone treatment and experiencing peers who had discontinued other drug use while on methadone (Zule & Desmond 1998) while Lovejoy and colleagues (1995) found that treatment outcomes were improved for addiction services when patients' negative attitudes were addressed and their resistance overcome.

Apart from the potential gain associated with patient involvement in the decision making process, there may be negative implications from excluding patients at this level. Where healthcarers do not communicate well with service users they may undermine patients' ability to make fully informed decisions regarding their own health (Quirt et al 1997). In addition, failure to acknowledge patients' power to determine their own treatment may result in non-compliance as patients flout clinical decisions made without their input (Playle & Keeley 1998).

Patients in methadone treatment in Ireland in 1998 saw many aspects of treatment services and service delivery undergo dramatic changes with the introduction of the MPS on 1 October. Its introduction resulted in many patients having new prescribers, new dispensers and new prescribing and dispensing sites. Many patients also experienced a change in their methadone's formulation from the 2mg/ml linctus (Physeptone®) to the 1mg/ml mixture. Patients may also have been obliged to undergo supervised urine testing and many will have received free drug treatment for the first time.

But despite a lengthy and thorough consultation and planning process spanning almost five years, there were no patient representatives on any of the strategic committees involved in the design and implementation of the MPS. The views of Irish patients were never investigated or recorded prior to the introduction of the MPS, nor have they been recorded until now.

#### 1.6. THE PHARMACIST/PATIENT RELATIONSHIP

The relationship between the opiate-dependent patient and the dispensing pharmacist is very important and it has been suggested that it is both complex and ambivalent (Sheridan & Barber 1996 & 1997, Matheson 1998a). Research has shown that the personality and attitude of the pharmacist, their rapport with the patient, and the atmosphere in the pharmacy are all important issues for patients on methadone (Matheson 1998a). Patients in the UK have reported self-selecting their dispensing pharmacy on the basis of the attitudes of pharmacists and staff (Roberts 1992, Matheson 1998a).

Primary carers are traditionally conditioned to provide a sympathetic, trusting and open service for patients, which may result in conflict in the management of drug misusers. when the carer can no longer be totally trusting, but must outline and potentially enforce set limits on patient behaviour (Herman & Gourevitch 1997). Research has also found that some pharmacists have out-dated attitudes to methadone treatment (Muhleisen 1998) which may prevent them from becoming involved in its provision. In addition, community pharmacists have businesses to run, and will have concerns regarding the overall impact of the provision of methadone to drug misusers on their customer base (Sheridan et al 1997, Muhleisen 1998). Research has found that a high proportion of community pharmacists had experienced disruption, threats or violence in the workplace (Smith & Weidner 1996a, Matheson et al 1999b). A significant minority reported regular feelings of fear and insecurity, which were associated with a number of risks particular to community pharmacies as opposed to other retail businesses, including the robbery of drugs and incidents relating to the supply of prescriptions (Smith & Weidner 1996a). Smith and Weidner (1996a) described how community pharmacists related their security concerns to the provision of services for IV drug misusers and reported many incidents involving people in this category.

The direct association between community pharmacists' fears and the treatment of IV drug misusers has implications for community pharmacy involvement in the provision of care for this patient group (Smith & Weidner 1996b, Sheridan & Barber 1997). The stigmatisation of patients in methadone treatment by community pharmacists has been shown to result in embarrassment and negative self-esteem, which one researcher suggested resulted in subsequent negative behaviour among patients (Matheson 1998c). The extent to which patients in methadone treatment realise that community pharmacists do not trust them was illustrated by methadone patients in one Scottish study, who said that, if they were community pharmacists, they would not trust drug misusers enough to dispense methadone for them (Neale 1998). Patients in methadone treatment are particularly aware of these negative attitudes and research indicates that they would like the same level of respect as afforded to other pharmacy customers (Matheson 1998a).

The use of pharmacy/patient contracts may help to clarify the terms of this relationship, or it may make patients feel that pharmacists do not respect or trust them, resulting in

further resentment and animosity. One study reported that patients had an implicit understanding of what behaviour was acceptable in the community pharmacy setting, and suggested that to apply overly strict conditions could antagonise patients unnecessarily (Neale 1999).

Changes in pharmacists' attitudes can be difficult to achieve, with one study among pharmacy students showing little change in their professional or personal views following specialist training (Sheridan et al 1994). But other researchers have suggested that addressing negative and misinformed attitudes through training could encourage more pharmacists to provide services, enhance the process of service delivery (Sheridan et al 1997, Caplehorn et al 1998a, Muhleisen 1998) and result in better retention rates for patients (Caplehorn et al 1998b). There is an onus on both sides to make the relationship work: while research suggests that pharmacy students and community pharmacists need to be educated to encourage more positive attitudes, drug misusers also need to be educated on what they can expect from pharmacists (Matheson 1998c).

Perhaps positive reports such as one from Hamburg which showed that pharmacists' fears that patients on methadone would cause problems for pharmacy staff and other customers were not realised (Kalke 1997) will encourage Irish pharmacists to be less fearful and cautious in their attitudes to the management of drug misusers. The provision of free methadone may also reduce the incidence of arguments between community pharmacists and their patients on methadone, as research from Australia showed that payment was a common source of conflict (Muhleisen 1998).

The importance of the relationship between the patient in methadone treatment and their pharmacists justifies its exploration to identify key elements and issues on both sides for those involved in the MPS.

# 1.7. SOURCES OF SUPPORT FOR COMMUNITY PHARMACISTS WHO DISPENSE METHADONE

Community pharmacists work largely in isolation, with UK and Australian research indicating that contacts with other members of the primary healthcare team are relatively infrequent (Smith 1990, Muhleisen 1998). Some pharmacists worry about the overall impact of the provision of methadone treatment on their businesses, and fear an absence of real support, should it be needed (Sheridan et al 1997, Matheson 1998c). Research from the UK has also indicated that community pharmacists had serious concerns about the violent or unpredictable nature of drug misusers (Smith & Weidner 1996a) and research studies from Scotland and Australia report that pharmacy staff experienced high incidences of threats, violence or disruption (Muhleisen 1998, Matheson et al 1999b).

As well as the value of peer support and interdisciplinary contact on a day-to-day basis, support following disruptive incidents with their patients is essential for the personal and professional wellbeing of community pharmacists who provide methadone treatment services.

The appointment of the Eastern Health Board (EHB) Addiction Service's liaison pharmacists may represent one way of addressing community pharmacists' fears by meeting their need for "role support" as described by Shaw and colleagues (1978). The role of the liaison pharmacist within Addiction Pharmacy, as examined by this project, can be divided into two main facets: (a) to co-ordinate community-based pharmaceutical services for drug misusers within the region, and (b) to support the pharmacists who provided these services. A UK report highlights the necessity for both aspects of the role, to improve communications between pharmacists and prescribers, to ensure that good practice standards can be met and maintained and in order that community pharmacists working with drug misusers have adequate and effective support (Department of Health 1996).

A support role similar to that of the Greater Glasgow Health Board Area Pharmacy Specialist in Drug Abuse was designed for the EHB liaison pharmacists (Roberts et al 1998). They provided professional advice and guidance for community pharmacists to ensure that patients in the MPS in the EHB region received appropriate pharmaceutical services. This work was done on the basis that while individual pharmacists had different ways of delivering methadone treatment, some common modalities should apply. Research in the area of needle exchange supports this theory by suggesting that the application of external standards to individualised, autonomous systems could have value in ensuring patients receive uniform, high quality services (Donoghue et al 1992). For example, in accordance with the Pharmaceutical Society of Ireland's *Policy on Drug Abuse 1996*, one liaison pharmacist circulated a sample pharmacist/patient agreement for use in establishing ground rules with patients availing of methadone dispensing services within the EHB region.

In addition, the liaison pharmacists had a role in organising specialist training initiatives for community pharmacists who dispensed methadone in the EHB region. Community pharmacists' skills in the management of drug misusers are widely recognised (Harrison 1994, Gelbhart 1994, Kalke 1997) but the literature suggests that training that centres on the development of an understanding and a rapport with patients on methadone could be particularly helpful to them (Harrison & Flinkow 1973, Anon 1985, Anon 1991).

Methadone prescribers and other members of drug treatment teams represent another potential source of support for pharmacists who dispense methadone. There are many confidentiality issues associated with multi-disciplinary treatment modalities, and arguments continue to be made both in favour and against a fully integrated multi-disciplinary approach (McCart et al 1989, Schwarz 1993, D'Sa 1995, Celler et al 1995). In addition, patients have expressed concern regarding the extent of their confidentiality within the primary healthcare setting (Carman & Britten 1995). But while there is a need to protect patient confidentiality, closer communication between prescribers and pharmacists has been recommended as it has been shown to impact positively on patient care, both in the community and in the specialist hospital setting (Nuffield Report 1986, Sprouse & Whitmore 1995). Research found frequent communication between community pharmacists and GPs regarding general prescribing issues (Hughes & McFerran 1996), but some experts suggest that community-based pharmacies should be geographically integrated into community-based team sites to ameliorate patient care and improve patient confidentiality (Ford & Jones 1995, Crowe et al 1995). The value of

the pharmacist as a fully integrated member of the team has also been established within the tertiary drug treatment setting (Magura et al 1988).

Full pharmacy involvement in the healthcare team can benefit patients and other members of the team in a number of ways. Firstly, since pharmacists usually see patients more frequently than other members of their methadone treatment team, they can provide feedback to the team regarding the health status and level of compliance of patients in methadone treatment (Farrell et al 2000). Secondly, it has been suggested that a significant number of those who are in methadone treatment continue to use other prescribed drugs (Strang et al 1990, Farrell et al 1994, Wodak 1994, Garretty et al 1997, Charnaud & Griffiths 1998, Farrell et al 2000). It is also suggested that patients in methadone maintenance who concurrently abuse benzodiazepines are more likely to exhibit explosive or antisocial behaviour (Forza et al 1998). With consent from the patients involved, community pharmacists can inform methadone prescribers if patients in methadone treatment present prescriptions from additional prescribers, for medicines that may impact on their methadone treatment. A study carried out prior to the introduction of the MPS reported that approximately one fifth of the urine samples from patients in an Irish methadone clinic were positive for benzodiazepines (Taj et al 1995). Information provided by community pharmacists on concurrent prescribing for patients in methadone treatment could be helpful in reducing the abuse of psychoactive medication and could also help healthcarers to predict and understand their patients' psychological states.

In addition to the impact on patients and other members of drug treatment teams, full pharmacy participation in healthcare teams can also be of benefit to the pharmacists themselves. Information on current drug use (including illicit drugs) as derived from recent urinalysis could alert pharmacists to the risk of overdose due to polydrug use in particular patients, an issue of particular concern for pharmacists who supervise methadone self-administration. This information regarding current drug use could warn pharmacists to be alert for signs of intoxication, which could help them to avoid compromising patient safety by administering or dispensing additional supplies of methadone.

Good communication with methadone prescribers could also reduce the incidence of problems associated with methadone prescriptions. Such problems include incomplete Controlled Drug prescriptions, which should not be dispensed and can result in patients having to return to their prescribers. Inaccurately interpreted prescribing information and undetected prescription errors can result in dispensing mistakes, and may compromise patient safety. These incidences can also cause delay and inconvenience for patients and primary carers and should be avoided if at all possible. Regular pharmacist/prescriber contact, initiated equally by both parties, with shared information regarding patients' treatment plans should help to improve interdisciplinary understanding, resulting in more accurate prescription writing and safer, more efficient dispensing practices.

# 1.8. DRUG TREATMENT IN IRELAND BEFORE THE METHADONE PROTOCOL SCHEME

## 1.8.1. The Irish Healthcare System

When this research was undertaken Government funded Irish healthcare services were provided by eight regional health boards, each of which was responsible for a defined geographical area. Private healthcare services were available nation-wide but free healthcare was provided under the General Medical Scheme (GMS) for those on social welfare benefits and for others on limited incomes (which represented approximately one-third of the Irish population).

Those requiring medical treatment could attend local general medical practitioners (GPs), who provided services free of charge for patients who qualified under the GMS, and other patients were seen on a private basis.

### 1.8.2. Structure of the Eastern Health Board (EHB)

The EHB provided health services for more than 1.3 million people living in counties Dublin, Wicklow and Kildare (EHB 1997). The Board's activities were divided into four programmes which were individually managed by Programme Managers, under the supervision of one Chief Executive Officer. The Addiction Service's first programme manager was appointed in September 1996. In September 1997 the programme was

restructured to include Health Promotion and Adult Mental Health Services and in 1998 it expanded to include the area of Social Development.

It is important to note that in mid-1999 the EHB region was subdivided and three separate Health Boards (Northern Area, East Coast Area and South Western Area) were formed, under the overall auspices of a revamped Eastern Regional Health Authority. However, as the bulk of this research work had been carried out prior to this change, and the geographical area in question remained identical, it is referred to as the EHB region throughout this study.

#### 1.8.3. Structure of the EHB's Addiction Service

The EHB's Addiction Service was divided geographically into three sectors: Dublin North (Community Care Areas 6,7 & 8), Dublin Southeast (Community Care Areas 1, 2 & East Wicklow), and Dublin Southwest (Community Care Areas 3, 4, 5, Kildare & West Wicklow). Each sectoral management team comprised a Consultant Psychiatrist, an Area Operations Manager, a GP co-ordinator and a liaison pharmacist, and was under the supervision of the Programme Manager. The Consultant Psychiatrists were the clinical directors in each area, the Area Operations Managers were the administrators and the GP co-ordinators and liaison pharmacists managed the GP and pharmaceutical inputs respectively.

Due to recruitment problems a third liaison pharmacist was not appointed until July 1999. Therefore for the duration of this study there was one liaison pharmacist for Dublin North and a second (the researcher) was responsible for Dublin Southeast and Southwest.

# 1.8.4. Methadone Treatment in the Eastern Health Board (EHB) region prior to the introduction of the Methadone Protocol Scheme

By the mid-1980's opiate addiction had been recognised as a serious problem in Dublin (Dean et al 1985, Butler 1991) and was generally associated with socio-economic deprivation (Butler 1993). Until September 1992 the National Drug Treatment Centre, Trinity Court was the only methadone-prescribing drug treatment centre in Ireland. Located in Dublin's city centre, Trinity Court provided some methadone maintenance but methadone was generally prescribed for short periods, in relatively low doses, with an

underlying abstinence philosophy (Butler 1991). All of the methadone prescribed at the centre was administered and dispensed by nursing staff, operating under the supervision of clinicians. People who required treatment for opiate misuse pre-September 1992 who did not attend Trinity Court could either undergo symptomatic detoxification using non-opiate drugs, or attend one of the few GPs who were prepared to prescribe methadone. Community pharmacists dispensed all of the methadone prescribed privately: most of it was dispensed at a few key community pharmacies.

Physeptone®, the 2mg/ml formulation of methadone, was the only formulation of methadone that was available on the Irish market at this time. It was designed and licensed for the treatment of cough, and contained sugar, alcohol and chloroform, which made it less than ideal for regular long-term use. Because it was relatively dilute and had to be stored in a Controlled Drugs cabinet, Physeptone® presented storage problems for pharmacists and difficulties for patients who drank large volumes on a daily basis.

In September 1992, due to concerns about the rise in HIV infection among intravenous drug misusers in Dublin (reported at 16% seroprevalence by Bury and O'Kelly in 1989), the EHB opened a Drug Treatment Centre (DTC) in southwest Dublin. The DTC provided outpatient methadone detoxification and methadone maintenance for IV opiate misusers. A pharmacist was employed to administer and dispense methadone doses prescribed by doctors working on-site. Over the following years a number of DTCs were established in other parts of Dublin.

But despite the EHB's efforts to provide adequate services, DTCs rapidly became saturated as increasing numbers of opiate misusers sought treatment for addiction. As people were maintained on Physeptone®, the treatment programmes filled to capacity, preventing the EHB from offering services to additional patients seeking help. The EHB intended patients who had stabilised in these tertiary services to return to the care of their GPs and community pharmacists. But GPs and community pharmacists were resistant to treating opiate misusers and their involvement in methadone prescribing and dispensing was slow to increase (CDTL Statistics). In addition, opportunities for diversion or abuse were high as Physeptone® was being dispensed in large volumes, which led to fears of methadone-related deaths, as were seen in Manchester during the same period (Cairns et al 1996).

# 1.8.5. The Methadone Pilot Project

In March 1996, in response to these issues, the EHB established a pilot project to look at the viability of returning stabilised patients to GPs' surgeries and community pharmacies in a structured way. A number of stable patients were identified within the DTCs, and they were transferred to the care of participating GPs and community pharmacists under this Methadone Pilot Project (MPP). Details of each patient were held centrally on a Central Drug Treatment List (CDTL), and each patient was allocated to a nominated GP and community pharmacy (DOHC 1997).

The CDTL was a computerised confidential record of patients registered in methadone treatment in Ireland (excluding those in palliative care). It was located in National Drug Treatment Centre, Trinity Court, but applied to patients nation-wide and could be accessed by telephone during office hours. Relevant details held on the CDTL could be made available as necessary to prescribers and pharmacists only.

Under the MPP each patient in community-care based methadone treatment had a methadone treatment card at a designated community pharmacy. Prescribers who wished to commence methadone treatment for a patient used a standard "Treatment Application Form" to register the patient's details on the CDTL. Details required include patient name, address, date of birth, methadone treatment history, and the nature and estimated duration of the proposed methadone treatment programme. The form also required a photograph of the patient and details of the community pharmacy that had agreed to dispense his methadone. Once these details were processed, a treatment card was produced for the patient, which resembled a credit card in size and included the patient's photograph. This card was sent directly to the dispensing pharmacy, where it remained for the duration of methadone treatment so that the pharmacist could verify the identity of the patient.

In 1996 the EHB also replaced Physeptone® with methadone 1mg/ml in all established DTCs and for patients in the MPP. The 1mg/ml formulation was licensed for the treatment of opiate addiction and was dispensed free of charge. It was sugar-, alcoholand chloroform-free and green in colour, compared to Physeptone®, which was brown. The colour difference enabled patients to differentiate between methadone prescribed by statutory agencies and the MPP and that prescribed by other doctors. In addition, the

EHB also established satellite drug services, where doctors wrote methadone prescriptions for local drug misusers, for dispensing by local community pharmacists. Satellite drug services facilitated GPs who were willing to see patients on methadone, but who had concerns about seeing them at their own surgeries. Satellite drug services also had nursing staff, counsellors, supervised urinalysis facilities and security staff on-site.

# 1.8.6. Commitment to increased controls on the use of methadone and increased primary carer involvement in the provision of treatment – the introduction of the Methadone Protocol Scheme (MPS)

In 1998 the EHB's Addiction Service's stated aims were to promote drug-free lifestyles and, in partnership with other statutory and voluntary agencies, to provide prevention, treatment, rehabilitation and aftercare programmes that minimised the harmful effects of drug addiction, and prevented the spread of HIV and other infections (EHB 1998). Some of the most significant changes to the provision of methadone treatment for opiate misusers in Ireland were made during that year. These changes were undertaken following the Department of Health's Government Strategy to Prevent Drug Misuse (1991) and in keeping with the subsequent Report of the Expert Group on a Protocol for the Prescribing of Methadone (Department of Health 1993). These reports highlighted the need to standardise and control the supply of methadone while also extending the involvement of primary carers in the provision of services for drug misusers, with the development of a "shared care" treatment model.

Over the previous two years the MPP had encouraged a number of GPs and community pharmacists to provide methadone treatment because the patients involved were stable and their numbers were limited enough to manage within the community setting. A subsequent independent analysis of the MPP carried out by Professor Gerard Bury under the auspices of the Department of General Practice in University College, Dublin indicated that the transfer of stable patients to primary carers had not affected their treatment outcomes (Department of Health & Children 1997).

Following this report on the MPP, and as the number of patients transferring from DTCs escalated, the DOHC established a Methadone Treatment Services Review Group. Its terms of reference were to redefine the roles of GPs and community pharmacists in the

treatment of opiate addiction, to examine the working relationships between primary and tertiary based methadone treatment services and to outline protocols for good practice in the prescribing and dispensing of methadone (DOHC 1997). The committee included a consultant psychiatrist, a GP representative, a member of the EHB's Addiction Service management team, a representative of the Minister for Health & Children, the Chief Pharmacist with the Department of Health & Children and this Ph.D. student, as a representative of the Pharmaceutical Society of Ireland, and it was chaired by a consultant in public health. The group recommended that the MPP should be expanded to form the MPS, to include all of those requiring methadone treatment in Ireland, and that controls and services should be developed to facilitate this process (Department of Health & Children 1997).

Around this time the EHB's Addiction Service recruited two liaison pharmacists (one of whom was the Ph.D. student) to provide a link between the tertiary drug services and community pharmacists working with the MPP and to co-ordinate pharmacists working within the DTCs. Five GP co-ordinators were also recruited to liaise with GPs who were involved in the provision of methadone treatment under the MPP.

Then the DOHC formed the MPS Implementation Committee to oversee the expansion of the MPS and its ultimate introduction on a national level. Its membership included an EHB Addiction Service GP co-ordinator and this Ph.D. student, as an EHB Addiction Service liaison pharmacist. Representatives from the regional health boards throughout Ireland were also invited to join the committee at key stages in the implementation process. The Implementation Committee was charged with designing and planning regulatory changes to control the availability and supply of methadone and to standardise methadone treatment, while also expanding the involvement of primary carers (namely GPs and community pharmacists) in the prescribing and dispensing of methadone respectively.

# 1.9. THE METHADONE PROTOCOL SCHEME (MPS)

# 1.9.1. The Interim Period (July - September 1998)

Before the MPS was introduced on 1 October 1998 methadone was being prescribed in four different ways (see Table 1.1 for details). The variety of treatment methods meant that there was a lack of standardisation in the level of care being provided for patients. In addition, as Physeptone® prescribers were not obliged to register their patients on the CDTL it was not possible to ascertain exactly how many patients were in methadone treatment at any given time, or how many prescribers or community pharmacists were involved in its provision. The system was also open to abuse by patients who chose to attend multiple prescribers and multiple community pharmacies.

Table 1.1: Mechanisms for the prescribing of methadone treatment in Ireland prior to the introduction of the MPS.

	Methadone formulation dispensed	Free treatment	Dispensing site	Prescriber obliged to register patients to CDTL*
DTC**	Methadone 1mg/ml	Yes	DTC	Yes
GP under the MPP	Methadone 1mg/ml	Yes	Community pharmacy	Yes
GP under the GMS	Physeptone®	Yes	Community pharmacy	No
Private doctor	Physeptone®	No	Community pharmacy	No

<sup>\*</sup> Central Drug Treatment List

In accordance with strategies devised by the MPS Implementation Committee, the DOHC intended to publish the *Supervision of Prescription and Supply of Methadone* regulations to the Misuse of Drugs Acts 1977 & 1984 on 1 October 1998, resulting in the introduction of the MPS. The nation-wide introduction of the MPS would have four primary effects:

- (1) All patients would be transferred from Physeptone® to methadone 1mg/ml.
- (2) All doctors proposing to prescribe methadone 1mg/ml would be obliged to undergo training with the Irish College of General Practitioners (ICGP) and agree to participate in audit.

<sup>\*\*</sup> Drug treatment centre (EHB region only)

- (3) All those being prescribed methadone 1mg/ml would be registered on the Central Drug Treatment List (CDTL) and would be allocated to a nominated methadone prescriber and dispenser (or to a statutory DTC).
- (4) Only patients with valid methadone treatment cards would be dispensed methadone by community pharmacists.

The vast majority of Irish heroin misusers and patients in methadone treatment were residing in the greater Dublin area (Butler 2001) and it fell to the EHB Addiction Service to ensure adequate services were in place to manage their transfer from private to statutory drug treatment on 1 October 1998. Although patients attending private Physeptone® prescribers were not readily identifiable, it was necessary to have adequate treatment services in place in advance to manage their transfer to methadone 1mg/ml on 1 October 1998.

Therefore, in July 1998, the DOHC published interim Regulations under the Misuse of Drugs Acts 1977 & 1984 which represented the first step in the introduction of the MPS (Appendix 1, p.1-6). Written advice regarding these legislative changes was given to general practitioners (GPs) and community pharmacists on 3 July (see Appendix 1, p.7-9). Under these regulations methadone (both Physeptone® linctus and methadone 1mg/ml mixture) could only be dispensed if prescribed using a specific form issued by the GMS. Community pharmacists returned these prescriptions to the GMS Payments Board after they were dispensed and they were used to estimate the numbers and location of patients who would need methadone treatment from 1 October. In addition, in September 1998 the Department of Health notified all GPs and community pharmacists in writing that the MPS was to be introduced and Physeptone® would no longer be available on the Irish market after 30 September 1998 (see Appendix 1, p.10-22). Because of the short-term legal measures that were applied between 16 July and 30 September 1998 this period became known as the Interim Period.

# 1.9.2. Introduction of the Methadone Protocol Scheme (1 October 1998)

The following is a summary of the primary aspects of the MPS as they currently exist, in accordance with recommendations from the *Report of the Methadone Treatment Services Review Group* (DOHC 1997):

- Problem opiate users are offered a range of treatment options including rehabilitation, detoxification and methadone maintenance.
- Methadone is the only drug used in the maintenance treatment of opiate addiction.
- Only specialist prescribers initiate methadone treatment.
- Prescribers treating opiate addicts follow Guidelines from the Medical Council and ensure that they have adequate external support to enable them to do so.
- GPs who prescribe methadone work closely with local tertiary drug treatment services and with the CDTL.
- Tertiary drug treatment services have been established in many areas.
- Each patient in community-based methadone treatment has a valid treatment card at the community pharmacy where their methadone is dispensed.
- The CDTL provides an up-to-date record of all patients in methadone treatment in Ireland (excluding those under the care of palliative care consultants).
- Information held on the CDTL is confidential and only made available as necessary to relevant prescribers and pharmacists.
- Community pharmacists only dispense methadone for patients who have valid treatment cards at their pharmacies.

#### 1.9.3. Effects of the Introduction of the Methadone Protocol Scheme

As information on the prescribing and dispensing of Physeptone® was incomplete, there were no accurate records of the numbers of patients in methadone treatment and the numbers of primary carers involved in the provision of that treatment prior to the full introduction of the MPS, so it is not possible to establish the full extent of the impact of its introduction on the numbers involved in methadone treatment in Ireland. Nevertheless, when data from the MPP were examined they show that 81 GPs and 66 community pharmacists were involved in the provision of methadone treatment for approximately 600 patients in December 1997 (CDTL Statistics, EHB 1997). By December 1998, one year later, and two months after the MPS was introduced an additional 45 GPs and 78 pharmacies had been recruited to the MPS (CDTL Statistics).

Between 31 August and 30 November 1998 a total of 717 additional patients were absorbed into tertiary drug treatment services within the EHB region while a number of additional patients also sought methadone treatment in other health board regions

(CDTL Statistics). In addition to those patients previously prescribed Physeptone® who attended statutory drug treatment services after it was discontinued, research suggests that the provision of free prescribing and dispensing services should have encouraged previously hidden drug misusers to attend drug services (Wells et al 1995).

By July 1999 there were a total of 143 GPs and 190 community pharmacists prescribing and dispensing methadone for a total of 2,107 patients nation-wide. In addition, there was one in-patient detoxification unit, thirteen DTCs and 31 satellite drug services within the EHB region, caring for a further 1,916 patients (CDTL Statistics).

# 1.10. KEY ASPECTS IN THE PROVISION OF PHARMACEUTICAL SERVICES UNDER THE MPS

The involvement of pharmacists, particularly community pharmacists, in the provision of methadone treatment in Ireland was considered essential for the implementation of the MPS. If their participation and co-operation were to be maximised and encouraged, it was important to establish their views on the MPS and patients who were in methadone treatment.

It was also necessary to ensure that patients in community-based treatment under the MPS received adequate and appropriate pharmaceutical services. Community pharmacist input was important in two respects: (i) the extent of their participation, and (ii) the nature and quality of the services they provided. Ideally patients in methadone programmes should receive a treatment package that is tailored to their particular situation, but in practice patients' needs can only be met within the limitations of their treatment programmes. Nevertheless pharmacists who dispense methadone for drug misusers, whether in the community or within a statutory DTC, should strive to offer treatment services that are of a professional standard, while operating within the set limitations of patients' programmes.

Guidelines are available to help in the development of some aspects of pharmaceutical services, in their delivery and in evaluating their efficacy (Pharmaceutical Society of Ireland's *Policy on Drug Abuse* 1996, Royal Pharmaceutical Society of Great Britain

1997). These include aspects 1.10.1 to 1.10.4. below. But there are many aspects of pharmaceutical services for those in treatment under the MPS that are not governed by standards such as these, and are nevertheless vitally important to those who participate in the programme. These aspects also need to be examined to investigate current practices and their impact on patients in methadone treatment under the MPS (see 1.10.5. to 1.10.8. below).

# 1.10.1. On-site supervised dosing

Irish pharmaceutical guidelines advocate the provision of on-site supervision and give direction regarding the availability of privacy for those being supervised (Pharmaceutical Society of Ireland's *Policy on Drug Abuse* 1996). Supervising drug misusers' self-administration of methadone in the pharmacy reduces the incidence methadone-related over-doses (Swenson 1988, Gruer 1997) and improves patient compliance (Scott & McNulty 1996). In 1994 the Glasgow Area Pharmaceutical Committee advocated the provision of on-site supervision by community pharmacists in the Greater Glasgow Health Board area and by April 1996, 59% (125/212) of the community pharmacies in the area were doing so (Roberts et al 1998). This represented 79% of all the community pharmacies dispensing methadone in the region (Gruer et al 1997). In 1995 research from England and Wales found a relatively high incidence of "take-home" methadone doses, prompting researchers to recommend a review of their national prescribing guidelines (Strang et al 1996).

The need for the privacy of patients in methadone treatment to be respected by community pharmacists has been documented (Matheson 1998a, Ezard et al 1999). The provision of a private space for the administration of medicines is a matter for all community pharmacists to consider as feelings of stigmatisation have been related to the level of privacy in the community pharmacy (Matheson 1998b).

But although many patients experience difficulties when obliged to drink their methadone under supervision, others find it useful in safeguarding their personal safety, and confirming their compliance with treatment (Best et al 1997, Neale 1998). Similar views were expressed by patients involved in piloting an on-site supervision service at a sample of London community pharmacies (Luger et al 2000).

# 1.10.2. The distribution of "take-home" methadone doses

Patients generally regard "take-home" methadone doses as a reward or privilege and research shows that they value them above most other incentives including dose increases (Rowan-Szal et al 1994, Kidorf et al 1995, Amass et al 1996, Chutuape et al 1998). Patients also report difficulties with high frequency attendance regimens, which can interfere with other aspects of their lives (Neale 1998). Treatment programmes control the frequencies of "take-home" methadone to reduce the risk of patients selling their methadone, or exchanging it for other drugs or alcohol. In addition, while research has shown that patients who have parental responsibilities are more likely to store their "take-home" methadone safely (Calman et al 1996), incidents of fatal overdose have been associated with "take-home" supplies both among children (Binchy et al 1994, Calman et al 1996) and adults (Cairns et al 1996, McCarthy 1997).

The important role of the community pharmacist in the provision of child-resistant containers cannot be overestimated. The Pharmaceutical Society of Ireland's *Policy on Drug Abuse 1996* recommended the use of child resistant containers and plastic bottles for all "take-home" methadone doses.

#### 1.10.3. Methadone's Formulation

As recommended by the DOHC (1997) and by the Pharmaceutical Society of Ireland (*Policy on Drug Abuse* 1996), all patients in treatment under the MPS were dispensed methadone 1mg/ml, which, by 1998, was available in four different formulations. These formulations differed in a number of key characteristics, including, for example, their taste and viscosity. No feedback is available to date on the importance of formulation to Irish patients or on their product preferences. For community pharmacists participating in the MPS there were practical considerations associated with dispensing multiple formulations of methadone 1mg/ml. Stocking more than one product necessitated an increased volume of safe storage space. It also raised the minimum volume of methadone kept on-site at a given time, thereby increasing the risk of robberies.

#### 1.10.4. The pharmacist as an information source

Research has shown that patients in methadone treatment would like more drug information (Matheson 1998a). Australian policy recommends that community pharmacists advise patients to store methadone safely and warn them of the dangers of

combining methadone with other drugs (Smith & Temple 1998) and Irish pharmaceutical guidelines also advocate the use of the community pharmacist as a source of expert advice in the field of drug misuse (see the Pharmaceutical Society of Ireland's *Policy on Drug Abuse* 1996).

## 1.10.5. Methadone Dispensing Site

Under the MPS the allocation of a patient to either a local DTC pharmacy or a local community pharmacy was made by the clinical team and facilitated by a liaison pharmacist. Patients requiring intensive clinical input were generally allocated to a DTC pharmacy. These included patients who were being initiated in methadone treatment, destabilised patients and patients with dual or multiple addictions or other complex problems. Stable patients who were being prescribed their methadone by GP in their surgeries were allocated to community pharmacies, as were patients attending prescribers based in satellite services. Patients were generally not consulted, and because of the pressure on treatment services they were usually obliged to accept the services offered. Their allocated methadone dispensing services could have caused problems for patients who worked, travelled or did not reside permanently at their registered addresses.

# 1.10.6. Methadone dispensing - patient waiting times

Patients in drug treatment are very sensitive to any delay in their methadone dispensing as they expect to be dispensed on arrival and so may experience acute craving and physical withdrawal during a delay period (Matheson 1998c). They may also interpret the delay as a form of discrimination by the pharmacist, particularly in the community pharmacy setting, if they believe that other customers are served before them (Ezard et al 1999).

Attitudinal issues aside, the length of time that patients wait for their methadone is a measure of the efficiency of the dispensing pharmacy. Waiting times are also an indicator of cohesion in the healthcare team, as delays can be due to problems at the prescriber/pharmacist interface. No guidance has been given to Irish community pharmacists regarding the length of time that their patients should have to wait for their methadone to be dispensed.

# 1.10.7. Methadone Dispensing Services Opening Hours

Research has shown that the hours that their dispensing services operate are of paramount importance to patients in methadone treatment. Longer opening hours facilitate patients arriving on time, while research showed that the time of day that patients consumed their daily methadone dose also affected their heroin use (Best et al 1997).

Pharmacy services in DTCs generally open during office hours from Monday to Friday and for a limited period on Saturday and Sunday mornings. These limited hours may have made attendance at DTCs more difficult for patients than attendance at community pharmacies which had longer opening hours, particularly at weekends.

### 1.10.8. Refusal of methadone doses

The Pharmaceutical Society of Ireland's *Policy on Drug Abuse 1996* does not give specific advice regarding the circumstances (if any) in which community pharmacists should withhold or refuse to dispense a methadone dose. It does state, however, that community pharmacists should clarify in advance when individual methadone prescribers wish to be informed if doses are missed, if patients present in an intoxicated state or if methadone prescriptions appear to have been altered by patients.

Pharmacists may refuse to dispense doses for reasons that can be divided into two categories: patient non-compliance and problems at the prescriber/dispenser interface. One study found that patients had an intrinsic understanding of what behaviour was acceptable in the community pharmacy setting and accepted that the pharmacist would withhold their dose if they presented in an intoxicated state (Neale 1999). But patients on methadone can be abusive, particularly if intoxicated, and a pharmacist who refuses a methadone dose risks being exposed to such abuse (Muhleisen 1998). The circumstances surrounding an instance when a pharmacist refuses a methadone dose can vary but the decision to withhold a dose is often traumatic for the patient and difficult for the pharmacist.

The incidence of refused doses is an indicator of the level of stability achieved by patients in methadone treatment. It is also related to the extent of the knowledge of the healthcare professionals involved, as pharmacists need to consider patient safety with

respect to intoxication and possible reduction in opiate tolerance, in instances where patients had missed consecutive methadone doses. Clearer professional guidance in this area could help to reduce confusion and support community pharmacists in their decision-making process. The incidence of refused methadone doses is also as sign of the level of co-operation within the multidisciplinary team, as it relates to the provision of legal and legible methadone prescriptions.

#### 1.11. PURPOSE & AIMS OF THIS RESEARCH STUDY

Using the introduction of the MPS as its key intervention, this study questioned whether this legislative change affected pharmaceutical services for those in methadone treatment in Ireland, and if there had been a discernible change, how it had impacted on the patients and pharmacists involved.

The following research aims were identified:

- (1) To establish how Irish community pharmacy-based methadone dispensing services were affected by the introduction of the MPS.
- (2) To examine community pharmacists' perspective on the MPS.
- (3) To investigate patients' views on pharmaceutical services under the MPS.

This research examined the nature and extent of community pharmacy involvement in the provision of methadone dispensing services for opiate misusers in Ireland, before and after the introduction of the MPS in October 1998. In order to gain more complete insight into pharmaceutical aspects of methadone treatment before and after the introduction of the MPS, the liaison pharmacist ("the researcher") undertook studies with both service providers and with service users.

It investigated how community pharmacy-based pharmaceutical services were affected by the introduction of the MPS, and examined the role of an Addiction Service liaison pharmacist in facilitating community pharmacist involvement. It also examined the views of Irish community pharmacists on community-based methadone treatment programmes, patients in methadone treatment and on the MPS itself.

This study was the first ever to investigate the quantitative and qualitative views of Irish drug misusers on their pharmaceutical services under the MPS. It examined pharmaceutical aspects of the MPS from the perspective of the service user, exploring their views and preferences regarding the pharmaceutical services provided and the pharmacists who provided them. This study also provides an opportunity to compare self-reported data from community pharmacists and patients regarding essential aspects of pharmaceutical services under the MPS.

These studies were designed as practical tools to investigate aspects of recent and ongoing developments in the provision of pharmaceutical services for drug misusers, specifically in relation to one primary intervention, the introduction of the MPS. The introduction of the MPS on 1 October 1998 offered a quasi-experimental context wherein the impact of regulation on those involved with methadone treatment could be investigated.

Most of this practice research was carried out by the liaison pharmacist in the EHB's Addiction Service's Southwest and Southeast sectors from December 1997 to November 1999. This liaison pharmacist had been a member of the Department of Health & Children's Methadone Treatment Services Review Group and was subsequently on the Department of Health & Children's Implementation Committee, which was established to oversee the introduction of the MPS. The liaison pharmacist was not directly involved in the provision of pharmaceutical services for drug misusers, and thought it imperative that the direction of developments in pharmaceutical aspects of the MPS, and the monitoring of its impact should not rely solely on her personal views. This research represents her efforts to collate objective data on the current situation, utilising maximum input from those directly involved.

Although the researcher could influence elements of the MPS at the planning stage, national policy favoured the full introduction of the scheme on 1 October 1998. Ethical considerations (as discussed later) meant that no-one requiring methadone treatment could be excluded from the MPS, which eliminated the option of developing a scientific experiment, using a control group for comparison purposes in studying the effects of its introduction. In addition, research became more difficult after mid-1999, when the researcher resigned her post as liaison pharmacist with the EHB, as subsequent studies

would have needed full co-operation from EHB management in accessing staff and/or patients. Within these limitations, the changes in policy and practice that were taking place created a passive or quasi-experimental environment (Robson 1993), aspects of which were described and explored by this study.

# **CHAPTER 2**

# **Methodology**

#### 2.1. RESEARCH STRATEGY

The research strategy was based on the hypothesis that the MPS would have a positive effect on the provision of methadone treatment in Ireland. The individual study designs were developed primarily in response to the research questions being asked, with an emphasis on the practical implications for those involved, and with the intention of disseminating the study findings rapidly in order to affect practice and influence local planning and decision-making processes. During the course of the research, feedback on findings from the initial studies was given to respondents, to representatives of the Department of Health & Children and to tertiary drug service managers. So although the initial research (Surveys 1 and 2) was primarily quantitative in nature, it also generated hypotheses tested in subsequent studies and findings that helped to shape the ultimate quasi-experiment (i.e. the MPS).

In determining research design a thorough exploration of current literature was undertaken, and the researcher liaised with colleagues and peers involved in similar projects in the UK. In addition to the directly related issues, associated subjects such as aspects of the community pharmacist's role, the role of interdisciplinary liaison workers and the value of patients' views were also investigated. The researcher was very familiar with the situation in drug services in Ireland, and had also worked within the NHS in the UK, and so was intuitively able to identify similarities and differences between the systems, thereby establishing the key foci of this work. Once the initial community pharmacist survey had been completed, subsequent surveys were designed at the request of, and with input from, those working in the field.

These investigations into pharmaceutical services under the MPS had two aspects: (a) quantitative, enumerative, descriptive "surveys" with some analytical aspects and (b) qualitative, interpretative, exploratory in-depth work (see chronological diagram in Appendix A.2.1.). The use of qualitative research methods in conjunction with broader survey techniques can be helpful in the exploration of sensitive, cultural issues and in identifying small percentage changes and their causes in limited samples (Davies 1989, McKeganey 1995, Gerber 1999, O'Muircheartaigh 1999). Mixing research methods helped to overcome their individual limitations: quantitative studies risk giving significance to inconsequential, but statistically significant findings while qualitative

research may give significance to a particular view because of a single interesting anecdote (Stimson 1995).

The absence of a control group meant it was not possible to draw causal inferences from the study findings. But this shortcoming was overcome to some extent by the use of an interrupted time series design in the study of community pharmacists (Robson 1993) and by triangulation between community pharmacist and patient groups (Denzin 1970).

#### 2.2. QUANTITATIVE SURVEYS

In the absence of a control group and given the explicit purpose and aims of this research, surveys offered the most immediate way of arriving at a full and accurate descriptive profile of the situation. In addition, they could be carried out longitudinally to examine changes over time, and, by carrying out concurrent cross-sectional surveys amongst community pharmacists and their patients, they could also amass data from two different perspectives (Oppenheim 1992). The sampling techniques employed are discussed separately in the individual studies.

Self-completed postal surveys were used in the quantitative work carried out among community pharmacists. They were considered more appropriate than face-to-face interviews because they were less invasive, quicker to complete and could be completed by participants in their own time, rather than to a fixed schedule. They were also more efficient, allowing the researcher to access a greater number of pharmacists in significantly less time than that required to carry out an equal number of qualitative interviews. In addition, as the researcher would have carried out such interviews, structured questionnaires were viewed as less likely to be biased by researcher effects.

Covering letters accompanied the postal surveys (with follow-up letters to non-respondents) which explained the purpose and importance of the surveys and assured respondents of total confidentiality (see letters in Appendices A.3.1. & A.3.2., A.4.1. & A.4.2., A.5.1. & A.5.2.). Respondents were also informed that the researcher would process their returns. Stamped self-addressed envelopes accompanied all questionnaires, which were coded so that non-responders could be identified. This

coded information was discarded prior to the analysis of the data. (See questionnaires in Appendices A.3.3., A.4.3. & A.5.3.)

Due to potential literacy problems among patients in methadone treatment, standardised structured interviewing techniques were used in the administration of the survey of their views (Oppenheim 1992). Surveys administered to patients in this way have been shown to produce accurate descriptive and comparative data on the services provided in drug treatment programmes (McLellan et al 1992). A cross-sectional sample of patients participated in individual interviews on a voluntary basis. Because the identities of individual patients registered in methadone treatment were protected by the Central Drug Treatment List (CDTL) a totally random sample could not be targeted. Instead, anonymised statistics were used to identify a target sample that was numerically representative of all those in methadone treatment in a number of key aspects, and quota sampling techniques were subsequently employed to further refine the sampling process.

The research instrument aimed to capture data on aspects of patients' pharmaceutical services at one specific time point as well as limited retrospective data on their previous treatment experiences. Participants were informed verbally of the nature and rationale behind the study in advance of their interviews, with a standard information leaflet being provided. They were also assured of total confidentiality and were asked to sign a consent form before being included in the study.

When designing the survey instruments it was important that the questions asked related to the primary issues from the respondents' perspective, so that they believed that the studies were worthwhile, and were prepared to participate. The researcher's extensive background knowledge and familiarity with the field of methadone treatment and liaison with peer researchers enabled her to identify the key issues.

Survey questionnaires (for both community pharmacists and patients) were developed in response to specific requests for information from Addiction Service management and other external enquirers. The questionnaires were structured and used primarily closed and multi-choice questions, with most questions requesting descriptive data, although some exploratory enquiries were also included. It was essential that the questions asked

were specific and that the optional responses given for closed questions were appropriate, to ensure high completion rates and reduce the potential for misinterpretation among respondents. The questionnaires were also designed with a view to ease of coding and analysis.

Care was taken in deciding on the language used in wording survey questions to ensure that they were culturally sensitive and fully interpretable by participants. Wording was particularly important in addressing personal or behavioural issues, where external inferences and associated meanings could influence participants' responses (Davies & Baker 1987, Fillmore 1999). Attention was also given to the options and scales used to enable and encourage respondents to express their opinions. Therefore, issues were first addressed using a multi-choice or closed question, which was followed by an openended question, for those who wanted to expand on their views.

Respondents' attitudes were measured using a five point Likert scale. Such scales give subjects a choice of five identified attitudinal positions (i.e. strongly agree, agree, neither agree nor disagree, disagree, strongly disagree) and can be used to measure reliability within a study (Oppenheim 1992). In this instance attitudinal statements were used to investigate respondents' views on aspects of complex issues and as a form of triangulation with the responses given elsewhere in their questionnaires.

Quantitative data were analysed using standard statistical sofware (SPSS, Version 9). The data were examined using both tests of difference and tests of association, as appropriate to identify statistically significant differences and similarities. While surveys are not without their difficulties and limitations (Bryman & Bulmer 1988, Davies 1989, Oppenheim 1992, McKeganey 1995), factorial and regression analyses were used to identify relationships between a number of independent variables. Factor analysis can help to simplify study findings, although care should be exercising in drawing conclusions, as data may be open to interpretation by the researcher (Black 1993).

#### 2.3. QUALITATIVE RESEARCH STUDIES

Little qualitative research has been carried out in the drugs field in Europe or the United States and that which has been done is less well recognised than concurrent quantitative work (EMCDDA 2000a). Traditionally researchers tend to concentrate on one or the other approach, generally due to a lack of resources. But ideally they should be able to pursue relevant issues using the best methods available, which may involve using mixed methods, a change from qualitative to quantitative or visa versa (Davies 1989, Denzin & Lincoln 1998).

More complex or in-depth information can be derived using qualitative research techniques, especially where sample sizes are small and the issues being explored are sensitive (Caplehorn & Saunders 1993, McKeganey 1995, Chernomas 1997, Gerber 1999, Maher et al 1999, Schwartz & Sprangers 1999). In addition, qualitative research is believed to be better than quantitative in investigating the consequences of implementing policy to create programmes (Denzin & Lincoln 1998) and in detecting response shifts over time (Davies 1989, Maher et al 1999, Schwartz & Sprangers 1999).

Triangulation using multiple research methods also improves validity where findings are consistent and may uncover new issues, questions or outcomes where they differ (Denzin 1970, Bryman & Bulmer 1988, Davies 1989, McKeganey 1995). Multiple methods can also be used in a complementary fashion to enhance interpretability or to address different research questions within the same study. In addition, secondary methods can be used to assess the plausibility of threats to validity in the primary research method, which is particularly useful when dealing with quasi-experiments such as these where some findings may be open to misinterpretation or bias (Robson 1993). The simultaneous use of quantitative and qualitative methods is particularly common in medical research (Gerber 1999).

#### 2.4. PREPARATORY WORK & PILOT STUDIES

This research work was carried out following exploratory discussions with key informants working in the provision of primary (i.e. community-based) and tertiary (i.e. specialist)

methadone treatment services, as well as those working within the broader healthcare field. Their advice on the content and layout of the instruments used was invaluable. (See copy of the covering letter sent with the pilot of Survey 1 in Appendix A.3.4.)

On the primary care level, the researcher, as liaison pharmacist, had access to, and responsibility for, supporting the community pharmacists working with the MPS. But she was also aware of the myriad other demands on their time, and knew that it was essential that any research undertaken with them was focussed, service orientated and succinct. In addition, as a liaison pharmacist, the researcher needed the support and cooperation of certain key pharmacists who held high-profile positions regarding many professional matters. Before carrying out any work the researcher liaised with these independent individuals to gain their support and glean their ideas, with a view to incorporating them in the subsequent studies.

On a tertiary care level, studies carried out by the researcher, as liaison pharmacist with the EHB Addiction Service, were undertaken with the co-operation and support of the second liaison pharmacist, the GP co-ordinators and the clinical directors. Following initial discussions, the research questionnaires were circulated to each of them prior to piloting, so that they had an opportunity to express their views.

Pilot studies were done in advance of all quantitative studies, to facilitate fine-tuning of the research instruments (see individual studies for further details). They were useful in determining the wording, order, layout and spacing of the instruments, as well as identifying key answers to the multi-choice questions. Pilot samples were selected on the basis of their prior knowledge and ways of thinking, so that they resembled the ultimate samples surveyed.

### 2.5. EVALUATION

For research to be of value it should be credible and internally reflexive (i.e. it must take account of researcher and research strategy effects) and the research methods employed here attempted to address these issues. In addition, quantitative study findings should be generalisable, with sample size and selection being an important

factor in determining confidence in the representativeness of quantitative study findings. These factors were also taken into consideration during the sampling process to ensure that participants in these studies were representative of their populations as a whole.

It should be noted, however, that Pharmacy Surveys 2 and 3 (Chapter 4 & 5) and the Survey of Patients' Views (Chapter 8) did not target non-service providers and non-service users respectively, but were confined to pharmacists and patients participating in the MPS. This means that the data collected by these quantitative studies relates to the relevant participant populations only.

#### 2.6. RELIABILITY

Reliability is a quality control issue that looks at whether a particular question always elicits the same answer (Litwin 1995). Reliability is threatened by a variety of features including (Robson 1993):

- (1) Subject error, where the respondent changes their mind and therefore their responses change.
- (2) Subject bias, where the respondent deliberately tries to give what they perceive as the right (or wrong) answer.
- (3) Observer bias, where the researcher misinterprets the subjects response (either inadvertently or due to their own personal views or biases) during data collection or analysis.

Methods used to measure reliability include test-retest (where the same sample is retested at a later time point and findings are compared) and intra-observer testing (where the same observer carries out multiple tests over a period of time).

Another method of measuring reliability is inter-observer testing, where multiple observers undertake studies on the same sample and findings can be reviewed to establish how each respondent rated the same phenomena. Inter-observer reliability testing can be carried out by comparing findings on a number of key questionnaire responses between two or more researchers, to look for significant differences that could be due to observer bias. A number of researchers were employed in data collection for

the Survey of Patients' Views (Chapter 8), but as researchers were allocated to individual research sites and completed all of the questionnaires filled at these sites, inter-observer reliability testing could not be used to show differences that were exclusively due to researcher bias, as opposed to other external factors or treatment conditions.

In addition, "alternate form testing" measures reliability by asking the same question in a variety of ways and internal consistency testing looks at agreement between responses that measure the same thing (Litwin 1995).

Test re-testing methods were not considered feasible in the studies undertaken here. Asking community pharmacists to complete their questionnaires twice (resulting in them being asked to participate in a total of six surveys in less than 18 months) would more than likely have had a detrimental effect on their relationships with the researcher, as their liaison pharmacist, hence significantly reducing the overall response rates. It could also have impacted on the validity of the research finding due to respondent fatigue. Tracking patients in methadone treatment for retesting would have had serious ethical implications in relation to patient confidentiality, and was also avoided. In addition, even if test-retest had been undertaken, the ever-changing nature of the practices being investigated in both community pharmacist and patient surveys could have influenced the findings collated over time (Litwin 1995). Many of the other methods described above were employed in assessing reliability and they are discussed separately as relevant to each study undertaken.

#### 2.7. VALIDITY

While Fisher (1966) has shown that random sampling leads to high validity, in the real world it presents difficult practical and ethical problems. Where random sampling is not possible Cook and Campbell (1979) advocate quasi-experimentation, using samples that are 'intact groups' instead of random selection, and addressing individually any existing or potential threats to validity. Validity is threatened by selectivity or overconfidence in some data, misinterpretation of co-occurrences as correlations, false extrapolations from observed data and unreliable sources (Denzin & Lincoln 1998). It is particularly

important to establish internal validity in quasi-experiments, surveys and case studies. Validity is improved by checking for representativeness, controlling for researcher effects (i.e. biases) and the use of triangulation.

Although strengthened by complete sampling in some instances, it is possible that the findings from these studies were dependent on the settings in which they took place. The combination of the timing regarding the introduction of the MPS and the relationship between participants and the researcher may have been responsible for exceptional findings. In addition, given than many of the community pharmacists and patients involved in this research were experiencing relatively new phenomena during the study period, it is possible that their views were influenced by recent specific and unique personal incidences, rather than universally experienced events.

However the phenomena that may have resulted in low generalisability were produced primarily due to conditions associated with the quasi-experiment being studied. These data related to a particular time and a unique situation in the introduction of a statutory methadone treatment programme in Ireland, a situation that can never be reproduced. Robson (1993) described how research can prove causality by repeated exposure and withdrawal of the experimental intervention, resulting in changed behaviour between new and baseline stability levels, but this was not possible in this instance, as it would have been clinically unethical and practically impossible to discontinue the MPS following its introduction.

In a study where all efforts had been made to minimise subject and observer biases, it is also important to ensure that the study is measuring what it sets out to measure i.e. construct (or face) validity must be ensured. There are many ways of determining face validity, but in general it is accepted that the use of intuitive reason is appropriate. This means that methods that seem reasonably able to measure or observe the test hypotheses are suitable in most instances. Theories which attempt to quantify elements that cannot be directly observed or measured threaten face validity, but it is strengthened by the use of triangulation and/or multiple methods (Robson 1993).

Measures taken to assess validity are outlined separately for each of the studies undertaken.

### 2.8. OBJECTIVITY & CREDIBILITY

Since this research was carried out in an essentially non-scientific environment it was important to establish a degree of objectivity in the approach taken. This was done by having multiple inputs at the planning and delivery stages, and using mixed methods to reach a greater understanding of the entire situation. Credibility was ensured by documenting and justifying the methods used at every stage in the research studies, both quantitative and qualitative. With quasi-experimental designs such as this the pattern of outcome, design and context must be considered when seeking to interpret the results of a particular experiment.

There are intrinsic, well-documented limitations associated with bias in self-report studies among patients (May & Foxcroft 1995, Schwartz & Sprangers 1999, Shum & Rips 1999) and drug misusers (Davies & Baker 1987, Harrison 1995, McKeganey 1995). Nevertheless, researchers commonly use self-report instruments to investigate aspects of primary care services (Lipman et al 1982, Bates et al 1995, Assa & Sheppard 2000, Finkelstein et al 2000, Rabin et al 2000), and have been shown to produce reliable findings (Oxman et al 2000).

In addition, administered patient surveys which employ structured instruments have been shown to produce accurate information on compliance with medical treatments for conditions such as hypertension (Haynes et al 1980) and reliable data on the age of onset of tobacco, alcohol and illicit drug misuse (Johnson & Mott 2001). Another study reported that a self-completed multiple choice questionnaire was a reliable and valid instrument for assessing craving among current marijuana smokers (Heishman et al 2001). In addition, research has shown that self-report among drug misusers produces data on drug misuse that are consistent over time (Adair et al 1995 & 1996) and another study found that self-reported alcohol consumption data were reliable (Høyer et al 1995).

Data from the UK has also shown that brief structured interviews using standard questionnaires with consecutive attenders can provide meaningful data on outcomes for those in opiate or alcohol treatment (Tober et al 2000). They can also produce useful descriptive and comparative data on aspects of drug treatment services (McLellan et al 1992) and consistent self-reports of current drug taking behaviour (Goldstein et al 1995,

Høyer et al 1995, Joyner et al 1996, Adair et al 1996, Darke 1998). Face-to-face interviews have also been shown to produce more reliable data on alcohol consumption compared with telephone interviewing, particularly for survey samples in lower income demographic subgroups (Greenfield et al 2000). These findings support the research method employed here to investigate aspects of respondents' pharmaceutical services.

In qualitative studies, researchers strive not so much for reliability or validity, but rather for authenticity, as they aim to minimise the flaws and biases associated with self-reporting. This is particularly difficult in the field of addiction, where participant trustworthiness may come into question, and where participants' beliefs and behaviours may become confused with social and personal morality issues (May & Foxcroft 1995). Issues also arise out of the questioning process itself (how questions are phrased and delivered) and from participants' own objectives for the study. For example, self-report among heroin misusers has been shown to be influenced by interviewer bias effects, with participants reporting consistent external factors (such as employment status, housing etc.) but much heavier drug use and more serious addiction when interviewed by 'straight' as opposed to peer-researchers (Davies & Baker 1987). In addition, qualitative studies have to recognise that participants may hold beliefs that are unrelated or sometimes actually contradict their behaviour (e.g. as reported by Backett 1989 & 1992), so that in practice even authentic self-report may not reflect reality.

#### 2.9. RESEARCHER EFFECTS

Although well placed to access relevant information and carry out these studies, it was important that the researcher recognised the limitations of her ability to amass full and accurate information. The community pharmacists targeted were professionals and business people with many demands on their time and each of them had a different relationship with the researcher as liaison pharmacist. The sample of in-treatment methadone patients involved in this work also had their own views on pharmacists and varying degrees of trust in "the system" that would protect the confidentiality of their responses.

In addition, as a liaison pharmacist employed by the Addiction Service, the researcher must acknowledge her own potential biases and how they might affect the self-reported responses received or their subsequent interpretation. These and other "experimenter effects" will have influenced the findings in this work, and should not be ignored (Davies & Baker 1987, Robson 1993, May & Foxcroft 1995, Finch & Strang 1998).

# 2.10. ETHICS & CONFIDENTIALITY

Ethical considerations in carrying out research depend on the questions being asked and the methods used in seeking answers to those questions. Codes of conduct generally determine ethical aspects of research, which are enforced by ethical committees.

No such committee had been established in Ireland when these research initiatives were undertaken. Therefore, the ethical considerations here were difficult to address. Before each study was undertaken, the researcher discussed the ethical issues with members of all of the relevant healthcare professions (details are given separately later for each study). The potential harm to participants had to be weighed against the potential gains of carrying out the research, with both aspects being clarified in advance for potential participants.

Pharmacists surveyed in the course of this work were assured that their participation would not affect their relationship with the EHB's Addiction Service, their liaison pharmacist, methadone prescribers or their professional peers. The benefits of gaining information from those surveyed were elaborated. They included the potential gain in insight into the community pharmacist's role in the provision of methadone treatment and the opportunity for community pharmacists to show the importance of their input in facilitating the development of community-based methadone treatment. This was also a chance for them to review their current practice and to outline any problems they had experienced with a view to their ultimate resolution.

Patients participating in these research initiatives were assured that their identities would be protected, and that their responses would not affect their treatment. It was clarified that no information they gave would be reported directly to their dispensing pharmacist or prescriber. In addition, it was clarified that their participation in the studies would not affect their methadone treatment. Participants were informed that this was an opportunity to express their views, both positive and negative, and that their input would be used to understand their perspective on methadone treatment and could ultimately be used to guide service development.

# **CHAPTER 3:** Pharmacy Survey 1

A survey of all community pharmacies in South Dublin, Wicklow & Kildare (N=264) to establish the extent of community based methadone dispensing services for drug misusers in February 1998.

Date	Stage in MPS	Study title	Participants	No. respondents	Location
February 1998	Pilot (MPP) underway	Pharmacy Survey 1	All community pharmacists	201	Southern sectors of the EHB region
August 1998	Interim phase in introduction of MPS	Pharmacy Survey 2	Community pharmacists who dispensed methadone 1mg/ml	99	Nation-wide
March 1999	MPS established	Pharmacy Survey 3	Community pharmacists who dispensed methadone 1mg/ml	153	Nation-wide
after March 1999	MPS established	Longitudinal Study	Community pharmacists who responded to more than one of the above surveys	Varied, as specified in text	Southern sectors of the EHB region
June 1998 to <b>M</b> ay 1999	Pilot (MPP) & MPS	Liaison Queries	All enquiries received by the liaison pharmacist	848 enquiries	Southern sectors of the EHB region (primarily)
March 1999	MPS established	Patients' Views	Patients in methadone treatment	217	Nation-wide
February 2001	MPS established	Qualitative interviews	Drug misusers, ex- drug misusers, patients in methadone treatment, service providers	15	Three non- prescribing support services

## 3.1. INTRODUCTION

The Report of the Expert Group on the establishment of a Protocol for the Prescribing of Methadone (DOH 1993) included guidelines for GPs and community pharmacists involved in the provision of community-based methadone treatment programmes. In keeping with these guidelines, the EHB Addiction Service established the MPP in 1996, to commence the formal registration of patients in methadone treatment and to look at the viability of transferring patients stabilised in tertiary drug treatment centres to community settings using the treatment card system described earlier. When this transfer was not shown to have a detrimental effect on patients, the DOHC moved to expand the project to include all patients in methadone treatment in the proposed MPS by 1 October 1998. It also aimed to increase the involvement of GPs and community pharmacists in methadone treatment to meet the needs of stabilised patients, in the absence of a contractual obligation for them to do so. The liaison pharmacists were responsible for organising and co-ordinating community pharmacy based methadone treatment for patients in the EHB region.

A survey carried out around this time among community pharmacies in the greater Dublin area found that 38% of respondents were providing methadone dispensing services, but as the response rate to the survey was only 50% this data was not conclusive (Healy 1998). The Central Drug Treatment List (CDTL) had 2,966 patients registered as being in methadone treatment but it was not clear how many were being prescribed Physeptone®1mg/ml. In addition, as the registration of patients on Physeptone® was not obligatory, there may have been unregistered patients being dispensed Physeptone® at community pharmacies at that time. According to CDTL statistics, seventy-one community pharmacies were dispensing methadone 1mg/ml under the MPP, but they were not consulted during the project evaluation and neither were their views or experiences of dispensing methadone 1mg/ml recorded. No data was available regarding community pharmacies that dispensed Physeptone®.

In order to prepare for the imminent introduction of the MPS nine months later, the liaison pharmacist carried out this survey among the community pharmacists in the two south sectors of the EHB region in order to record baseline activity data in the

community pharmacies in that region in February 1998 similar to that available for Scotland (Matheson et al 1999b).

# Aims

- (1) Establish the extent of community pharmacy involvement in the provision of methadone dispensing services.
- (2) Investigate the potential for expansion of this service level.

# **Objectives**

- (1) To establish how many community pharmacists were involved in the provision of methadone dispensing services.
- (2) To ascertain the volume of patients currently receiving community pharmacy based methadone dispensing services.
- (3) To investigate the extent of Physeptone® dispensing by community pharmacists.
- (4) To look at the level of care being provided to those being dispensed methadone or Physeptone® by community pharmacists.
- (5) To establish the needs of community pharmacists regarding support and backup.
- (6) To investigate the attitudes of non-participating community pharmacists to the concept of methadone dispensing.

#### 3.2. METHOD

# 3.2.1. Questionnaire design & Piloting

A draft questionnaire was designed using primarily closed and multi-choice questions. The content of the questions asked was determined by the liaison pharmacist's extensive background knowledge of this area. They aimed to establish the extent and nature of current service provision, examine why non-providers were not involved, and investigate the potential value of a range of support services.

Respondents were asked to report some demographic data, and to record their current methadone dispensing status i.e. whether or not they were methadone dispensers. Once their dispensing status was established, the questionnaire referred providers and non-providers to different sections, with providers being asked for details of the services they

provided and non-providers being asked to respond to a list of suggested reasons why they chose not to dispense methadone.

The use of pharmacy/patient contracts were recommended by the Pharmaceutical Society of Ireland's *Policy on Drug Abuse* (1996) but they were not obligatory for patients in the MPP. In order to quantify the incidence of the use of pharmacy/patient contracts among patients on Physeptone®, this survey asked service providers if they used such contracts. Both categories of respondents were asked whether they felt any of the support services listed in the questionnaire would help them in providing (or encourage them to provide) methadone services for drug misusers. The tight structure of the initial sections of the questionnaire was balanced by the provision of an open-ended area at the end where respondents could report their views.

Prior to its use the pilot questionnaire was discussed with other researchers and colleagues involved in an earlier study in this area, and some questions were aligned to facilitate subsequent inter-observer comparisons.

The questionnaire was piloted amongst a group of five community pharmacists, three of whom worked outside the survey region, alterations were made, and the final questionnaire was circulated by post (see Appendix A.3.4. for pilot covering letter, Appendix A.3.3. for final questionnaire). It was deemed necessary to include two pharmacists who were actively dispensing methadone in the survey region in the pilot, to ensure that the questionnaire design was acceptable and appropriate, although their inclusion may have affected their ultimate responses to the survey proper.

A covering letter accompanied the survey, which explained its purpose and importance and assured respondents of confidentiality (see letter in Appendix A.3.1.). In all instances a stamped self-addressed envelope accompanied the questionnaire, and questionnaires were coded so that non-respondents could be identified. Six weeks later a second mail-shot was sent to non-respondents (see follow-up covering letter in Appendix A.3.2.).

# 3.2.2. Sample

All community pharmacies listed with the Irish Pharmaceutical Union (IPU) in the two south sectors of the EHB region were included in the sample. Newly established pharmacies and those not registered with the IPU (as membership was optional) were identified using personal and professional contacts and using the regional telephone directory, and they were also included in the survey. The inclusion of all of the community pharmacies in the catchment area will have reduced the impact of many of the factors that could have affected internal validity. However, the possibility of selective non-response among disinterested community pharmacists and those who held "unacceptable" views or who provided less than professional services cannot be ignored.

The initial postal survey of community pharmacists was carried out within the liaison pharmacist's catchment area and included all pharmacists, not just those registered to dispense methadone 1mg/ml. Therefore ethical concerns associated with accessing confidential information regarding the identity of pharmacies registered to dispense methadone 1mg/ml were not an issue here. The survey was also discussed in advance with the clinical directors of both EHB sectors involved.

# 3.3. RESULTS

# 3.3.1. Response rate

The over all response rate was 76.1% (201/264) with 58% of pharmacists (153/264) responding to the first mailshot. Full survey findings are available on the accompanying disk (see Appendix A.3.5.), in addition to respondents' qualitative comments (see Appendix A.3.6.). Almost two-thirds (65.7%, 132/201) of those who responded were pharmacy owners (data were missing on six cases).

# 3.3.2. Extent of Participation

Twenty-nine percent of the pharmacists who responded (29.4%, 59/201) were actively dispensing methadone and/or Physeptone®. Of those, almost one-third (32.2%, 19/59) were dispensing methadone 1mg/ml only, over one quarter (27.1%, 16/59) were dispensing Physeptone® only and 40.7% (24/59) were dispensing both formulations.

# 3.3.3. Activity

A total of 330 patients were being dispensed methadone 1mg/ml in the pharmacies surveyed and an additional 613 patients were being dispensed Physeptone® (one respondent did not report the number of patients he had on Physeptone®). Respondents reported a mean of 15.72 patients per pharmacy (SD=32.97, range=1-190, median=4, N=58, total patient numbers were not given for one pharmacy). Those pharmacies that dispensed both formulations of methadone had significantly more patients per pharmacy (mean = 21.9 patients each, SD=22.1, range=2-70, median=13, N=23, data were missing on one case and two top outliers were excluded) than those that dispensed only Physeptone® (mean=3.19 patients each, SD=2.14, range=1-8, median=3, N=16) and those that dispensed methadone 1mg/ml only (mean=3.74 patients each, SD=4.05, range=1-16, median=2, N=19) (ANOVA F=7.46, p<0.01).

Of the responding pharmacies that were providing methadone dispensing services (N = 59), a total of 15 respondents (25.4%) had more than 10 patients each, and five pharmacies (8.5%) had more than fifty patients each. Patients numbers were not given for one responding pharmacy (see Table 3.1. for details).

Table 3.1.: Grouped patient numbers per responding pharmacy (data were missing on one case).

No. patients	No. pharmacies (%)
1	11 (18.6)
2	10 (16.9)
3 – 5	13 (22.0)
6 - 10	9 (15.3)
11 – 15	2 (3.4)
16 – 35	7 (11.9)
36 - 50	1 (1.7)
> 50	5 (8.5)

Over one fifth (22%, 13/59) of the pharmacists surveyed that provided methadone dispensing services were supervising the consumption of methadone on-site at their pharmacies for at least one patient. Only one of these pharmacies provided Physeptone® only. Pharmacies provided this service for 10.4% (98/943) of the patients in their care (mean=7.54 patients per supervising pharmacy, SD=9.6, range=1-30,

N=13). Five of these pharmacies (38.5%, 5/13) supervised methadone consumption for just one patient each.

An additional 37.0% (17/46) of the pharmacists who were currently dispensing methadone and/or Physeptone®, but were <u>not</u> supervising doses, stated they were willing to provide supervision for their patients if they were asked to do so (Data missing on five cases).

#### 3.3.4. Standards of Care

# 3.3.4.1. "Take-home" methadone doses

Over 50% (54.4%, 496/912) of the patients who attended responding community pharmacies collected their methadone on a weekly basis. Two pharmacies (2/59, 3.4%) that were providing methadone or Physeptone® did not dispense to any patient on a once weekly basis. It is not known what formulation of methadone (i.e. Physeptone® or methadone 1mg/ml) these patients were being dispensed, how frequently they attended or whether they were administered supervised doses on-site.

# 3.3.4.2. Use of Pharmacy/patient Contracts

Almost one fifth (18.6%, 11/59) of pharmacists who responded who provided methadone treatment used written contracts with their patients. The use of pharmacy/patient contracts was associated with larger numbers of methadone patient numbers at the community pharmacy, although the relationship was not statistically significant (t=1.60, df=10.23, p=0.14. Used contracts: mean=41.64 patients, SD=64.99, N=11. No contracts: mean=10.04, SD=15.42, N=45). The majority of the pharmacists who used contracts (63.6%, 7/11) dispensed both methadone 1mg/ml and Physeptone®. Almost three-quarters (73.7%, 14/19) of pharmacists who dispensed methadone 1mg/ml only did not use written contracts with their patients (data were missing on two cases).

One pharmacist who did not use contracts with patients on methadone said:

"I support the aspiration that "addicts" should be treated like any other customers."

# 3.3.5. Support & Communication

Pharmacists were asked to respond to a series of suggestions, to indicate which would help (or encourage) them to provide methadone dispensing services for drug misusers. Details of their responses are given in Table 3.2. Most pharmacists cited the liaison pharmacist as the most useful support (60.7%) with training in dealing with drug misusers the second most popular suggestion (59.7%) and closer monitoring of methadone prescribers third (54.7%). When investigated in relation to their current dispensing status, those currently providing methadone treatment were significantly more likely to see value in the various support initiatives suggested, with one exception. There was no significant difference in the responses from both groups to the suggestion that methadone dispensing should be initiated universally in all community pharmacies in the locality.

One non-service provider said:

"The bottom line for me personally with this service [methadone dispensing] is that <u>all</u> pharmacies in the area should introduce it at the same time."

Of the support services offered, those not currently providing methadone dispensing services responded most favourably to suggested training in working with drug misusers (49.3%), support from the liaison pharmacist (47.9%) and closer monitoring of methadone prescribers (45.1%).

In relation to methadone prescribers, respondents said:

"At present the only doctors [prescribing methadone] in (two local areas) appear to be using a fly-by-the-seat approach."

"Strenuous efforts must be made to keep "rogue" prescribers in check – i.e. prescribers who write scripts for monetary reasons."

Respondents made the following comments regarding the importance of limiting the number of patients attending each community pharmacy:

"We provided Physeptone® on prescriptions from this one doctor. The result after about a year was that we had junkies from all over south county Dublin and even the Northside. This often resulted in the drug being sold outside. The theft and pilferage was considerable and staff were often threatened and abused. We had a couple of attempted break-ins and one hold-up. I want no more to do with junkies!"

"I would only be willing to dispense methadone to a few people who lived locally that I personally knew and would be prepared to stick to the protocols laid down."

"I am very reluctant to get involved in methadone dispensing because I worry about attracting "hopeful" addicts to the area. If <u>all</u> pharmacies were to become involved with a maximum number of addicts per pharmacy I would possibly reconsider.""

"I believe it would be possible to implement the Scheme [MPS] here if we restricted our contract to one or two individuals."

When asked specifically about the supportive role of the liaison pharmacists, pharmacists' responses are given in Table 3.3. Most pharmacists said that ensuring that each community pharmacy was only asked to provide methadone to a limited number of local patients would be useful (68.7%), while the provision of pharmacy/patient contracts (62.7%) and training in managing drug misusers (60.7%) were also seen as important. When investigated in relation to their current dispensing status, those currently providing methadone treatment were significantly more likely to see the value of all of these services.

Table 3.2: Pharmacists' responses to "What would support you in providing (encourage you to provide) methadone services?" (N=201)

	Pa	rticipants		Non	-participants			All		$\chi^2$ (p value) for
	Yes (%)	No (%)	MV	Yes (%)	No (%)	MV	Yes (%)	No (%)	MV	participants versus non-participants (df=2)
Training in the clinical aspects of drugs that are misused, including information on methadone.	47 (79.7)	4 (6.8)	8	52 (36.6)	39 (27.5)	51	99 (49.3)	43 (21.4)	59	31.11 (p<0.01)
Training in dealing with drug misusers.	50 (84.7)	3 (5.1)	6	70 (49.3)	31 (21.8)	41	120 (59.7)	34 (16.9)	47	21.92 (p<0.01)
Support and back-up from the EHB via the community liaison pharmacist.	54 (91.5)	1 (1.7)	4	68 (47.9)	30 (21.1)	44	122 (60.7)	31 (15.4)	48	33.51 (p<0.01)
Invitation to attend clinical team meetings at local drug services.	42 (71.2)	7 (11.9)	10	48 (33.8)	39 (27.5)	55	90 (44.8)	46 (22.9)	65	23.56 (p<0.01)
Universal initiation of methadone dispensing in all the community pharmacies in your area.	35 (59.3)	10 (16.9)	14	63 (44.4)	35 (24.6)	44	98 (48.8)	45 (22.4)	58	3.78 (p=0.15)
Simplified remuneration scheme.	44 (74.6)	5 (8.5)	10	55 (38.7)	34 (23.9)	53	99 (49.3)	39 (19.4)	63	21.53 (p<0.01)
Remuneration for modification of your premises to provide a private area for the supervision of methadone consumption.	26 (44.1)	21 (35.6)	12	45 (31.7)	42 (29.6)	55	71 (35.3)	63 (31.3)	67	6.52 (p<0.05)
Free vaccination of your staff against hepatitis B.	44 (74.6)	6 (10.2)	9	62 (43.7)	33 (23.2)	47	106 (52.7)	39 (19.4)	56	15.99 (p<0.01)
Closer monitoring of methadone prescribers.	46 (78.0)	5 (8.5)	8	64 (45.1)	30 (21.1)	48	110 (54.7)	35 (17.4)	56	18.21 (p<0.01)

Table 3.3: Pharmacists' responses to "What can the EHB community liaison pharmacist do to help you in providing (encourage you to provide) a methadone service for drug misusers?" (N=201)

	Pa	rticipants		Non	-participants			All		χ² (p value) for participants versus non-
	Yes (%)	No (%)	MV	Yes (%)	No (%)	MV	Yes (%)	No (%)	MV	participants (df=2)
Provide written procedures and guidelines for methadone dispensing in community pharmacy.	44 (74.6)	9 (15.3)	6	67 (47.2)	30 (21.1)	45	111 (55.2)	39 (19.4)	51	14.01 (p<0.01)
Provide a written pharmacy/patient contract, outlining the rules for patients being dispensed methadone in a community pharmacy (pick-up times, unacceptable behaviour etc.)	49 (83.1)	4 (6.8)	6	77 (54.2)	26 (18.3)	39	126 (62.7)	30 (14.9)	45	14.81 (p<0.01)
Organise training for community pharmacists in the clinical aspects of drugs that are misused.	45 (76.3)	5 (8.5)	9	58 (40.8)	31 (21.8)	53	103 (51.2)	36 (17.9)	62	20.94 (p<0.01)
Organise training for community pharmacists in how to deal with drug misusers.	50 (84.7)	3 (5.1)	6	72 (50.7)	28 (19.7)	42	122 (60.7)	31 (15.4)	48	20.32 (p<0.01)
Organise for community pharmacists to visit their local drug services.	39 (66.1)	8 (13.6)	12	47 (33.1)	33 (23.2)	62	86 (42.8)	41 (20.4)	74	18.68 (p<0.01)
Provide community pharmacists with written information on methadone.	43 (72.9)	7 (11.9)	9	53 (37.3)	31 (21.8)	58	96 (47.8)	38 (18.9)	67	21.41 (p<0.01)
Provide patients on methadone with written information on methadone.	38 (64.4)	8 (13.6)	13	47 (33.1)	32 (22.5)	63	85 (42.3)	40 (19.9)	76	16.85 (p<0.01)
Ensure that each community pharmacy is only asked to provide methadone to a limited number of local patients.	50 (84.7)	1 (1.7)	8	88 (62.0)	23 (16.2)	31	138 (68.7)	24 (11.9)	39	11.96 (p<0.01)

# 3.3.6. Reasons why pharmacists chose not to dispense methadone

The 142 pharmacists who were not actively dispensing methadone 1mg/ml or Physeptone® were asked why they had decided not to do so. Their responses are given in Table 3.4.

Table 3.4.: Pharmacists' responses to "Which of the following describe why your pharmacy does not provide methadone services to drug misusers?"

	Yes (%)	No (%)	Missing cases
No request for such a service.	90 (63.4)	18 (12.7)	34
Security reasons – risk to staff, fear of robbery/hold-up etc.	89 (62.7)	16 (11.3)	37
Pharmacy staff feels uncomfortable dealing with drug misusers.	79 (55.6)	19 (13.4)	44
Business reasons – other customers may object, shoplifting etc.	77 (54.2)	23 (16.2)	42
Pharmacy is too small to provide a confidential service.	49 (34.5)	36 (25.4)	57
Concerns relating to inappropriate prescribing.	42 (29.6)	33 (23.2)	67
Pharmacy would be isolated as the only one in the area providing such a service.	36 (25.4)	42 (29.6)	64
Local opposition to the provision of services for drug misusers.	33 (23.2)	47 (33.1)	62
Pharmacy is too busy to provide an efficient service.	27 (19.0)	50 (35.2)	65
No support from EHB	19 (13.4)	42 (29.6)	81
Personal view that methadone programmes are ineffective.	18 (12.7)	58 (40.8)	76

The primary reasons why these pharmacists did not provide methadone dispensing services were because they had not been asked (63.4%) or because they had security concerns (62.7%). Comments regarding security aspects included the following:

<sup>&</sup>quot;They (drug misusers) are not to be trusted and that is the main problem. They would steal from their 'dying granny'. So we do not want them in our shop."

<sup>&</sup>quot;I have been held up five times during my career. I have had a Stanley knife held to my two year old son while I opened the safe. I am not willing to place myself, my staff or my customers at risk again."

<sup>&</sup>quot;The methadone dispensing scheme is doomed to failure because of underlying security problems. What is needed is a greater number of high security rehabilitation centres and not to jeopardise the health (mental and physical) of community pharmacy employees who are already vulnerable to attack."

Many respondents (55.6%) said that their staff would feel uncomfortable managing drug misusers in methadone treatment and that other customers might also find it disconcerting. Some qualitative comments are given below.

"My locum is a lady and would hand in her notice if I started dispensing for addicts. As locums are like gold dust particularly regular Saturday locums – I can't afford to lose her."

"As keen as I am to get involved in limited methadone dispensing neither my regular locum nor my staff want anything to do with the project. This is understandable, especially since they live locally."

"My pharmacy is very near (named area) where the drug problems are huge. We know quite a lot of the addicts who are on methadone maintenance and would have no problem with them. However they are still in regular contact with the local heroin dealers of whom my staff are <u>scared</u>. Our fear is that we would have to keep methadone in stock, which would be practically advertised locally by those on the programme, and having gone through hell in the '80s with daytime raids, we are leaving ourselves open to the same again. We realise that someone has to do it, but many other pharmacies are much better equipped re: security than we are."

"We had a syringe hold-up in the last few weeks, which leaves staff unsure about getting involved."

"The principle objection to providing a methadone service would be the objections of other patients and customers. An education of the general public would have to be a large part of the programme for the provision of a methadone service."

"Most pharmacies are reluctant to deal with methadone patients because of the effects they may have on existing customers."

Only 12.7% (18/142) of respondents said that they held the personal view that methadone programmes were ineffective. Examples of their comments are:

"To my mind this scheme is a somewhat cynical exercise in seeking a low cost solution to a problem which requires much larger investment."

"These methadone treatment schemes resemble the Dutch boy with his finger in the dyke holding back the sea – with the dyke crumbling all around him!"

# 3.4. DISCUSSION

All the pharmacists in the target area were surveyed in the course of this study and, as the response rate was high, these data provided a useful measure of baseline activity at that time. But because the area surveyed was limited to the two south sectors of the Eastern Health Board (EHB) region, the generalisability of these study findings was limited and direct comparisons could not be made with findings from the earlier survey (Healy 1998). Nevertheless, as the geographical area surveyed here was included in the earlier study and the response rate here was higher than Healy's (76% compared to 50%), it was still useful to cautiously compare these findings with those recorded earlier.

This study showed that a number of community pharmacists were dispensing methadone for drug misusers within the surveyed area. The number of community pharmacists dispensing methadone in this region was similar to that reported by Healy (59 pharmacies compared to Healy's 55). These dispensing levels were lower than those recorded in England and Wales in 1995 (Sheridan et al 1996) and in Scotland in 1995 (Matheson et al 1999b), which suggested that the involvement of Irish community pharmacies in the provision of methadone treatment at that time was not as developed as in these countries. This finding highlighted the need for community pharmacists to be encouraged to start dispensing methadone, as comparisons with other countries implied potential for increased involvement.

Activity data recorded here within methadone dispensing pharmacies were very similar to those recorded Healy in the greater Dublin area around this time (Healy 1998), which strengthens the reliability of these findings. More UK pharmacists had three patients or less (6%) and fewer had more than twenty patients each (6%) (Sheridan et al 1996), which suggested that when pharmacists in these EHB sectors commenced methadone dispensing they were more likely than their colleagues in the UK to attract a high number of drug misusers. This supported the need expressed by pharmacists for the universal initiation of methadone dispensing and the limitation of patient numbers in each dispensing pharmacy.

The extent of supervised dosing seen in this region was similar to that reported by Healy in 1998 and was low by some international standards (Roberts 2001a, Matheson et al.)

1999b). This indicated that high volumes of methadone were being dispensed into the community at that time, which may have resulted in problems for service providers including accidental overdose and the diversion of methadone to the black market as incidences of fatal overdose have been associated with "take-home" supplies both among children (Binchy et al 1994, Calman et al 1996) and adults (Cairns et al 1996, McCarthy 1997).

This survey showed that many pharmacists who had never dispensed Physeptone® were actively dispensing methadone 1mg/ml under the MPP, which implied that aspects of the MPP appealed to community pharmacists, and encouraged them to dispense methadone for drug misusers.

Pharmacy/patient contracts were using significantly more frequently than in Scotland (Matheson et al 1999b), which was in keeping with the Pharmaceutical Society of Ireland's *Policy on Drug Abuse* (1996). The statistically insignificant association between increased patient numbers and the use of pharmacy/patient contracts may show a greater degree of specialisation in these community pharmacies. This specialisation among community pharmacists has also been noted elsewhere (Sheridan et al 1996).

The liaison pharmacist was the most popular source of support for respondents, which suggested that they valued this direct link between the tertiary and primary services. However, caution should be exercised in interpreting this finding, as respondents were aware that one of the liaison pharmacists was carrying out the research, and there may have been an element of subject bias in their responses (Robson 1993). However, the active encouragement of local health boards has also been identified as a key encouragement to community pharmacist involvement in the provision of services for drug misusers in Scotland (Matheson & Bond 1999). This finding may highlight community pharmacists' perceived isolation from other members of the drug treatment team. It may also show the importance of having a single individual responsible for developing and nurturing interdisciplinary and interagency relationships between members of complex drug treatment teams. Community pharmacists generally work autonomously and develop working relationships with key local health-carers. But they may find it more difficult to work with larger, less personal organisations, and the use of a liaison pharmacist can reduce the problems associated with interaction at this level.

Respondents' support for the suggestion that methadone prescribers should be closely monitored illustrated their concerns regarding the practices of methadone prescribers at that time. The registration of patients being prescribed Physeptone® was voluntary and there were no evaluations or audit systems for doctors who chose to prescribe methadone privately. These circumstances led to treatment practices that were not standardised, and the potential for multiple prescribing, resulting in concern among community pharmacists for the health and safety of those for whom they dispensed methadone. The extent of this concern was reported by this survey, and was ultimately addressed by the introduction of the MPS, under which doctors wishing to prescribe methadone were obliged to train and participate in audit with the Irish College of General Practitioners (ICGP) (DOHC 1997).

The organisation of training was also perceived as useful to community pharmacists, both current methadone dispensers and non-dispensers. They saw the organisation of this training as part of the liaison pharmacist's role. Training has been shown to have a positive impact both in relation to professional's attitudes and their service provision (Harrison & Flinkow 1973, Anon 1985, Anon 1991, Matheson & Bond 1999, Matheson et al 1999b). The training requirements identified by respondents related specifically to the management of drug misusers, rather than the clinical aspects of their treatment. This suggested that community pharmacists were comfortable with their prior knowledge of methadone and the medical aspects of treatment, but they felt less familiar with the practical and sociological aspects of dealing with drug misusers. A number of training sessions were subsequently organised by the liaison pharmacists for community pharmacists in the EHB and Southern Health Board regions, with an emphasis on these management issues, and to give pharmacists an opportunity to provide each other with peer support. Pharmacists were also invited to attend training sessions that were organised by the ICGP for GPs interested in prescribing methadone, which gave pharmacists an opportunity to meet specialist prescribers as well as other members of the community-based drug treatment team.

Following the analysis of this survey the liaison pharmacists ensured that hepatitis B vaccines were made available on request to all participating pharmacists and their staff. However, although the majority of participating pharmacists said the provision of vaccines was useful for them, it was interesting that a study carried out in the northern

sector of the EHB region almost 3 years later found that less than 20% of those dispensing methadone under the MPS at that time had been vaccinated (Killen & Zayed 2001).

This survey showed that many community pharmacists believed that the provision of methadone treatment should be shared as widely as possible between pharmacies in a given area. The universal initiation of methadone dispensing in all of the community pharmacies in a locality was the only support mechanism equally valued by pharmacists who dispensed methadone and by those who did not. This was an important finding for the liaison pharmacist, charged with encouraging community pharmacists to commence methadone dispensing, given that over two fifths of non-methadone providers thought this would encourage them to get involved. It guided the liaison pharmacist for the southern sectors of the EHB region in the development of a "all-or-none" recruitment strategy. This meant that the liaison pharmacist concentrated on a predefined locality and worked to secure a promise from the local community pharmacists that they would all start dispensing methadone simultaneously. This recruitment strategy reduced targeting of individual pharmacies by local activists who were opposed to methadone treatment and dispersed the risk of robbery among all of the pharmacies involved. It was also efficient for the liaison pharmacist because training initiatives and personal visits were easier to organise for a specific local area. In addition, it enabled the liaison pharmacist to work closely with prescribers and GP co-ordinators in a given area for a limited length of time and produce pharmaceutical services for several patients from that area.

Both qualitative and quantitative responses to this survey showed that community pharmacists viewed the liaison pharmacist's role in limiting the number of patients allocated to each pharmacy as crucial. The data showed that most community pharmacies in this area refused to provide any methadone services, while a limited number provided methadone dispensing services for the majority of patients. This concentration of drug misusers resulted in problems for local communities as patients travelled long distances to have their prescriptions dispensed. This issue was subsequently addressed by the use of methadone treatment cards, which limited the number of patients in each pharmacy to those whom the pharmacist had agreed to accept and who had been registered with that pharmacy on the Central Drug Treatment

List (CDTL). The use of treatment cards was only obligatory for patients in the MPP at this stage, but they were ultimately required by all patients in methadone treatment under the MPS. The MPS Guidelines also recommended that no more than fifty patients should attend any one pharmacy, so that the numbers attending pharmacies where patients had previously congregated were also reduced (DOHC 1997).

The similar number of dispensing pharmacies found here and by Healy (1998) not only validated both study findings but also supported Sheridan and Strang's suggestion (1998) that non-respondents were likely to be non-service providers, as the higher response rate reported here (76% compared to Healy's 50%) was primarily related to a greater response from non-service providers. This indicated that this survey had accessed a number of resistant community pharmacists who were not service providers and who were not responsive to the earlier study. Information on their attitudes and motivations could provide useful insight for liaison pharmacists working to gain their cooperation.

Compared to respondents who were currently dispensing methadone, non-dispensing respondents to the current survey were less likely to report that the supports offered (including the provision of training and external support) would encourage them to do so. Most respondents who were not prepared to dispense methadone were not against methadone in principle. Similar to findings from the UK (Sheridan et al 1996), the primary reason why they did not do so was because they had not been asked. However, this survey did not establish whether these pharmacists had not been asked because there was no demand for methadone dispensing services within their local communities, or if local drug misusers and GPs had not asked them to dispense methadone because they believed they were unlikely to do so.

As seen elsewhere (Sheridan et al 1997, Matheson & Bond 1999, Roberts 2001b), they also had fears regarding the safety of themselves, their staff and customers, their merchandise and their businesses as a whole. The identification of these fears was essential for the liaison pharmacist whose task it was to encourage these pharmacists to participate in the MPP. Reports of local opposition to the provision of services for drug misusers was higher here than seen in Scotland (Roberts 2001b) as were pharmacists' concerns that they would be isolated as the only pharmacy in the area providing

methadone dispensing services (Roberts 2001b). This information was also used in the development of the "all-or-none" approach to pharmacist recruitment.

This study provided baseline data on methadone dispensing activity in one geographical area eight months prior to the introduction of the MPS. It gave policy makers and managers of the MPS useful insight into the level of community pharmacy participation in methadone dispensing at that time, and provided direction for liaison pharmacists in developing strategies to promote and support further community pharmacy involvement. Given that the situation was in a constant state of flux, and in view of the need to establish adequate community-based methadone dispensing services prior to the national introduction of the MPS on 1 October 1998, further research was necessary to investigate the extent of the progress that had been made over the following six month period.

# **CHAPTER 4:** Pharmacy Survey 2

A survey of all community pharmacies participating in the Methadone Pilot Project (MPP) in August 1998 during the interim stage of the introduction of the Methadone Protocol Scheme (MPS).

Date	Stage in MPS	Study title	Participants	No. respondents	Location
February 1998	Pilot (MPP) underway	Pharmacy Survey 1	All community pharmacists	201	Southern sectors of the EHB region
August 1998	Interim phase in introduction of MPS	Pharmacy Survey 2	Community pharmacists who dispensed methadone 1mg/ml	99	Nation-wide
March 1999	MPS established	Pharmacy Survey 3	Community pharmacists who dispensed methadone 1mg/ml	153	Nation-wide
after March 1999	MPS established	Longitudinal Study	Community pharmacists who responded to more than one of the above surveys	Varied, as specified in text	Southern sectors of the EHB region
June 1998 to May 1999	Pilot (MPP) & MPS	Liaison Queries	All enquiries received by the liaison pharmacist	848 enquiries	Southern sectors of the EHB region (primarily)
March 1999	MPS established	Patients' Views	Patients in methadone treatment	217	Nation-wide
February 2001	MPS established	Qualitative interviews	Drug misusers, ex- drug misusers, patients in methadone treatment, service providers	15	Three non- prescribing support services

# 4.1. INTRODUCTION

In July 1998 the DOHC published interim Regulations under the Misuse of Drugs Acts 1977 & 1984 which represented the first step in the introduction of the MPS. Under these regulations methadone (both linctus and mixture) could only be legally dispensed if prescribed using a specific form issued by the General Medical Services (GMS). These regulations were the preliminary stage in the introduction of the substantive new national methadone programme, so that statutory drug treatment services could be arranged for patients who would require them following the discontinuation of private methadone prescribing under the MPS. Pharmaceutical aspects of patient care were of primary concern to the EHB's liaison pharmacists, since they were responsible for ensuring that patients transferring from private to statutory drug treatment services would have adequate pharmacy services in place to receive them.

Survey 1 carried out six months previously in two sectors of the EHB region showed that a significant minority of community pharmacies were dispensing methadone in the area, as either 1mg/ml mixture or 2mg/5ml linctus. In addition, it showed that the majority of those who dispensed methadone 1mg/ml also dispensed Physeptone®. As Physeptone® would no longer be available after the MPS was introduced on 1 October 1998, patients being prescribed Physeptone® at that time would have to be assimilated into statutory drug treatment agencies and provided with methadone 1mg/ml. This meant that the statutory drug services needed to ensure that they were adequately prepared for an influx of additional patients on or around that time. Respondents to Survey 1 also gave practical feedback regarding the usefulness of a number of suggested changes and support services which could be undertaken and developed to help them in the provision of pharmaceutical services for drug misusers.

Between March and August 1998 the liaison pharmacist and others on the MPS Implementation Committee (as established by the DOHC) worked to change community-based methadone treatment programmes and to provide support and back-up to community pharmacists in accordance with feedback from the respondents included in Survey 1. Training in the management of drug misusers was provided, a review of the financial aspects of the MPS was undertaken, a grant was made available to community pharmacists to alter their premises to create a private area for the supervision of

methadone self-administration, free hepatitis B vaccines were provided on request for community pharmacists and their staff and the Irish College of General Practitioners (ICGP) began developing an audit system for methadone prescribers. In addition, the liaison pharmacist in the southern sectors of the EHB region had utilised an "all-or-none" approach to the initiation of methadone dispensing (as described in Chapter 3), provided written procedures and guidelines for methadone dispensing, a sample pharmacy/patient contract and other written information on methadone, arranged for interested community pharmacists to visit their local drug services and meet local methadone prescribers, and limited the numbers attending each participating community pharmacy.

In August 1998 a second survey (Survey 2) was undertaken of all the pharmacists registered to dispense methadone 1mg/ml nation-wide at that time. It aimed to provide information on the number and whereabouts of patients who were being dispensed methadone 1mg/ml or Physeptone® by the community pharmacists registered with the Methadone Pilot Project and to investigate aspects of the dispensing services they provided. On the brink of the introduction of the Methadone Protocol Scheme nationwide, this survey aimed to investigate the standards of care being provided for patients in methadone treatment within community pharmacies. The study aimed to investigate how methadone was dispensed for patients to take home, particularly in relation to safety issues such as the use of child-resistant closures and the supply of measures with multi-dose containers. It was hoped that findings from this survey would also help the liaison pharmacists to estimate the numbers of patients who would need to be transferred from Physeptone® to methadone 1mg/ml on or before 1 October 1998. In addition, this survey aimed to establish whether the efforts of the liaison pharmacists and others on the MPS Implementation Committee had been successful in meeting the needs of community pharmacists as expressed earlier by respondents included in Survey 1.

### Aims

- (1) To investigate developments in the extent of the provision of community pharmacy based methadone dispensing services during the previous months.
- (2) To estimate the extent of Physeptone® dispensing in community pharmacies also currently dispensing methadone 1mg/ml.

(3) To examine pharmacists' attitudes towards their patients on methadone and/or Physeptone®.

# **Objectives**

- (1) To establish how many community pharmacists were involved in the provision of methadone dispensing services at this stage.
- (2) To estimate the number of patients receiving community pharmacy based methadone dispensing services during the Interim Period.
- (3) To investigate the extent of Physeptone® dispensing by community pharmacists also registered to dispense methadone 1mg/ml.
- (4) To look at the standards of care being provided to those being dispensed methadone or Physeptone® by community pharmacists.
- (5) To establish the extent of the communication between community pharmacists and methadone prescribers/drug services.
- (6) To investigate the attitudes of community pharmacists to their patients on methadone and Physeptone®.

# 4.2. METHOD

#### 4.2.1. Instrument

A draft questionnaire was designed using both closed and multi-choice questions. The questionnaire was designed to be completed easily and quickly. It contained questions on the respondents themselves, pharmacy staff and the location of responding community pharmacies. The questionnaire asked respondents about methadone dispensing activities at their premises and about their patients' methadone prescribers. It asked respondents about the services they provided for their patients on methadone – whether their patients had asked them for advice or information, whether they provided on-site supervised dosing and about how they dispensed "take-home" methadone doses. The questionnaire also had an attitudinal section with eleven statements, which employed a five point Likert Scale. Some questions included in this questionnaire had previously been asked in Survey 1, which was carried out six months earlier. A copy of the questionnaire can be found in Appendix A.4.3.

(3) To examine pharmacists' attitudes towards their patients on methadone and/or Physeptone®.

# **Objectives**

- (1) To establish how many community pharmacists were involved in the provision of methadone dispensing services at this stage.
- (2) To estimate the number of patients receiving community pharmacy based methadone dispensing services during the Interim Period.
- (3) To investigate the extent of Physeptone® dispensing by community pharmacists also registered to dispense methadone 1mg/ml.
- (4) To look at the standards of care being provided to those being dispensed methadone or Physeptone® by community pharmacists.
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The questionnaire's format was discussed with researchers who had recently completed a similar survey in the greater Dublin area (Healy 1998), to ensure that the final data were comparable. In addition, community pharmacists and other health-carers who had been involved with Survey 1 were given an opportunity to express their views on the content and format of this questionnaire.

A stamped, self-addressed envelope accompanied each questionnaire, which was coded so that non-responders could be identified. Covering letters explained the purpose and importance of the survey and assured respondents of confidentiality (see covering letters in Appendix A.4.1. & A.4.2.).

# 4.2.2. Pilot Study

As Survey 2 targeted all of the community pharmacies participating in the MPP at this time, community pharmacists involved in piloting the survey were not asked to complete the draft version of the questionnaire, but rather to feed back their views on how it could be changed or improved. This was to avoid the influence that prior completion of the questionnaire could have on their ultimate response to the survey. The questionnaire for Survey 2 was piloted amongst a group of five pharmacists, two of whom were fulltime community pharmacists and three of whom worked part-time in both the EHB Addiction Service and in community pharmacy. The questionnaire's format was also discussed with peer researchers to ensure that the final data could be compared where appropriate.

The questionnaire was modified in accordance with the feedback from the pilot study and the final version was circulated by post (see Appendix A.4.3.). Non-responders received a second mail-shot four weeks after the first (see covering letter in Appendix A.4.2.).

# 4.2.3. Sample

Survey 2 was circulated by post to all 101 community pharmacies registered to dispense methadone 1mg/ml with the Central Drugs Treatment List (CDTL) at the end of July 1998. When returns were analysed, two of the registered pharmacies surveyed were no longer actively dispensing methadone 1mg/ml, and so their responses were excluded from the study.

The inclusion of the total number of registered pharmacies eliminated threats to validity due to sampling technique. But community pharmacies where only Physeptone® was dispensed (i.e. methadone 1mg/ml was not) were not included, which meant that study findings could not be generalised to all Irish community pharmacies providing methadone dispensing services at that time, only to those participating in the MPP.

# 4.2.4. Reliability & Validity

As described in the Methodology section (see Chapter 2) test re-testing methods were not employed in this pharmacy survey due to the longitudinal aspects of the overall research design. Instead where possible, the data were triangulated with findings from Healy's earlier study of pharmaceutical services for those in methadone treatment in community pharmacies in the greater Dublin area (Healy 1998). In addition, the use of a Likert Scale created opportunities to measure internal consistency within the survey.

The inclusion of all of the pharmacies involved in the MPP will have reduced the impact of many of the factors affecting internal validity, as will longitudinal aspects of this work (Litwin 1995). The high response rate will also have reduced the possibility of selective non-response among community pharmacists who held "unacceptable" views or who provided less than professional services. Participatory piloting was avoided to reduce the threat of exposure amongst members of this intact group, but a number of respondents had participated in Survey 1 carried out six months previously, which may have affected their responses here.

## 4.2.5. Ethics & Confidentiality

As liaison pharmacist with the Addiction Service, this researcher was able to access confidential information regarding the identity of all pharmacies registered to dispense methadone 1mg/ml, which facilitated the targeting of specific community pharmacies for the purposes of this research. A covering letter was included with the questionnaire, to ensure that the survey's purpose was clear, and those involved could decide in an informed way whether they wanted to participate (see Appendix A.4.1.).

Questionnaires were coded to avoid duplication, but the key to the code was accessible to the researcher only and was not used to identify individual responses, and so protected respondents' confidentiality.

# 4.3. RESULTS

# 4.3.1. Demographics

The over all response rate to Survey 2 was 83.8% (83/99) with almost three-quarters of respondents (73.7%, 73/99) returning the first mailshot. Details of all questionnaire responses are given in disk format (see Appendix A.4.4.)

Over 60% (61.4%, 51/83) of those who responded were pharmacy owners. Over 60% (62.7%, 52/83) of respondents were male. Pharmacy owners were significantly more likely to be male ( $\chi^2$ =5.54, df=1, p=0.02), with almost three-quarters (72.5%, 37/51) of owner respondents being male.

Respondents had spent a mean of 14.32 years working in community pharmacy (SD=11.46, range=1-49 years, median=11, N=83, data were missing on one case). Almost half of the respondents (48.2%, 40/83) had worked in community pharmacy for ten years or less, 31.3% (26/83) had worked as community pharmacists for eleven to twenty years and 19.3% (16/83) were practising community pharmacy for over twenty years (data were missing on one case).

Respondents had spent a mean of 9.22 years working in their current community pharmacies (SD=10.13, range =1-40 years, N=83, data were missing on one case).

The mean number of staff per pharmacy (including respondents) was 5.35 (SD=3.08, range=2-18, N=83, data were missing on one case). The mean number of pharmacists working in each pharmacy (including respondents) was 1.96 (SD=0.79, range=1-4, N=83, data were missing on one case). Twelve percent (10/83) of the pharmacies surveyed had no male staff members (data were missing on one case).

Only two of the pharmacies included in the survey were located in areas outside the EHB region. Less than one fifth (14/83, 16.9%) of the respondents were located in shopping centres, 31.3% (26/83) were found in main shopping streets, 49.4% (41/83) were in small groups of local shops and two (2.4%) were located in rural areas.

# 4.3.2. Extent & duration of the provision of methadone dispensing services

Respondents had been dispensing methadone with the MPP for an average of 12.74 months (SD=9.11, range=1-30, N=80). Over one-third of the pharmacies surveyed (34.9%, 29/83) had commenced dispensing methadone 1mg/ml in the preceding six months (data were missing on three cases).

Forty-one percent (34/83) of those surveyed said they had never dispensed Physeptone®. Of those who had dispensed Physeptone®, 83.3% (40/48) continued to do so. Those currently dispensing Physeptone® had been doing so for an average of 50.81 months (SD=39.06, range=6–156 months, N=36, data were missing on four cases).

# 4.3.3. Activity

As shown in Table 4.1, there were an average of approximately 16 patients receiving methadone treatment in each of the responding pharmacies. Respondents had a total of 972 patients on methadone 1mg/ml with an average of 12 patients each and the pharmacies that dispensed Physeptone® had a total of 373 patients on Physeptone® with an average of 10 patients per pharmacy.

[Note that two respondents reported that they did dispense Physeptone® but they did not report the number of patients for whom they dispensed Physeptone®. Therefore these respondents were only included in the analyses relating to their patients on methadone 1mg/ml in Table 4.1. and were excluded from all other calculations of the mean numbers of patients per pharmacy.]

Table 4.1: No. patients in methadone treatment in responding community pharmacies (methadone 1mg/ml and Physeptone®) (see note above)

	Sum	Mean no. patients/ pharmacy	SD	Range	N	Missing
No. patients on methadone 1mg/ml	972	11.71	21.05	1 - 155	83	0
No. patients on Physeptone®	373	9.82	14.34	1 – 68	38	2
No. patients on methadone 1mg/ml in pharmacies that did <u>not</u> dispense Physeptone®	229	5.33	8.09	1 – 48	43	0
No. patients attending pharmacies that dispensed both formulations of methadone	1,064	28.0	33.81	2 – 175	38	2
Total no. patients in methadone treatment	1,293	15.96	26.32	1 – 175	81	2

Details of patient numbers in participating pharmacies are given in Table 4.2. A total of 31.4% (26/83) of respondents provided methadone dispensing services for one or two patients, while 7.2% (6/83) had more than fifty patients each (data were missing on two cases).

Table 4.2: Grouped patient numbers per responding pharmacy (data were missing on two cases).

No. patients	No. pharmacies (%)
1	14 (16.9)
2	12 (14.5)
3 – 5	17 (20.5)
6 - 10	11 (13.3)
11 – 15	4 (4.8)
16 – 35	13 (15.7)
36 - 50	4 (4.8)
> 50	6 (7.2)

Pharmacies that dispensed both Physeptone® and methadone 1mg/ml were providing treatment for 82.3% (1,064/1,293) of the patients being dispensed methadone at responding community pharmacies (data were missing on two cases). As shown in Table 4.3, pharmacies that dispensed both formulations of methadone had significantly

more patients and were in the MPP for significantly longer than those that did <u>not</u> dispense Physeptone®.

Table 4.3: No. of patients and time participating in the Methadone Pilot Project (MPP) as related to the methadone formulations community pharmacies dispensed

		Mean	SD	N	t	df	р	Missing
								cases
No. patien	nts Methadone 1mg/ml only dispensed	5.33	8.09	43	- 4.03	40.76	<0.01	2
	Methadone 1mg/ml & Physeptone® dispensed	28.00	33.81	38				
No. month	ns Methadone 1mg/ml only dispensed	12.17	8.79	35	- 2.07	69	0.04	12
in MPP	Methadone 1mg/ml & Physeptone® dispensed	16.39	8.36	36				

# 4.3.4. Pharmaceutical services provided

# 4.3.4.1. On-site Supervised dosing

Over one-third (36.1%, 30/83) of those surveyed said they were currently supervising the self-administration of methadone on-site at their pharmacies. In total, 26.3% (340/1,290) of patients were receiving at least some supervised doses, with a mean of 11.33 supervised patients in each of the thirty supervising pharmacies (SD=21.29, range=1–100). There was no link between the provision of a supervision service and the length of time that pharmacists had been in the MPP (t=0.28, df=69, p=0.78).

#### 4.3.4.2. "Take-home" methadone doses

Pharmacists were asked about the way that they dispensed methadone for their patients to take home. Over half of those surveyed (44/83, 53.0%) reported that they never supplied methadone in plastic bottles while 39.8% (33/83) had previously used them (data were missing on six cases). Only 49.4% (41/83) always used child-resistant closures (CRCs) (data were missing on five cases) and 30.2% (25/83) never gave patients a measure with their multi-dose methadone dispensings (data were missing on nine cases). See full details in Table 4.4.

Table 4.4: "Take-home" methadone doses (N=83)

	Always	Usually	Never	Missing
				cases
In a plastic bottle	20 (24.1)	13 (15.7)	44 (53.0)	6
With a CRC	41 (49.4)	21 (25.3)	16 (19.3)	5
With a measure	10 (12.0)	39 (47.0)	25 (30.2)	9

#### 4.3.4.3. Information

Twenty-three pharmacies (27.7%) reported receiving enquiries from patients in the previous week in relation to their methadone treatment. Four pharmacies (4.8%) reported receiving more than five enquiries each in the course of the previous week. A total of ninety-four enquiries were received (mean=1.17 enquiries per pharmacy surveyed, SD=3.78, range=0-30, N=80, data were missing on three cases).

As shown in Table 4.5., the use of the pharmacist as an information source was directly related to the total number of patients being dispensed methadone (in any formulation) in the pharmacy. The provision of information was also directly linked to the number of patients on methadone 1mg/ml, but this association was not seen with the number of patients on Physeptone® in each pharmacy.

Table 4.5.: The use of community pharmacists as an information source as related to their patient numbers

	Mean	SD	N	t	df	р
Information source	32.9	41.06	21	2.51	22	0.02
Not an information source	9.84	15.02	57			
Information source	26.35	34.47	23	2.76	22.89	0.01
Not an information source	6.33	7.7	57			
Information source	11.42	12.54	12	0.70	35	0.49
Not an information source	8.0	14.55	25			
	Not an information source Information source Not an information source Information source	Information source 32.9  Not an information source 9.84  Information source 26.35  Not an information source 6.33  Information source 11.42	Information source 32.9 41.06  Not an information source 9.84 15.02  Information source 26.35 34.47  Not an information source 6.33 7.7  Information source 11.42 12.54	Information source         32.9         41.06         21           Not an information source         9.84         15.02         57           Information source         26.35         34.47         23           Not an information source         6.33         7.7         57           Information source         11.42         12.54         12	Information source       32.9       41.06       21       2.51         Not an information source       9.84       15.02       57         Information source       26.35       34.47       23       2.76         Not an information source       6.33       7.7       57         Information source       11.42       12.54       12       0.70	Information source         32.9         41.06         21         2.51         22           Not an information source         9.84         15.02         57           Information source         26.35         34.47         23         2.76         22.89           Not an information source         6.33         7.7         57           Information source         11.42         12.54         12         0.70         35

Pearson's correlation showed that the number of enquiries received was also positively associated with the total number of patients in methadone treatment (r=0.78, df=76, p<0.01) and with the number of patients on methadone 1mg/ml (r=0.86, df=78, p<0.01) but again, this association was not seen with the number of patients on Physeptone® (r=0.15, df=35, p=0.37).

No qualitative data was collected regarding the nature of the enquiries received.

# 4.3.5. Support & Communication

When asked about the extent of communication between themsleves and local methadone prescribers and drug treatment services during the previous week, 49.4% (41/83) of the pharmacists surveyed reported making a total of 170 contacts. This resulted in a mean of 2.05 contacts per pharmacy surveyed during the previous week (SD=6.36, range=0–50, N=83). Problems with methadone prescriptions gave rise to 32.9% (56/170) of the pharmacist-initiated contacts (e.g. they were illegible, incompletely written etc), while problems with prescribers' instructions for patients' pick-up days resulted in 20.6% (35/170) of these contacts.

Pearson's correlation showed that the number of contacts made by pharmacists was positively associated with their total number of patients in methadone treatment (r=0.83, df=37, p<0.01) and with the number of patients they had on methadone 1mg/ml (r=0.58, df=39, p<0.01). But this association was not seen with the number of patients on Physeptone® (r=0.22, df=22, p=0.31).

Pharmacists were also asked about the frequency with which they were contacted by prescribers or drug service staff during the previous week. Almost two-fifths (39.8%, 33/83) of the pharmacists surveyed had been contacted, with a total of ninety-five contacts being made. This resulted in a mean of 1.19 contacts per pharmacy surveyed (SD=2.59, range=0–15). One fifth of pharmacies (20.5, 17/83) had been contacted once during the previous week, while almost one fifth (19.3%, 16/83) had been contacted more than once (data were missing on three cases).

Pearson's correlation showed that the number of times prescribing services contacted responding pharmacies was positively associated with their total number of patients in methadone treatment (r=0.68, df=76, p<0.01), with the number of patients they had on methadone 1mg/ml (r=0.58, df=78, p<0.01) and with the number of patients on Physeptone® (r=0.53, df=33, p<0.01).

No qualitative data were collected on the reasons why pharmacists contacted methadone prescribers or why prescribing services contacted them.

# 4.3.6. Pharmacists' Views

#### 4.3.6.1. General Views

Pharmacists were asked to indicate their views using a five point Likert scale, where a score of "1" indicated that they "strongly agreed" with the statements and a score of "5" indicated that they "strongly disagreed". Their responses are given in Table 4.6.

Almost half of those who responded (49.4%) "agreed" or "strongly agreed" that they found it satisfying working with patients on methadone, which suggested that they had a personal interest in the treatment and welfare of their patients. However, only 44.6% of respondents "agreed" or "strongly agreed" that they could ensure patients swallowed their methadone if supervised on-site and 65.1% of respondents "agreed" or "strongly agreed" that the provision of supervised dosing might deter other customers. Both of these findings highlighted negative attitudes towards on-site supervision. Almost threequarters of respondents (74.7%) "agreed" or "strongly agreed" that they needed to know if patients were using drugs in addition to those dispensed at the pharmacy to avoid the risk of overdose, which suggested that most respondents felt professionally responsible for the safety of their patients and wanted to be involved in their overall treatment.

# 4.3.6.2. Views of respondents who provided on-site supervision compared to the views of other respondents

Respondents' views were condensed to a three point scale so that "agreed" and "strongly agreed" became "agree" (score=1), "neither" (score=2) and "disagree" and "strongly disagree" became "disagree" (score=3). When respondents with "neither" view were excluded from the analysis, pharmacists who currently supervised methadone consumption on-site were significantly more likely to "agree" or "strongly agree" that they found it satisfying working with patients on methadone than those who did not provide supervision. They were also more likely to "agree" or "strongly agree" that they could ensure patients swallowed their methadone, while they were less likely to "agree" or "strongly agree" that the provision of a supervision service would deter other customers. There was no link between respondents providing a supervision service and their views on the other attitudinal statements. Details are shown in Table 4.7.

Table 4.6: Responses to Attitudinal Statements (five point scale) (N=83)

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	
I find it satisfying working with clients on methadone.	12 (14.5)	29 (34.9)	33 (39.8)	5 (6.0)	1 (1.2)	3
I am concerned that some of the methadone I dispense may not be taken by the patient for whom it was prescribed.	14 (16.9)	27 (32.5)	13 (15.7)	16 (19.3)	11 (13.3)	2
I find it difficult coping with clients on methadone when they are abusive or threatening.	20 (24.1)	25 (30.1)	15 (18.1)	14 (16.9)	2 (2.4)	7
It is easy to contact someone at the local satellite/drug clinic when I need their help.	3 (3.6)	32 (38.6)	22 (26.5)	14 (16.9)	4 (4.8)	8
Clients on methadone are no worse than other customers when it comes to theft from the pharmacy.	8 (9.6)	35 (42.2)	20 (24.1)	13 (15.7)	5 (6.0)	2
I feel I know enough about methadone to be able to make a positive contribution to the client's treatment.	9 (10.8)	47 (56.6)	16 (19.3)	7 (8.4)	0	4
Security is the primary issue when dealing with drug users.	16 (19.3)	31 (37.3)	19 (22.9)	13 (15.7)	0	4
I am confident that I can make sure a client has swallowed his methadone.	14 (16.9)	23 (27.7)	22 (26.5)	8 (9.6)	2 (2.4)	14
I am confident that I would recognise the signs of intoxication if a client presented under the influence of alcohol or drugs.		49 (59.0)	5 (6.0)	11 (13.3)	1 (1.2)	5
When (if) I supervise methadone self administration it may deter other customers from using the pharmacy.		35 (42.2)	8 (9.6)	11 (13.3)	3 (3.6)	7
I need to know whether the client is using other drugs, to protect him from the risk of overdose.	25 (30.1)	37 (44.6)	13 (15.7)	5 (6.0)	1 (1.2)	2

Table 4.7.: Pharmacists' Views as related to the provision of on-site supervision services, measured on a condensed Likert Scale (SA/A = "Strongly Agree"/ "Agree", N= "Neither Agree nor Disagree", D/SD = "Disagree"/ "Strongly disagree"). Supervising pharmacies, N=30, Non-supervising pharmacies, N=53.

	Supervising pharmacies				Non-supervising pharmacies						
	SA/A	N	D/SD	MV	SA/A	N	D/SD	MV	$\chi^2$	df	р
	(%)	(%)	(%)		(%)	(%)	(%)				
I find it satisfying working with patients on methadone.	19 (63.3)	10 (33.3)	0 (0)	1	22 (41.5)	23 (43.4)	6 (11.3)	2	4.67	1	0.03
I am concerned that some of the methadone I dispense may not be taken by the patient for whom it was prescribed.	18 (60.0)	2 (6.7)	8 (26.7)	2	22 (43.4)	11 (20.8)	19 (35.8)		1.40	1	0.24
I find it difficult coping with patients on methadone when they are abusive or threatening.	15 (50.0)	6 (20.0)	7 (23.3)	2	30 (56.6)	9 (17.0)	9 (17.0)	5	0.56	1	0.46
It is easy to contact someone at the local satellite/drug clinic when I need their help.	13 (43.3)	5 (16.7)	9 (30.0)	3	22 (41.5)	17 (32.1)	9 (17.0)	5	0.81	1	0.37
Patients on methadone are no worse than other customers when it comes to theft from the pharmacy.	14 (46.7)	7 (23.3)	8 (26.7)	1	29 (54.7)	13 (24.5)	10 (18.9)	1	0.78	1	0.38
I feel I know enough about methadone to be able to make a positive contribution to the patient's treatment.	20 (66.7)	7 (23.3)	1 (3.3)	2	36 (67.9)	9 (17.0)	6 (11.3)	2	1.29	1	0.26
Security is the primary issue when dealing with drug users.	15 (50.0)	6 (20.0)	6 (20.0)	3	32 (60.4)	13 (24.5)	7 (13.2)	1	0.91	1	0.34
I am confident that I can make sure a patient has swallowed his methadone.	26 (86.7)	2 (6.7)	0 (0)	2	11 (20.8)	20 (37.7)	10 (18.9)	12	15.73	1	<0.01
I am confident that I would recognise the signs of intoxication if a patient presented under the influence of alcohol or drugs.	25 (83.3)	0 (0)	3 (10.0)	2	36 (67.9)	5 (9.4)	9 (17.0)	3	1.08	1	0.30
When (if) I supervise methadone self administration it may deter other customers from using the pharmacy.	13 (43.3)	2 (6.7)	14 (46.7)	1	41 (77.4)	6 (11.3)	0 (0)	6	26.77	1	<0.01
I need to know whether the patient is using other drugs, to protect him from the risk of overdose.	25 (83.3)	4 (13.3)	1 (3.3)	0	37 (69.8)	9 (17.0)	5 (9.4)	2	1.30	1	0.26

#### 4.4. DISCUSSION

This survey was carried out six weeks after the interim regulations to the Misuse of Drugs Acts had been introduced and two months before the MPS was to be implemented nation-wide. The study had a high response rate, although non-responders (16%) may have had a different perspective and their inclusion in the survey would have made the findings more reliable. Nevertheless, data were collected from the majority of the community pharmacies participating in the MPP at that time which gave national policy-makers, and in particular the liaison pharmacists, vital information necessary for planning the final steps in the introduction of the MPS. They were also useful in assessing the changes that had taken place in community pharmacy-based methadone dispensing services over the preceding six months since Healy's survey was carried out (Healy 1998). Additionally, they could be compared with findings from other surveys of community pharmacies that were carried out as part of this study (see Chapter 6).

If one uses IPU data to estimate the total number of community pharmacies in Ireland, almost one tenth (9.8%, 99/1,009) of Irish community pharmacies were registered to dispense methadone 1mg/ml when this survey was carried out in August 1998 (CDTL Statistics, McManus 2001). A comparison with Scotland where over 50% participation had been achieved in 1995 (Matheson et al 1999b) shows that Irish community pharmacy based methadone dispensing services were relatively underdeveloped at this stage. The data showed that very few non-EHB pharmacies were participating in the MPP, which raised concerns regarding the provision of treatment services for patients registered to the CDTL in other health board regions following the full implementation of the MPS. This was followed up by the MPS's Implementation Committee, which invited representatives of each of the health boards to attend a number of strategy meetings.

It should be noted that pharmacists who dispensed Physeptone® but were not registered with the MPP were not targeted by Survey 2, so these participation data exclude them, and may therefore be significantly under-representative of the overall extent of methadone dispensing at this time.

The proportion of owner-respondents and male respondents were similar here to those reported by Healy's survey (Healy 1998), which suggests that they may have been

representative of the owner/employee and gender balances among community pharmacists at that time. However, this cannot be confirmed, as no national data are available on the gender balance among community pharmacists. Data are available however, on the gender balance among private pharmacy owners, which showed that 58.1% were owned by men (Pharmaceutical Society of Ireland Statistics 1998), so data from this study indicated that male owners were more inclined to dispense methadone with the MPP than females were. This highlights the need for scheme organisers to be proactive in identifying and addressing the fears and concerns among female pharmacists.

The ratio of owners to employee respondents was representative of the proportion of owners to employees among community pharmacists registered with the IPU when this survey was carried out (McManus 2001). This suggests that methadone dispensing was not associated with community pharmacies where the proprietor pharmacist could undertake that activity without the need to consult with other staff or external shareholders. This has implications for service developers, as it suggests that pharmacy owners and employee pharmacists were equally likely to participate in methadone dispensing, and recruitment strategies need to be developed to encourage both parties to get involved. For example, while pharmacy owners might be more influenced by adequate remuneration or funding for structural modifications, employee pharmacists might find easily accessible day-to-day support systems more helpful. Given the need to continue to encourage community pharmacists to provide methadone dispensing services, this area merits further research and exploration.

The data suggested that the pharmacies that dispensed methadone 1mg/ml were potentially among the least secure as some had no male staff and many were located in exposed shopping streets without a security presence such as would normally be available, for example, in the shopping centre setting. This highlighted the isolation of community pharmacists participating in the MPP, and the extent to which they were vulnerable to robbery and abuse by non-compliant patients, and reaffirmed the necessity for close liaison with tertiary services and comprehensive structures for managing patients transferred to the community setting.

The present survey had a greater proportion of respondents who had worked as community pharmacists for ten years or less compared to that reported by Healy's survey (48% vs. Healy 1998 - 36%). This may show that this survey had a greater response from pharmacists in this age group or it may show an increase in the recruitment of younger pharmacists to methadone dispensing in the first half of 1998. This may show an attitudinal shift among community pharmacists, where recent graduates were more inclined to participate in methadone dispensing than their older colleagues. This may be related to the input of Addiction pharmacists and exposure to methadone treatment programmes that Irish pharmacy students receive as part of their undergraduate course.

The length of time that the majority of responding pharmacies had dispensed methadone 1mg/ml suggested that many of them had participated in the MPP from its initiation, although no data on community pharmacy involvement were recorded when the MPP was evaluated. One-third of respondents had joined the MPP within the previous six months, which suggested a high rate of recruitment during that period.

Dispensing Physeptone® privately could have been financially lucrative for community pharmacists as patients paid a 50% margin on privately dispensed medicines. In contrast, the MPP reimbursed the cost of the methadone and paid them a dispensing fee per instalment and a standard monthly care fee for each patient registered at their pharmacy. While the net income was similar for patients who were dispensed their methadone on a weekly basis, the absence of a separate fee for supervised doses and the fact that the monthly care fee was not linked to the number of dispensings meant that pharmacists who dispensed methadone more frequently than once weekly were not remunerated as well by the MPP as they were when dispensing Physeptone® on a private basis. In addition, there were bureaucratic delays to payments and a substantial amount of paperwork associated with the MPP.

Nevertheless, a number of those participating in the MPP in August 1998 had never dispensed Physeptone®, which suggested that the structures enforced by the MPP and the supports provided by the liaison pharmacist and others were encouraging previously reluctant community pharmacists to participate in methadone dispensing. Almost half of the responding pharmacies still had patients on Physeptone®, who would need to be

transferred to methadone 1mg/ml by 1 October 1998, six to eight weeks later. The information on these patients, in conjunction with data from the prescription forms returned to the General Medical Services (GMS) as discussed earlier (see Chapter 1), provided the liaison pharmacists with a useful starting point in the organisation of patient transfers. It was also a useful indicator for the MPS's Implementation Committee of the overall population of patients who were still being prescribed Physeptone® by private doctors.

Using responses from their community pharmacies, Survey 2 captured data on over 60% (61.7%, 1,153/1,870) of the registered patients who were attending community-based prescribers in August 1998, as well as collecting data on 140 of those who attended prescribers who were based in DTC "scripting clinics" at that time (CDTL Statistics). It can be assumed that the remaining 38.3% (717/1,870) of registered community-pharmacy based patients were either attending MPP pharmacies that did not respond to this survey or were being dispensed Physeptone® at community pharmacies that were not registered to the MPP and were therefore not investigated by this study. It should be noted, however, that the CDTL data may not be totally accurate as the registration of patients who were prescribed Physeptone® privately was not obligatory and details of private patients were not always corroborated so the same patients may have been registered a number of times. In addition, there was no obligation on private prescribers to remove patients from the CDTL if their treatment was discontinued.

Most of the patients in community-based methadone treatment at this time were attending pharmacies where both methadone 1mg/ml and Physeptone® were dispensed. The provision of both products had several implications for community pharmacists. It meant they had to carry stock of both, which increased their security risk and obliged them to have larger Controlled Drugs safes. It also had safety implications, particularly during this interim period, when all methadone was prescribed on a standard methadone prescription form and pharmacists had to exercise extreme caution where prescribers did not specify the strength of methadone required, or where products of different concentrations had similar names (e.g. Physeptone® was 2mg/5ml and Phymet® was 5mg/5ml). In addition, on a practical level, the provision of both concentrations of methadone meant that pharmacists were dealing with some private patients and others who were in the MPP. Payment by the patient has been shown to be

a common cause of aggravation in the pharmacy (Muhleisen et al 1998), and this may have been even more likely when patients were aware that others were receiving their methadone free of charge.

Findings from this survey suggested that pharmacies that had recently joined the MPP were not dispensing Physeptone®, and had thereby avoided problems associated with carrying both concentrations of methadone and the payment issue. They also had fewer patients than other pharmacies, which suggested that the liaison pharmacist and the structures imposed by the MPP (including the use of treatment cards) had been successful in limiting the numbers attending individual pharmacies, an issue of vital importance to the community pharmacists who responded to Survey 1. The evidence that many pharmacies that participated in the MPP had limited patient numbers should have encouraged other non-participating pharmacies to consider dispensing methadone by eliminating their fears of being inundated with patients.

Although no additional payment had been linked to the provision of supervised doses, the proportion of supervising pharmacies had more than doubled compared to Healy's findings earlier in 1998 (36% vs 16% Healy), and was comparable with that seen in Scotland in 1995 (Matheson et al 1999b). This finding was positive as it illustrated a greater level of control over the supply of methadone into the community, which has been shown elsewhere to reduce the incidence of accidental overdose (Swenson 1988).

Provision of supervision was not linked to the length of time that pharmacists had been in the MPP, which suggested that practical experience working with drug misusers was not a major factor influencing pharmacists' decision to provide supervision. This finding meant that the liaison pharmacist could not depend on pharmacists' increased familiarity with the MPP to encourage them to commence supervision services. Other criteria might have been involved such as the physical layout of their pharmacies or the willingness of their support staff to get involved. One survey carried out in London reported that only half of the community pharmacy support staff surveyed were happy to be involved in the provision of services for drug misusers, and researchers suggested that these staff should receive appropriate training and support (Sheridan & Cronin 2001). The fact that Irish community pharmacists and their staff were prepared to offer an on-site supervision service at all in the absence of a contractual obligation or a linked payment system

suggested that they recognised its clinical and social value, and their efforts should be supported in every way possible.

Study findings suggest that community pharmacists who did not supervise methadone doses may need training in the practical procedures involved, if they are to gain confidence in their ability to ensure patients swallow their methadone on-site. It should not be difficult to train pharmacists in this practice, and given that such training may increase their willingness to provide a supervision service, it should be organised as a matter of urgency. Their concerns that the provision of such a service might deter other customers would be more difficult to overcome, but may be addressed by MPP initiatives that limit of the numbers of patients attending each pharmacy and by evidence that those providing this service are able to do so without undue disruption.

When this study investigated the standards of care applied to the "take-home" methadone doses dispensed to patients attending Irish community pharmacies, it found that less than half of those who dispensed "take-home" doses used plastic bottles, although their use had doubled since Healy's study was carried out six months earlier (40% vs. 20%). The use of plastic bottles was subsequently recommended by the Pharmaceutical Society of Ireland (see Appendix 1, p.23, McDermott 1999) to avoid accidental breakages, which are often disputed, resulting in conflict between carers (particularly community pharmacists) and their patients. But there are no stability data for methadone stored in plastic, so many pharmacists refuse to use them on clinical grounds, and their use is largely dependent on the decisions of individual pharmacists. Despite these conflicting issues it appeared that community pharmacists had become more inclined to dispense methadone in plastic bottles during the first half of 1998, which may have been linked to personal experiences with individual patients.

In line with best practice guidelines published in 1991 in the UK (Royal Pharmaceutical Society of Great Britain 1991), the use of child resistant closures (CRCs) was also subsequently recommended by the Pharmaceutical Society of Ireland's Codes of Practice (McDermott 1999). But their limited use and the low rate of supply of measures with multi-dose methadone dispensings reported here both gave cause for concern, particularly given that incidences of fatal overdose among children (Binchy et al 1994, Calman et al 1996) and adults (Cairns et al 1996, McCarthy 1997) have been associated

with "take-home" methadone supplies. These findings suggested that key health promotion messages needed to be disseminated regarding both of these issues, and such an education initiative was undertaken by the liaison pharmacist and by outreach workers within the EHB region.

The use of community pharmacists as an information source was more common here than among respondents to Healy's survey carried out in early 1998 (28% vs 16%). This suggested that community pharmacists' expertise in the provision of community-based methadone treatment was being increasingly recognised and utilised by patients. In addition, the number of requests for information that were addressed by the community pharmacists surveyed here was linked to the number of patients they had in the MPP, and not to their numbers of patients on Physeptone®. This may show that patients participating in the MPP were more likely to view their pharmacist as an integral member of their overall drug treatment team or as a source of expert advice. It may suggest that pharmacists working with the MPP were more approachable and that their patients perceived them as more likely to respond to their enquiries. In addition, the fact that patients in the MPP were not paying their pharmacists for their methadone may have influenced their relationship. This finding may also highlight the greater need for information among patients who were dispensed methadone 1mg/ml, which was not surprising, given that it was comparatively new, and considering the low level of information and involvement patients and their representatives had in the planning and initiation of the MPS (see Chapter 8 & 9 for further discussion).

Community was a two-way process, with reported contacts initiated by both parties. In addition, judging from responses to the ease of contact between community pharmacies and local drug services, it seems that communication channels between primary and tertiary care were well established. These findings were positive, since communication at this level is vital to good practice (Department of Health UK Guidelines 1999, Pharmacy Guild of Australia 2000, Berbatis 2001) and was particularly important during this interim stage of the introduction of the MPS. The high incidence of problems with prescriptions could have been linked to the introduction of the new prescription form for methadone, which was not familiar to either prescribers or pharmacists, and was revised and

simplified by the MPS Implementation Committee prior to 1 October 1998 when the MPS was introduced.

The absence of any association between the number of pharmacist-initiated contacts and patient numbers for those on Physeptone® suggests that pharmacists who dispensed Physeptone® were familiar with the procedures involved and did not need to communicate with prescribers as much as they did if dispensing methadone 1mg/ml. The high number of enquiries originating with pharmacists who were dispensing methadone 1mg/ml may have been a reflection of the teething problems primary carers experienced during the interim period of the introduction of the MPS.

It was interesting to note the high proportion of respondents who agreed they would need to have information regarding any additional medication taken by patients to reduce the risk of overdose. In view of the patient confidentiality issues involved and ongoing policy discussions on the subject, this was explored further in Survey 3.

The low number of respondents who disagreed that they found it satisfying working with patients on methadone suggested that the MPP was able to provide participants with adequate levels of structure and support to ensure they were satisfied with their work. This was important since those planning the imminent introduction of the MPS viewed these pharmacists as pioneers whose participation would ultimately encourage others to get involved and, given that the total number of pharmacies in Ireland is small, word of mouth could have an important influence in the determination of pharmacists' attitudes.

The proportion of respondents to Survey 2 who reported that they knew enough to be able to positively contribute to patient care suggested that their confidence in their own skills was higher than that reported in one London study, where two-fifths of responding community pharmacists agreed that pharmacists did not have the educational background to be able to counsel patients about drug misuse (Sheridan & Barber 1997). This was interesting given that over 80% of the pharmacists who dispensed methadone in the southern sectors of the EHB region who participated in Survey 1 six months previously said they would find training in the clinical aspects of methadone treatment and the management of drug misusers helpful. It may show that Irish community pharmacists' confidence had grown as they became more familiar with methadone

treatment, and may also have been linked to the training initiatives provided for them during that time.

The high proportion of Irish pharmacists who agreed that the provision of a supervision service would "deter other customers" suggested that they perceived the provision of methadone dispensing services as far more potentially damaging to their businesses than Scottish pharmacists did (65% here vs. 34% reported by Matheson et al 1999b). These findings were interesting given that 42% of those surveyed in Scotland reported having discontinued methadone treatment due to behavioural problems or incidences of shoplifting. It is possible that the cautious attitude of Irish pharmacists was justifiable and their precautionary measures (such as the use of pharmacy/patient contracts) useful in the longer term, in preventing incidences that could endanger the provision of patients' services, although the views expressed elsewhere in this research tend to refute this suggestion (see Chapter 9).

Respondents' security concerns featured strongly in this survey, as did the difficulties they had experienced in managing patients who were abusive or threatening. Less than one-third of Scottish pharmacists agreed or strongly agreed that having drug misusers visit their premises would endanger staff safety which suggests that they felt much more secure than their Irish colleagues when managing drug misusers (Matheson et al 1999b). The data indicated that pharmacists did not believe that participation in the MPP protected them from the unpredictability of their patients' behaviour.

Although research from Australia showed no significant difference between the incidence of violent property crimes (including break-ins and hold-ups) between community pharmacies that dispensed methadone and those that did not (Berbatis 2001), research indicates that community pharmacists are universally at high risk of threatening or violent incidents with opiate misusers (Smith & Weidner 1996a). Other research has shown that fears relating to safety represent a barrier to pharmacist participation in methadone dispensing initiatives and should not be ignored in the determination of community pharmacy based treatment policies (Smith & Weidner 1996b, Matheson & Bond 1999).

It is difficult to see how a methadone programme can protect individual pharmacists from these dangers although the imposition of severe sanctions on non-compliant patients may be a useful preventative measure. Training initiatives that provide a forum for the discussion of individuals' fears have been shown to help healthcarers in overcoming their fears and prejudices, and may be of value here (Aggleton & Homans 1987).

# **CHAPTER 5:** Pharmacy Survey 3

A survey of all community pharmacies participating in the Methadone Protocol Scheme in Ireland in March 1999.

Date	Stage in MPS	Study title	Participants	No. respondents	Location
February 1998	Pilot (MPP) underway	Pharmacy Survey 1	All community pharmacists	201	Southern sectors of the EHB region
August 1998	Interim phase in introduction of MPS	Pharmacy Survey 2	Community pharmacists who dispensed methadone 1mg/ml	99	Nation-wide
March 1999	MPS established	Pharmacy Survey 3	Community pharmacists who dispensed methadone 1mg/ml	153	Nation-wide
after March 1999	MPS established	Longitudinal Study	Community pharmacists who responded to more than one of the above surveys	Varied, as specified in text	Southern sectors of the EHB region
June 1998 to May 1999	Pilot (MPP) & MPS	Liaison Queries	All enquiries received by the liaison pharmacist	848 enquiries	Southern sectors of the EHB region (primarily)
March 1999	MPS established	Patients' Views	Patients in methadone treatment	217	Nation-wide
February 2001	MPS established	Qualitative interviews	Drug misusers, ex- drug misusers, patients in methadone treatment, service providers	15	Three non- prescribing support service

# **5.1. INTRODUCTION**

On 1 October 1998 the DOHC introduced Regulations to the Misuse of Drugs Acts 1977 & 1984 (Statutory Instrument No. 225) which resulted in the implementation of the MPS nation-wide. Under the new regulations the private dispensing of methadone was illegal, Physeptone® was no longer marketed and only the 1mg/ml formulation could legally be dispensed. All patients in methadone treatment were registered on the Central Drug Treatment List (CDTL), each with a nominated prescriber and dispenser, and doctors wishing to prescribe methadone were obliged to attend specialist training with the Irish College of General Practitioners (ICGP). Statistics from the CDTL showed an increase in the proportion of Irish community pharmacies dispensing methadone 1mg/ml from 10% in August 1998 to 16% in February 1999 after the full introduction of the MPS. This was particularly so in areas outside the EHB region, where methadone dispensing, which had been practically nil before 1 October 1998, was reported by 4% of community pharmacies in February 1999 (McManus 2001, CDTL Statistics).

Data from Surveys 1 and 2 carried out in February and August 1998 respectively gave the liaison pharmacists, GP co-ordinators and MPS managers information about methadone dispensing practice during the MPP prior to the introduction of the MPS. But these surveys did not include all of the pharmacies involved: Survey 1 covered only a limited geographical area and Survey 2 did not include pharmacies that were not dispensing methadone 1mg/ml but which did supply Physeptone®.

March 1999 (six months after the introduction of the MPS) was considered to be an appropriate time to examine the pharmaceutical services community pharmacists provided under the MPS. Such a survey would provide information about all of the pharmacies dispensing methadone at that time. It could also more fully explore some of the issues raised in the earlier surveys, without the confounding variable of concurrent Physeptone® dispensing. Such issues included pharmacists' views regarding the information they received about their patients' total current drug use, pharmacists' relationships with others on the drug treatment team, and their views on the value of the liaison pharmacist. In addition, findings could be compared to those from Survey 2 carried out in August 1998 to show how the introduction of the MPS had affected

pharmaceutical services for drug misusers requiring methadone via the community pharmacy.

Self-completed postal questionnaires are of limited value in the collection of in-depth qualitative information (Davies 1989, Robson 1993, McKeganey 1995) and one-to-one interviews may have been more appropriate for the collection of pharmacists' views and comments, while the accuracy of the sections of this research that related to standards of care and support and communication issues could have been assessed by external audit. However, due to practical considerations and time constraints on the researcher, and given that surveys have been shown to produce accurate descriptive and comparative data on community pharmacy services (Assa & Sheppard 2000) and on drug treatment programmes (McLellan et al 1992), a self-completed postal questionnaire was deemed an appropriate research instrument in this instance.

#### Aims

- (1) To establish the extent of community pharmacy involvement in the provision of methadone dispensing services under the MPS.
- (2) To investigate the nature of the dispensing services being provided for drug misusers in methadone treatment.
- (3) To explore changes in community pharmacy involvement in the provision of methadone treatment between August 1998 and March 1999.

#### **Objectives**

- (1) To investigate patient distribution among the community pharmacies participating in the MPS in March 1999.
- (2) To investigate the factors involved in the motivation and recruitment of community pharmacists to the MPS.
- (3) To investigate the relationships between community pharmacists and others involved in community-based methadone treatment under the MPS.
- (4) To examine the nature and standard of the methadone dispensing services being provided for patients attending community pharmacies.
- (5) To look at pharmacists' views on, and attitudes to their patients on methadone.
- (6) To examine the data for changes that had occurred since Survey 2 had been carried out eight months earlier.

#### 5.2. METHOD

#### 5.2.1. Instrument

The questionnaire used in Survey 3 was considerably more in-depth than those employed in the earlier surveys. Most of the questionnaire was structured, to simplify its completion, but it also included a number of open-ended questions. It aimed to record data on a broad range of relevant issues. These included some questions about the respondents themselves, their views and motivations, the extent of their experience as community pharmacists and their training in managing drug misusers. In response to a recent publication linking child overdose with the use of babies' bottles in the measurement of methadone (Harkin et al 1999) and the evidence associating accidental overdose with "take-home" methadone supplies (Binchy et al 1994, Calman et al 1996, Cairns et al 1996, McCarthy 1997), the questionnaire also asked respondents for details of how they dispensed methadone "take-home" doses. As the value of on-site supervision was increasingly being recognised in other countries (Scott & McNulty 1996, Department of Health UK 1999) this questionnaire asked respondents about their supervision services and the provision they made for patients' privacy. Respondents were also asked about their use of written methadone dispensing procedures and pharmacy/patient contracts, which were recommended by the Pharmaceutical Society of Ireland's Policy on Drug Abuse (1996) and for their views and experience of managing patients in methadone treatment. The questionnaire examined the support systems available to community pharmacists working with the MPS by asking them about the relationships they had with their liaison pharmacists and with their patients' methadone prescribers, and about any problems they had encountered and the support they had received in resolving these problems. The questionnaire incorporated aspects of the questionnaires used in the previous studies (Surveys 1 & 2), as well as investigating respondents' views on a number of pertinent statements (see questionnaire in Appendix A.5.3.).

A covering letter accompanied the survey, which explained its purpose and importance, and assured respondents of confidentiality (see letter in Appendix A.5.1.). The questionnaires were coded and a second mail-shot was sent to non-respondents three weeks later (see covering letter in Appendix A.5.2.). Both mail-shots included FREEPOST self-addressed envelopes for returns. The questionnaires were confidential

but they were not anonymous as they were coded to avoid duplication during the second mail-shot.

# 5.2.2. Pilot & Preparatory work

In January 1999 a draft questionnaire was circulated to nineteen experts in the provision of methadone treatment. Since Survey 3 aimed to target all of the community pharmacists participating in the MPS, those involved in the pilot study were not asked to complete the draft version of the questionnaire, but rather to give their views on how it could be changed or improved. There was considerable interest in the pilot since it was the first research initiative undertaken into the community pharmacy-related aspects of the MPS.

Feedback from one GP co-ordinator included in the pilot resulted in the inclusion of a section on the formulations of methadone being dispensed under the MPS. Respondents were asked how many formulations of methadone they stocked and what factors determined the formulation dispensed to each patient.

Other suggestions related to the length, format and presentation of the questionnaire. The nurse and community welfare officer both expressed concerns regarding the overall length of the questionnaire so the order of the questions was altered, placing demographic questions, (which were easy to answer) at the end of the questionnaire and reducing the number of attitudinal statements. The other views on presentational aspects of the questionnaire were also incorporated before the questionnaire was circulated to the target sample.

#### 5.2.3. Sample

All of the community pharmacies registered with the MPS in February 1999 were included in the sample i.e. 146 pharmacies in the EHB region and 33 from outside that area (CDTL Statistics). It transpired that seven of the pharmacies had no patients on methadone when surveyed (four of which were outside the EHB region) so their responses were excluded from the analysis.

# 5.2.4. Reliability & Validity

Alternate-form testing was employed in aspects of Survey 3, when examining pharmacists' key motivations and their views on on-site supervised dosing i.e. the questionnaire used differently worded questions or response sets to obtain the same information about a specific topic (Litwin 1995). In addition, the application of a Likert Scale to participants' attitudinal responses created opportunities to measure internal consistency.

Respondents knew that these questionnaires were designed and processed by the liaison pharmacist with the EHB Addiction Service, which may have produced researcher effects that biased their responses. Similarly, analysis and interpretation of these responses by the liaison pharmacist may have introduced researcher biases. However, the concurrent survey of patients in the MPS permitted triangulation regarding issues such as the extent of supervised dosing and standards of care when dispensing "take-home" methadone doses (see Chapter 8) and should have strengthened the reliability of both studies.

By targeting all of the pharmacies registered with the MPS, threats to validity posed by sampling were eliminated. The longitudinal aspects of this study also improved its internal validity (Litwin 1995). The risk of selective non-response among non-compliant community pharmacists was reduced by the resultant high response rate, although the generalisability of some study findings (e.g. those relating to "take-home" methadone doses) was limited by high numbers of non-respondents.

As with Survey 2, participatory piloting was avoided to reduce the threat of exposure amongst members of this intact group (see Pilot & Preparatory Work above). However, a subsample of those surveyed here had participated in both Surveys 1 and 2, and this exposure may have affected their responses. The broad range of issues investigated by Survey 3 should also have reduced the ambiguity of individual responses and helped in the identification of causal relationships.

#### 5.2.5. Ethics & Confidentiality

The liaison pharmacist with the EHB's Addiction Service had access to the list of community pharmacies registered to dispense methadone 1mg/ml, which facilitated the

targeting of specific community pharmacies for the purposes of this research. The identities of those included in this list were totally confidential and were not divulged at any stage.

The covering letters included with the postal questionnaire explained the purpose of the survey, so that respondents could decide in an informed way whether they wanted to participate (see Appendix A.5.1. & A.5.2.).

Questionnaires were coded to avoid duplication during the second mailshot, but this code was deleted from returned responses, so that the data analysed did not identify individual respondents.

## 5.3. RESULTS

# 5.3.1. Demographics

The over all response rate to Survey 3 was 88.9% (153/172) with over three-quarters of the respondents (77.3%, 133/172) returning the first mailshot. A full account of the study findings are given in disk format (see Appendix A.5.4.).

Ninety-four respondents (61.4%) were pharmacy owners (three respondents did not specify their ownership status) and 60.8% (93/153) were male (two respondents did not report their gender). Pharmacy owner respondents were significantly more likely to be male ( $\chi^2$ =12.86, df=1, p<0.01) with only 27.7% (26/94) of owner respondents being female.

The mean number of years responding pharmacists were working in community pharmacy was 13.79 (SD=10.73, range=1–50 years) and the mean number of years pharmacists were in their <u>current</u> pharmacy was 9.56 (SD=9.67, range=1–44) (see details in Table 5.1.).

Table 5.1: No. years respondents had been practising community pharmacists/in their current community pharmacies (N=153)

	0 - 5 years	6 - 10 years	11 - 20 years	> 20 years	Missing
	(%)	(%)	(%)	(%)	cases
Practising community pharmacy	36 (23.5)	44 (28.8)	33 (21.6)	34 (22.2)	6
Working in current pharmacy	78 (51.0)	25 (16.3)	26 (17.0)	22 (14.4)	2

Over eighty percent (81%, 124/153) of responding pharmacies were in the EHB region, while 19% (29/153) were located outside the EHB region. Over two-fifths (43.1%, 66/153) were located in a small group of local shops while 37.9% (58/153) were in main shopping streets. Over 17% (17.6%, 27/153) were located in shopping centres and the remaining two pharmacies (1.3%, 2/153) were situated in rural areas.

The pharmacies surveyed had been dispensing methadone 1mg/ml for a mean duration of 11.92 months (SD=9.32, range=1-38 months, N=149). Almost three-quarters (73.4%, 91/124, data were missing on three cases) of respondents from the EHB region had dispense methadone 1mg/ml prior to the introduction of the MPS in October 1998 compared to 20.7% of those in other regions (6/29, data were missing on one case). Pharmacies in the EHB region were significantly more likely to have commenced dispensing methadone 1mg/ml prior to the introduction of the MPS ( $\chi^2$ =28.94, df=1, p<0.01).

Almost two-thirds (64.7%, 99/153) of those surveyed had dispensed Physeptone® prior to the introduction of the MPS (data were missing on four cases).

# 5.3.2. Activity Data

The pharmacies surveyed had a total of 1,608 patients in methadone treatment at that time (mean=10.51, SD=21.48, range=1-195, median=4, N=153 pharmacies). Forty-six patients were in treatment in the 29 pharmacies surveyed outside the EHB region (mean=1.59, SD=1.05, range=1-6), indicating that the vast majority of patients registered with community pharmacies in the MPS were located in the EHB region. Almost two-thirds of responding pharmacies had between one and five patients on methadone 1mg/ml (63.4%, 97/153). Six pharmacies (3.9%) had more than fifty patients each.

Pharmacies that had dispensed Physeptone® prior to the introduction of the MPS had a mean of 13.44 patients each (SD=25.93, range=1-195, N=99) while those that had not had a mean of 4.68 patients on methadone 1mg/ml (SD=5.13, range=1-23, N=50). Those pharmacies that had dispensed Physeptone® had significantly more patients (t=3.24, df=112.42, p<0.01).

#### 5.3.3. Methadone Prescribers

A total of 1,337 patients who were attending the pharmacies involved in this survey were registered with community-based prescribers (the remaining 271 patients attended prescribers based in drug treatment centres). CDTL Statistics showed that Survey 3 captured data on 91.9% (1,337/1,454) of the patients who were attending community-based prescribers at that time. Over half (51.0%, 682/1,337) of these patients were attending GPs in their own surgeries and 43.6% (583/1,337) attended satellite drug services (prescribing sites were not recorded for 72 patients).

#### 5.3.4. Pharmaceutical services

# 5.3.4.1. Written Dispensing Procedures

Only 32.0% of the pharmacists surveyed (49/153) had written dispensing procedures for methadone dispensing (data were missing on two cases). Twenty-one pharmacists (42.9%, 21/49) had formulated their own procedures while nineteen (38.8%, 19/49) used procedures supplied by the liaison pharmacist. Details of other sources are given in Appendix A.5.4.

#### 5.3.4.2. Pharmacy/Patient Contracts

Fifty-six pharmacists (36.6%, 56/153) had written contracts with their patients on methadone (data were missing on two cases). Twenty-eight of them (50.0%, 28/56) used contracts supplied by the liaison pharmacist and seventeen (30.4%, 17/56) used contracts they had formulated themselves. Details of other sources are given in Appendix A.5.4.

#### 5.3.4.3. On-site Supervision

Almost half (48.4%, 74/153) of the pharmacies surveyed were supervising on-site methadone self-administration at least one day per week for a total of 36.3% (583/1,608) of the patients involved in the survey (mean=7.88 patients per pharmacy, SD=17.55,

range=1–115). Seven pharmacists supervised consumption on-site for more than 15 patients each. Almost half (47.3%, 35/74) of those who supervised methadone doses on-site prepared these doses in advance (preparation data were not reported by four cases).

The highest reported incidence of on-site supervised dosing within the EHB region was in the northern sector (61.8%, 21/34), with 57.1% (28/49) reporting its provision in the south-east and 48.8% (20/41) in the south-west.

Thirty-three (33/74, 44.6%) of the respondents who supervised methadone doses said they had a suitable private area in which to do so. Ten of those with private areas (30.3%, 10/33, data were missing on three cases) had built them for this purpose, including the two pharmacies outside the EHB that had such areas.

There was a highly significant difference between patient numbers in pharmacies that provided on-site supervision and those that did not, with supervising pharmacies having significantly more patients (t=4.96, df=96.5, p<0.01, excluding top 5 outliers, supervising pharmacies: mean=11.77 patients, SD=12.35, N=69, non-supervising pharmacies mean=3.65 patients, SD=6.13, N=79). Supervised dosing was also significantly more likely among pharmacies in the EHB region than in pharmacies elsewhere in Ireland ( $\chi^2$ =13.88, df=1, p<0.01. EHB pharmacies: 55.6% (69/124) supervising, non-EHB pharmacies 17.2% (5/29) supervising).

# 5.3.4.4. Willingness to Supervise

Over 40% (40.5%, 32/79) of the non-supervising pharmacists were prepared to do supervision if asked (data were missing on four cases). Pharmacists in regions outside the EHB were significantly more likely to be willing to supervise than their non-supervising colleagues in the EHB region ( $\chi^2$ =6.90, df=1, p<0.01). Almost one-third (32.7%, 17/52) of non-supervising EHB pharmacies were willing to do so compared to almost two-thirds (65.2%, 15/23) of non-supervising pharmacies from other regions. Thirteen of the pharmacists who said they were willing to do supervision had access to a suitable private area (40.6%, 13/32). Four respondents did not specify whether they had suitable private areas.

Respondents who had experienced problems with their patients and who reported inadequate support in managing these problems were significantly less likely to be willing to provide on-site supervision ( $\chi^2$ =3.91, df=1, p<0.05). Almost half (47.5%, 29/61) of the respondents who reported no problems or adequate support if problems arose were willing to offer supervision compared to 16.7% (2/12) of those who had experienced a lack of support in managing problems with patients.

# 5.3.4.5. Unwilling to Supervise

Respondents gave diverse reasons for not doing on-site supervision, which could be grouped into six primary themes: lack of space/privacy, security concerns, potential effects on other customers, personal objections, time constraints and staff issues. Only one respondent said they had never been asked to provide this service. Some examples are given below (see Appendix A.5.5 for all of these comments).

"There is no area in the shop to allow discreet self-administration."

"Because my patient is violent, abusive and threatening to other customers and staff."

"We don't want to upset our other patients."

"A pharmacy is not a café."

"I'm on for it but the pharmacist who does the afternoon shift isn't."

"This is a very busy pharmacy and we have no time for this."

#### 5.3.4.6. "Take-home" methadone doses

Almost half of those surveyed (46.4%, 71/151) prepared "take-home" methadone doses in advance (data were missing on eight cases and two additional pharmacists supervised the consumption of all of the methadone they dispensed, so they were excluded from this analysis). Methadone doses were dispensed to take home in accordance with details reported in Table 5.2. Only 27.8% of respondents always dispensed methadone in plastic bottles, less than half (47%) always used child resistant tops and only 15.2% always dispensed methadone in individual dose containers.

Table 5.2.: Details of the devices used in dispensing "take-home" methadone doses (N=151 as two respondents never dispensed "take-home" doses)

	Always (%)	Usually (%)	Sometimes (%)	Never (%)	Missing cases
Plastic Bottles	42 (27.8)	19 (12.6)	8 (5.3)	30 (19.9)	52
Child resistant containers	71 (47.0)	24 (15.9)	16 (10.6)	10 (6.6)	30
Individual dose containers	23 (15.2)	6 (4.0)	22 (14.6)	32 (21.2)	68

Fifty-six percent (900/1,608) of patients were dispensed their methadone on a once weekly basis in a total of 127 pharmacies. Twenty-four pharmacies did not dispense any methadone on a weekly basis (15.7%, 24/153) but dispensed it all more frequently or for consumption on-site (data were missing on two cases.)

# 5.3.4.7. Supply of Pharmaceutical Measures

Almost 90% (89.5%, 137/153) of respondents reported having previously dispensed methadone in a multi-dose container. Of these, 83.9% (115/137) had previously supplied measuring devices for patients, but eighteen respondents (13.1%, 18/137) said they never supplied measures (data were missing on four cases). As shown in Table 5.3., 12.4% of respondents gave a measure with every multi-dose supply of methadone, while 40.9% said they always gave a measure with the first supply and gave one again on request from the patient. Pharmacists who never supplied measures were found in the three sectors of the EHB, in the Southern Health Board region (S.H.B.) and in the North Eastern Health Board region (N.EHB).

Respondents were more likely to report previously supplying a methadone measure when dispensing a multi-dose methadone container if:

- they currently supervised the consumption of methadone on-site at their pharmacy ( $\chi^2$ =7.87, df=1, p<0.01). Over ninety five percent (95.2%, 60/63) of supervising pharmacies had previously supplied measures compared to 78.6% (55/70) of non-supervising pharmacies.
- they had attended specialist training ( $\chi^2$ =5.36, df=1, p<0.05), with none of the respondents who had attended specialist training reporting that they never supplied measures compared to 17.1% (18/105) of those who had not.

• they were pharmacy owners ( $\chi^2$ =3.40, df=1, p<0.05). Over 90% (91.1%, 72/79) of owner respondents had previously supplied measures compared to 78.8% (41/52) of non-owner respondents.

Table 5.3.: Frequency of supply of pharmaceutical measures with multi-dose methadone dispensings (N=137, respondents who had never supplied a multi-dose container were excluded)

	No. respondents (%)
Always, with every bottle dispensed	17 (12.4)
Always with the first bottle dispensed	7 (5.1)
Always with the first bottle, again on request	56 (40.9)
Usually	4 (2.9)
Sometimes	6 (4.4)
Only on request	24 (17.5)
No response	23 (16.8)

#### 5.3.4.8. Methadone formulations

Two-thirds of the pharmacies surveyed (66.7%, 102/153) stocked one formulation of methadone, 22.2% (34/153) carried two and 9.8% pharmacies (15/153) stocked three or more formulations. The number of formulations stocked was not given in two cases. For pharmacies with more than one patient, stocking more than one formulation of methadone 1mg/ml was significantly associated with the number of months they had been dispensing methadone 1mg/ml (t= -2.17, df=83.93, p<0.05), with those who had been dispensing longer carrying more formulations. Pharmacies which stocked one formulation were dispensing methadone 1mg/ml for a mean of 11.22 months (SD=8.19, N=64 pharmacies) while those that stocked more than one formulation were dispensing methadone 1mg/ml for a mean of 15.15 months (SD=10.14, N=46 pharmacies).

Stock held in the pharmacy was the primary determinant in the decision to dispense one formulation or another. It was "always" the determining factor in 34.6% (53/153) of pharmacies. Instructions from the prescriber "always" determined the formulation supplied in 24.2% (37/153) of pharmacies, while patient preference was "always" catered for in twenty-one pharmacies (13.7%, 21/153).

#### 5.3.4.9. Refused or withheld methadone doses

Over one-third (36.6%, 56/153) of the respondents said they had previously refused to dispense a methadone dose (data were missing on five cases). The reasons why they would refuse to dispense or administer a dose were given by respondents in many instances, and they are listed in Table 5.4. However, caution should be exercised in generalising these data due to the high non-response rate as indicated by the high number of missing values. Over two-fifths (43.8%, 67/153) of respondents said they would "always" refuse to dispense a methadone dose to an intoxicated patient and 28.1% (43/153) said they would "always" refuse to dispense to a patient who had not attended for a number of days.

Table 5.4: Details of the circumstances under which respondents reported that they would withhold a dose of methadone (N=153)

	Always	Usually	Sometimes	Never	N/A	Missing values
Patient intoxicated	67 (43.8)	15 (9.8)	9 (5.9)		15 (9.8)	47
Patient had not attended for a number of days	43 (28.1)	18 (11.8)	18 (11.8)	4 (2.6)	14 (9.2)	55
Patient attended late	8 (5.2)	7 (4.6)	22 (14.5)	26 (17.0)	19 (12.4)	71

There was a statistically significant association between the supervision of methadone and the withholding of doses ( $\chi^2$ =14.27, df=1, p<0.01, N=148). Over half (53.5%, 38/71) of respondents who supervised methadone consumption reported previously withholding a methadone dose, while less than a quarter (23.4%, 18/77) of non-supervising respondents said they had done so.

The incidence of refused doses was also directly associated with the length of time that responding pharmacies had been dispensing methadone 1mg/ml (t=2.47, df=98.79, p<0.05). Respondents who had refused to dispense a methadone dose were in pharmacies which had dispensing methadone 1mg/ml for a mean of 14.65 months (SD=10.32, N=55) while respondents who had never refused to dispense a methadone dose were in pharmacies that had dispensed methadone 1mg/ml for a mean of 10.56 months (SD=8.6, N=90).

The prior refusal of a methadone dose was not associated with respondents' gender  $(\chi^2=0.01, df=1, p=0.96)$ .

# 5.3.5. Pharmacist Support

# 5.3.5.1. The liaison pharmacists

Details of respondents' views on the support services provided by the EHB liaison pharmacists are given in Table 5.5. Only respondents based in pharmacies in the EHB region (N=124) were included in these analyses as the liaison pharmacists had no official role beyond that region.

Table 5.5.: Pharmacists' responses to: "A previous survey indicated that the Drugs & AIDS Service's Liaison Pharmacists could help you by undertaking the tasks listed below. Please indicate whether you feel this has been done."

	Yes	No	Don't know	Missing
Limited the no. patients per pharmacy	91 (73.4)	12 (9.7)	13 (10.5)	8
Supplied written contract	69 (55.6)	31 (25.0)	11 (8.9)	13
Organised training	36 (29.0)	47 (37.9)	26 (21.0)	15
Supplied dispensing procedures	64 (51.6)	26 (21.0)	20 (16.1)	14

When asked, 73.4% (91/124) of respondents said that the liaison pharmacists had been successful in limiting the number of patients that were allocated to each pharmacy under the MPS (data were missing on eight cases). Almost one-third of respondents (29.0%, 36/124) said the liaison pharmacists had not organised training for them in how to deal with drug misusers (data were missing on fifteen cases).

Suggestions as to how the liaison pharmacist could be of help were numerous and varied (see full details in Appendix A.5.6.). Examples are given below. The primary themes that emerged were:

#### (1) Develop and direct pharmaceutical aspects of the MPS.

"Get more pharmacists to participate in the protocol – I know this is difficult but we must persevere."

<sup>&</sup>quot;Ensure that the [community] pharmacist meets the patient before they agree to dispense their methadone."

"The liaison pharmacist should be the only one to approach [community] pharmacists to take on new patients - no-one else should do this."

"Make it less hassle sorting out new patients."

"It would be helpful to have notice of when patient is to begin receiving methadone from me. When my patient arrived with his first prescription we had no methadone and the wholesalers refused to supply any since they hadn't been notified that we were registered [to dispense methadone 1mg/ml]. It took time and several phonecalls to organise supplies."

"Supply information on any vaccines required for staff and cleaning up procedures if patient gets sick."

"Persuade the powers that be to remove ridiculous and unnecessary legal requirements, now that prescribing methadone has been so tightly regulated."

# (2) Liaise with GPs about pharmacy related issues.

"Help GPs to understand things from the [community] pharmacist's perspective."

"The liaison pharmacists should lobby to get the prescription forms changed to a better lay-out. They should also inform GPs of the difficulties we [community pharmacists] have with incorrectly filled in forms. Frequent problems include: (1) wrong dates, (2) no signature, (3) wrong intervals."

"The liaison pharmacists should insist and demand that doctors fill in prescriptions properly and that they do not hand out five weeks' prescriptions at a time. A big change can occur with some patients in days due for example to cocaine usage, and for a doctor not to see that patient for 35 days seems almost criminal."

"Organise an emergency contact number for doctors – sometimes it is very difficult to contact them."

# (3) Implement identified procedural recommendations.

"My patient is not tested (by blood or urine tests) to see if he is abusing other drugs currently while on methadone. It would be encouraging to know that when spot-checked he showed "clean". Otherwise it is really impossible for me to gauge this unless be arrives spaced or agitated into the pharmacy."

"There should be an EHB policy that only Pinewood or Martindale methadone is used. Phymet® is too expensive and having to stock different brands makes stock control more difficult."

# (4) Provide information and organise training initiatives for community pharmacists.

"Discussion and advice on dealing with difficult situations – so that vital back-up is available – this is happening and very valuable to me."

"Organise local seminars involving both GPs and pharmacists."

"Provide advice on dealing with difficult situations."

# 5.3.5.2. Training Opportunities for Community Pharmacists in the MPS

Only one fifth of respondents (20.3%, 31/153) had attended training on the management of drug misusers (data were missing on two cases). Despite community pharmacists' expectation that the liaison pharmacists would provide training for them, the most common sources of training were the regional health boards (all sources are given in Appendix A.5.7.). When asked for details of topics they would like to know more about, respondents were most likely to list dispensing procedures for methadone and its therapeutic use. Examples of other topics which community pharmacists would like training in are given below (see full list in Appendix A.5.8.).

"The clinical effectiveness of methadone as a treatment for drug abuse and as a starting block for getting patients drug free."

"Patient withdrawal from methadone - not just leaving them on the same dose for life."

"How doses are determined."

"How to deal with problem patients and the safety of staff."

"More about how they tackle these problems world-wide and the options available.

"Diagnosis of symptoms in stoned patients – whether they are on cannabis, benzodiazepines etc."

"What is being done to tackle the increase in cocaine abuse and the use of other drugs??"

## 5.3.5.3. Problems with patients on methadone

Over half (56.9%, 87/153) of those surveyed said they had never experienced any problem with their patients on methadone, while 37.9% (58/153) had experienced problems (data were missing on eight cases). The majority of respondents (56.9%, 33/58) who had experienced problems said they had received adequate support, while 43.1% (25/58) said they had not received adequate support.

Some qualitative comments from those who said they had not received adequate support are given below with full details available in Appendix A.5.9.. They suggested that community pharmacists expected support primarily from methadone prescribers and from the Gardai. Many pharmacists did not know who could support them, and others stated categorically that they dealt with their own problems in-house.

"Generally the doctor is notified and the situation improves but there is no proper system for dealing with problems." "Not as much support [from the Gardaí] as I would like, and often the support they do give is not very sensitive."

"Who would I turn to??"

"I don't bother looking for support that isn't easily forthcoming. We deal with these things ourselves."

Respondents who had experienced problems in operating the methadone had a mean of 18.74 patients each (SD=31.83, N=58) while those who had no problems had a mean of 5.13 patients each (SD=7.85, N=87), indicating that as patient numbers increased, problems were more likely to occur (t=3.19, df=61.64, p<0.01). However, there was no association between patient numbers and whether respondents received adequate support in managing the problems when they occurred (t=1.56, df=56, p=0.13).

# 5.3.6. Contact with methadone prescribers

# 5.3.6.1. Ease & Frequency of Contact

Almost 80% (78.5%, 120/153) of respondents said it was "easy" or "very easy" to contact the doctors who prescribed methadone for their patients in the MPS, while 15.0% (23/153) said they found it "difficult" or "very difficult" to contact them (data were missing on six cases).

Respondents had contacted methadone prescribers a mean of 1.34 times each in the course of the previous week (SD=4.87, range=0–50, sum=169, N=126, data were missing on 27 cases). The primary reasons for contact were to clarify prescription inaccuracies (27.8%, 47/169), concerns relating to prescribed methadone dosages (16.6%, 28/169) and because prescriptions were illegible (10.1%, 17/169). (For examples see sections on the role of the liaison pharmacist and on how links between pharmacists and GPs could be improved.)

## 5.3.6.2. What information did pharmacists give methadone prescribers?

As shown in Table 5.6. almost 90% (88.9%, 136/153) of respondents said they would inform the prescriber if they withheld a methadone dose (data were missing on seven cases). Over four-fifths (83.7%, 128/153) said they would let their methadone prescriber know if a patient presented a prescription for psychoactive medication from another doctor (data were missing on five cases).

Table 5.6.: Information transfer from community pharmacists to methadone prescribers

	Yes (%)	No (%)	Sometimes* (%)	Missing cases
If you withheld a methadone dose, would you tell the prescriber involved?	136 (88.9)	1 (0.7)	9 (5.9)	7
If a patient on methadone was prescribed another psychoactive medicine by a different doctor/GP would you inform the methadone prescriber?	128 (83.7)	5 (3.3)	15 (9.8)	5

<sup>\*</sup> respondents were asked to explain their responses

Pharmacists who said they would "sometimes" inform the prescriber if they withheld a dose outlined the factors which determined whether or not the prescriber was contacted, and these are listed in full in Appendix A.5.10.. The primary determinants were circumstantial e.g. one pharmacist said "I would ask the patient to explain the circumstances or the reasons why he was missing first", and the pharmacist's ability to contact the prescriber. As one explained -"I would do [tell him] if the prescriber could be contacted."

Pharmacists who said they would "sometimes" inform the prescriber if a patient was concurrently prescribed psychoactive medication by another prescriber outlined the factors which determined whether or not they did so, and these are listed in full in Appendix A.5.11.. The primary determinants were the prescribers involved, the drugs prescribed, confidentiality issues and ease of contact.

<sup>&</sup>quot;It would depend on the two doctors and the relationship between them. Anyway, it's not likely that the patient would come here – he would nearly always go to another pharmacy to avoid detection."

<sup>&</sup>quot;Sometimes it seems to be OK for a patient to go to a second doctor, for example, to his own GMS doctor."

<sup>&</sup>quot;If the patient had been newly prescribed the drug the GP would be contacted."

<sup>&</sup>quot;I respect the patient/doctor confidentiality."

<sup>&</sup>quot;Doctors can be very difficult to contact."

# 5.3.6.3. What information did pharmacists want from methadone prescribers?

As shown in Table 5.7. almost 80% (77.8%, 119/153) of respondents said they would want to know if a patient on methadone was using other drugs (data were missing on seven cases). Only 11.8% (18/153) of those surveyed believed that they would currently be informed of this (data were missing on eight cases).

Table 5.7.: Information transfer from methadone prescribers (or prescribing services) to community pharmacists

	Yes* (%)	No (%)	Don't know (%)	Missing cases
Would you want to know if a patient was using other drugs or being prescribed other medication while you were dispensing his methadone?	119 (77.8)	12 (7.8)	15 (9.8)	7
Would you be informed if a patient was using other drugs (e.g. heroin) or being prescribed other medication while you were dispensing his methadone?	18 (11.8)	42 (27.5)	85 (55.6)	8

<sup>\*</sup> respondents were asked to explain reasons why they would want to know

Many respondents did not specify their reasons for wanting (or not wanting) to know if their patients were taking additional drugs or medicines. But of the respondents who expressed a preference and gave reasons for their decisions, 26% (38/146) said they would want to know because they wanted to be able to provide full patient care, 18.5% (27/146) said they needed to know so that they could check for interactions with prescribed medications and 9.6% (14/146) of respondents said that they would want to know because such behaviour was in breach of the patient's treatment contract.

5.3.6.4. Pharmacists' ideas for improving communication with methadone prescribers Many pharmacists gave suggestions on how their links with prescribing GPs could be improved (see Appendix A.5.12. for full details). The primary emergent themes were:

(1) Joint decision making regarding the practical aspects of patient care.

"Prescribers should be prepared to accept help from pharmacists regarding their advice and views on patients and how they are doing."

"It would be useful to know the aim or projected aim of the programme for each patient."

"We should be able to get involved in planning the treatment regimen with the GP i.e. the pharmacist and doctor should working together in best interests of the patient."

# (2) Regular, routine GP contact regarding patient care.

"I feel at the moment the onus is always on the pharmacist to make contact with the GP re-changed doses etc. It would be helpful if the GP took the initiative and phoned to explain changes on weekly prescriptions etc."

"The doctor always rings me if there is any change in the prescription. This is important and very helpful."

"I would like if the doctor indicated changes of dosage and supply quantities in advance to facilitate dose preparation."

"Prescribers in clinics should be available to deal with queries on methadone prescriptions. Their mobile phone numbers should be made available."

# (3) Increased interactive initiatives to build mutual respect and understanding.

"Doctors appear to see our role as administrators and do not seem that bothered about legibility, or indeed fully completing their prescriptions. It is obvious from looking at the forms that they are viewed as an unavoidable nuisance. This causes unnecessary stress for me and the patients as they have to return with scripts to doctors to correct - which is a continuous problem."

"An informal meeting with prescribing GPs would help to put a face to the names!"

#### 5.3.7. Pharmacists' Views

#### 5.3.7.1. Motivation

As shown in Table 5.8. the three most common reasons respondents gave for starting to dispense methadone were requests from local GPs (36%), requests from patients (25.5%) and requests from liaison pharmacists (18.3%). The primary reason why pharmacists who had never dispensed Physeptone® commenced methadone dispensing was because a liaison pharmacist asked them (38%, 19/50) while most of those who had dispensed Physeptone® started dispensing because a local GP asked them (48.5%, 48/99) (data were missing on four cases).

As shown in Table 5.9., 85% of respondents said they felt they had a professional responsibility to provide a methadone dispensing service and 73.2% said the service was necessary for their local community. Almost three-quarters (72.5%) said they supported the provision of services for drug misusers. Over two-fifths (45.8%) said they dispensed methadone because they were requested to do so by a liaison pharmacist.

Table 5.8.: Reasons why respondents started to dispense methadone or Physeptone® (N=153, data were missing on eleven cases, multiple responses accepted)

	No. respondents (%)
Requested by a local GP.	55 (36.0)
Requested by a local patient.	39 (25.5)
Requested by a liaison pharmacist.	28 (18.3)
Requested by a local drug service.	18 (11.8)
Methadone Protocol Scheme introduced.	14 (9.2)
Other	13 (8.5)
Requested by a GP co-ordinator.	7 (4.6)
Requested by the local community.	4 (2.6)

Table 5.9.: Reasons why community pharmacists dispensed methadone 1mg/ml (N=153, multiple responses accepted)

	Yes (%)	No (%)	Missing
			cases
I support the provision of services for drug misusers.	111 (72.5)	5 (3.3)	37
I believe methadone programmes are clinically effective.	68 (44.4)	17 (11.2)	68
I feel I have a professional responsibility to provide such services.	130 (85.0)	3 (2.0)	20
I believe this service is necessary for the local community.	112 (73.2)	6 (3.9)	35
A doctor/GP asked me to provide a service.	59 (38.6)	41 (26.8)	53
A liaison pharmacist asked me to provide a service.	70 (45.8)	29 (19.0)	54

#### 5.3.7.2. General Views (see Table 5.10.)

The views expressed by respondents were measured on a five point Likert Scale ("1=strongly agree", "2=agree", "3=neither agree nor disagree", "4=disagree" and "5=strongly disagree"). Over two-thirds (67.3%) of respondents "agreed" or "strongly agreed" that it was better for patients to get their methadone at a community pharmacy rather than at a drug treatment centre, which showed that community pharmacists believed in the value of the services that they can offer to drug misusers. Over sixty percent (62.8%) of those surveyed "agreed" or "strongly agreed" that patients on methadone were easy to manage and 62.1% "agreed" or "strongly agreed" that they knew enough about methadone to be able to make a positive contribution to patient care, again illustrating their belief in their professional role in the treatment of opiate misusers. Nearly two-thirds of them (64.1%) "disagreed" or "strongly disagreed" that they felt physically vulnerable when dealing with drug misusers, which suggested that they were able to manage patients in the MPS. Almost 40% (38.6%) of respondents "agreed"

or "strongly agreed" they were concerned that some of the methadone they dispensed might not have been consumed by the patient for whom it was prescribed while 31.4% "agreed" or "strongly agreed" that they preferred patients to drink their methadone onsite. These views suggested that a sizeable minority of respondents had professional concerns regarding the potential diversion of the methadone that they dispensed.

Table 5.10.: Pharmacist's views measured using a five point Likert Scale. (N = 153)

	Strongly Agree	Agree	Don't know	Disagree	Strongly disagree	MV
Patients on methadone are easy to manage.	N (%) 7 (4.6)	N (%) 89 (58.2)	N (%) 16 (10.5)	N (%) 26 (17.0)	N (%) 5 (3.3)	10
It is better for patients to get their methadone at a community pharmacy than at a drug treatment centre.	26 (17.0)	77 (50.3)	25 (16.3)	14 (9.2)	3 (2.0)	8
I am concerned that some of the methadone I dispense may not be consumed by the patient for whom it was prescribed.	13 (8.5)	46 (30.1)	32 (20.9)	51 (33.3)	6 (3.9)	5
I feel I know enough about methadone to be able to make a positive contribution to patient care.	18 (11.8)	77 (50.3)	27 (17.6)	23 (15.0)	2 (1.3)	6
I prefer patients to drink their methadone in front of me than to take it home with them.	16 (10.5)	32 (20.9)	21 (13.7)	59 (38.6)	10 (6.5)	15
Patients on methadone are NO WORSE than other customers when it comes to theft from the pharmacy.	22 (14.4)	60 (39.2)	35 (22.9)	22 (14.4)	7 (4.6)	7
I feel physically vulnerable when dealing with drug misusers.	5 (3.3)	25 (16.3)	13 (8.5)	79 (51.6)	19 (12.4)	12

## 5.3.8. Statistical analysis of attitudinal data

The attitudinal statements studied were investigated in an attempt to identify any significant relationships between them and a number of key respondent characteristics. The analysis of these relationships would be useful in determining characteristics that could be used as predictors of pharmacists' attitudes to the provision of methadone dispensing services.

Cronbach's Alpha co-efficient was initially used to measure internal reliability within the list of attitudinal statements. A result of 0.7 or greater would have shown that pharmacists' attitudes were consistent with each other and a summed score for "attitude"

could have been defined (Oppenheim 1999), which could have been used in subsequent regression analysis. However, when the seven attitude statements were examined for internal consistency, their alpha coefficient was 0.62, a value too low to allow them to be recomputed for use as a single "attitude" variable. This was not surprising, given that the statements related to separate issues, and were designed to investigate a number of relevant topics, rather than to explore a limited number of attitudinal issues. More thorough piloting, with a focus on the development of an internally reliable attitudinal scale, could have raised the alpha co-efficient and improved the quality of the data derived from this section of the survey.

## 5.3.8.1. Factor analysis

Given that it was not possible to re-compute the seven attitudinal statements as one "attitude" variable due to their low alpha co-efficient, a factor analysis was conducted to explore possible relationships between subgroups of statements within the scale. This process yielded two new "attitude" factors with Eigenvalues equal to or greater than 1.00. A Promax rotation of these factors yielded the factor structure given in Table 5.11. (see correlation matrix in Appendix A.5.13.)

The first factor accounted for 35% of the variance in respondents' attitudes (Eigenvalue=2.4), and seemed to represent belief in the value of normalising methadone treatment by providing it in the community pharmacy. This factor was comprised of respondents' positive views on the superiority of the community pharmacy over the DTC as a methadone dispensing site, the easy management of patients in methadone treatment, and the absence of feelings of physical vulnerability when managing patients on methadone. It seemed to relate to respondents' belief in their own ability to manage and provide services for patients in methadone treatment and was called "confidence", with more negative scores being associated with higher respondent confidence.

The second factor identified accounted for a further 21% of the variance (Eigenvalue=1.5) and appeared to relate to respondents' lack of trust in patients on methadone and a need for control when dispensing methadone. It was associated with respondents' desire to have a greater input into patient care, preferring patients drinking their methadone under supervision and having concerns that some methadone may be diverted. This variable appeared to relate to the power relations between respondents

and their patients, and consequently it was called "control", with more negative scores relating to more controlling respondent attitudes.

Table 5.11.: Factor analysis of attitudinal variables (Promax rotation)

	Factor 1 Confidence	Factor 2 Control
It is better for patients to get their methadone at a community pharmacy than at a drug treatment centre.	0.83	0.07
Patients on methadone are easy to manage.	0.78	- 0.17
I feel physically vulnerable when dealing with drug misusers.	- 0.67	- 0.06
Patients on methadone are NO WORSE than other customers when it comes to theft from the pharmacy.	0.43	0.47
I feel I know enough about methadone to be able to make a positive contribution to patient care.	0.36	0.57
I am concerned that some of the methadone I dispense may not be consumed by the patient for whom it was prescribed.	- 0.45	0.69
I prefer patients to drink their methadone in front of me than to take it home with them.	-0.01	0.76

# 5.3.8.2. Univariate analysis

In an effort to identify key characteristics that could be used to predict pharmacists' attitudes, the new attitudinal variables were analysed in conjunction with a number of respondents' demographic characteristics and some features of service provision among responding pharmacies.

The predictor characteristics examined were:

- (a) Respondent gender
- (b) Respondent's pharmacy ownership (or employee) status
- (c) The number of years since respondents had registered as pharmacists
- (d) Prior experience of external support in managing methadone patients
- (e) Prior attendance at specialist methadone training
- (f) The length of time responding pharmacies had been dispensing methadone 1mg/ml
- (g) MPS patient load per responding pharmacy
- (h) The provision of on-site supervision

Following a study of the corresponding box and scatterplots, to gain familiarity with the data, a univariate analysis was carried out on these characteristics using the newly computed continuous scores for the new "attitude" variables (see details in Tables 5.12. & 5.13.). Independent sample t-tests were carried out on the "attitudes" with categorical predictor variables while Pearson's correlations were used in the analysis of these "attitudes" and other continuous predictor variables.

The analysis suggested that ownership status was a statistically significant predictor of respondents' "confidence" levels (with the owners being significantly more "confident" than the employees who responded to this survey). They also indicated that the variable "confidence" was positively associated with the length of time that respondents had been practising as community pharmacists and the number of MPS patients that attended their pharmacies.

An examination of the variable "control" suggested that respondents who were currently providing on-site supervision were significantly more likely to report "controlling" attitudes, and that respondents' attitudes became more "controlling" the longer they had been practising as community pharmacists.

Table 5.12.: Statistical results of univariate analysis on attitudinal factors "confidence" and "control" versus key categorical predictors.

Attitudinal factor	Predictor variable	t	df	р		Mean	SD	N
Confidence	Ownership status	- 2.01	111	0.05	Owner Employee	- 0.17 0.21	0.98 0.97	67 46
	Sex	- 1.27	111	0.21	Male Female	- 0.1 0.14	0.89 1.15	73 40
	Attended specialist training	- 0.27	111	0.79	Trained Untrained	- 0.07 - 0.01	1.05 0.98	21 92
	Support with problems	- 1.95	18.2	0.07	Yes/none needed No	- 0.11 0.61	0.88 1.46	93 17
	Currently providing supervision	- 0.24	112	0.81	Yes No	- 0.02 0.02	0.99 1.01	63 51
Control	Ownership status	0.04	111	0.97	Owner Employee	- 0.01 - 0.02	1.05 0.93	67 46
	Sex	- 0.82	111	0.42	Male Female	- 0.07 0.09	1.07 0.84	73 40
	Attended specialist training	- 0.89	111	0.38	Trained Untrained	- 0.19 0.26	1.12 0.97	21 92
	Support with problems	1.31	19.3	0.21	Yes/none needed No	0.07 - 0.35	0.93 1.26	93 17
	Currently providing supervision	- 4.41	112	<0.01	Yes No	- 0.34 0.43	0.93 0.92	63 51

Table 5.13.: Statistical results of univariate correlations of attitudinal factors "confidence" and "control" versus key continuous respondent characteristics

	Predictor	Pearson's Correlation	р	N
Confidence	No. years as community pharmacist	- 0.02	0.82	114
	No. patients on methadone	- 0.03	0.74	109
	No. months dispensing methadone 1mg/ml	0.10	0.30	113
Control	No. years as community pharmacist	- 0.31	<0.01	114
	No. patients on methadone	80.0	0.42	109
	No. months dispensing methadone 1mg/ml	- 0.08	0.40	113

# 5.3.8.3. Multiple regression analysis

Multiple regression analysis is useful in identifying the most significant predictors of attitude. It involves the inclusion of numerous features associated with a sample of respondents, along with their attitudinal responses, in a single analysis, which can then pinpoint the extent to which these features influence each other. Variables that predict more than 10-15% of the variance seen are regarded are useful in the study of social science (see, for example, García 1995, Peters et al 1995).

However, when multiple regression analysis was carried out with the key characteristics listed above using "confidence" as the dependent variable, it showed that they predicted only 2.6% of the attitudinal variance seen (F<sub>8,96</sub>=1.35, p=0.23). "Confidence" appeared to be significantly related only to whether or not respondents had received external support in managing problems (see statistical data in Table 5.14) with respondents who reported receiving support with their problems and those who had never experienced problems (combined as a single group) being significantly more "confident" than respondents who had experienced problems and had not received support. No other key characteristics showed a statistically significant relationship with respondents' reported "confidence".

When the same analysis was repeated using the "control" variable, the predictors examined accounted for 18.9% of the variance seen ( $F_{8,96}$ =4.03, p<0.01). Two characteristics were statistically significant predictors of respondents' "controlling" attitude (see Table 5.15.). As shown by the earlier univariate analysis, more "controlling" attitudes were positively associated with the provision of on-site supervision, but this

regression analysis also showed them to be related to patient numbers, with "controlling" attitudes falling as patient numbers increased.

Table 5.14. Multiple regression analysis of attitudinal factor "confidence" and key predictor variables.

	В	Standard error, b	t	Significance of t
Respondent sex	0.04	0.23	0.19	0.85
Ownership status	0.38	0.23	1.69	0.09
Prior attendance at specialist training	0.05	0.26	0.19	0.85
Prior experience of external support with problems	0.69	0.28	2.41	0.02
Provision of on-site supervision	<0.01	0.21	- 0.04	0.97
No. patients	< 0.01	0.01	- 0.13	0.90
No. years trained as community pharmacist	<0.01	0.01	0.43	0.67
No. months in MPS	<0.01	0.01	0.63	0.53

Table 5.15. Multiple regression analysis of attitudinal factor "control" and key predictor variables.

	В	Standard	t	Significance
		error, b		of t
Respondent sex	- 0.03	0.20	- 0.16	0.87
Ownership status	0.11	0.20	0.56	0.58
Prior attendance at specialist training	- 0.18	0.23	- 0.77	0.44
Prior experience of external support with problems	- 0.46	0.25	- 1.84	0.07
Provision of on-site supervision	0.57	0.18	3.09	<0.01
No. patients	- 0.01	0.01	- 2.92	< 0.01
No. years trained as community pharmacist	0.02	0.01	1.80	0.07
No. months in MPS	<0.01	0.01	- 0.04	0.97

# 5.3.9. Comparisons between Surveys 2 & 3

The data from this and the earlier survey of pharmacy participation in the dispensing of methadone 1mg/ml (Survey 2) were compared on two levels. Aspects of pharmacy involvement in the dispensing of methadone 1mg/ml can be compared as a whole under

the Methadone Pilot Project in August 1998 and under the Methadone Protocol Scheme in March 1999. Nation-wide pharmacy participation data from the CDTL showed a total of 99 community pharmacies were registered to dispense methadone 1mg/ml in August 1998, 83 of whom responded to the survey. Responses to Survey 2 can be compared with those from the 153 (of 172) pharmacies that were registered with the MPS six months later that responded to Survey 3. Data from this comparative analysis are presented below.

In addition, paired data from pharmacies that participated in both Survey 2 and Survey 3 were examined to investigate changes in dispensing practice in this particular group of pharmacies during the study period. Findings from this study are outlined in Chapter 6.

## 5.3.9.1. Participation levels

CDTL Statistics showed a 74% (99/172) increase in the number of community pharmacies that were dispensing methadone 1mg/ml in August 1998 as compared with March 1999. However, the total number of patients registered in methadone treatment at community pharmacies remained almost constant between August 1998 (N=1,870 patients) and February 1999 (N=1,860 patients). These figures represented 55% and 51% of the total number of patients registered in methadone treatment in August 1998 and March 1999 respectively (CDTL Statistics), although the August 1998 data cannot be regarded as complete, given that details regarding patients on Physeptone® may not have been accurate.

When the top four outliers were excluded from the calculations to improve the normality of the curve, there was a statistically insignificant fall in the mean number of methadone patients per responding pharmacy between August 1998 and March 1999 (t=1.90, df=127.42, p=0.06). In August 1998 there was a mean of 12.14 patients in methadone treatment in responding pharmacies (SD=15.79, N=78, data were missing on two respondents) while in March 1999 they had a mean of 8.23 patients each (SD=12.39, M=150). [Note: The top outliers excluded had more than 78 patients each, but the statistical outcome remained the same if these top outliers were included.]

## 5.3.9.2. Pharmaceutical Services

There was a rise in the overall incidence of supervision from 36.1% (30/83) in August 1998 to 48.4% (74/153) in March 1999 but the rise was not significant at the 5% level ( $\chi^2$ =1.49, df=1, p=0.22).

The supply of measures with multi-dose methadone containers (as opposed to <u>never</u> supplying them) showed a highly significant increase following the introduction of the MPS ( $\chi^2$ =15.96, df=1, p<0.01). In Survey 2, 30.2% (25/83) of respondents never supplied measures compared to 13.5% (18/133) in Survey 3.

Mann-Whitney's test showed that the views expressed by respondents in Survey 3 were not significantly different to those reported in Survey 2. Details are shown in Table 5.16. As the researcher did not stipulate that the same respondent had to complete both Surveys 2 and 3, these attitudinal data have individual value only and cannot be directly compared to look for attitudinal changes over time.

Table 5.16.: Overall views reported in Surveys 2 and 3

	Survey	Strongly	Agree	Neither	Disagre	Strongly	MW	Z	р
		agree	(%)	agree nor	e (%)	disagree	U		
		(%) disagree (%)			(%)				
I am concerned that some of the methadone I dispense may not	2	13 (18.1)	23 (31.9)	10 (13.9)	15 (20.8)	11 (15.3)	5005.0	-0.76	0.45
be consumed by the patient for whom it was prescribed.	3	13 (8.8)	46 (31.1)	32 (21.6)	51 (34.5)	6 (4.1)			
Patients on methadone are NO WORSE than other customers when it	2	8 (11.0)	31 (42.5)	18 (24.7)	11 (15.1)	5 (6.8)	5046.5	-0.67	0.50
comes to theft from the pharmacy.	3	22 (15.1)	60 (41.1)	35 (24.0)	22 (15.1)	7 (4.8)			
I feel I know enough about methadone to be able to make a positive contribution	2	9 (12.7)	40 (56.3)	16 (22.5)	6 (8.5)	0 (0)	4878.0	-0.86	0.39
to patient care.	3	18 (12.2)	77 (52.4)	27 (18.4)	23 (15.6)	2 (1.4)			

#### 5.4. DISCUSSION

In March 1999, six months after the MPS was introduced, 16% (172/1,073) of Irish community pharmacies, and 40.4% (143/354) of community pharmacies within the EHB region, were dispensing methadone 1mg/ml (McManus 2001, CDTL Statistics). Since Physeptone® was no longer marketed in Ireland, these pharmacies were the only primary care outlets for methadone, and so this survey represented the first comprehensive investigation of community-based methadone dispensing services in Ireland. Data derived from this study paints a detailed picture of dispensing practice at that time, and also elaborates on the views and attitudes of the pharmacists involved.

The proportion of Irish community pharmacists that were dispensing methadone 1mg/ml rose from 10% in August 1998 to 16% in February 1999 (McManus 2001, CDTL Statistics). The active percentage rose from 29% to 40% within the EHB region during that time. Another retrospective study also noted the rapid recruitment of Irish community pharmacists to the MPS around this time (Keenan et al 1999).

A group of community pharmacies which was not subjected to the regulatory changes associated with the MPS could have been a useful control for comparison purposes in examining how the introduction of the MPS affected pharmacists' attitudes and their dispensing practices. However, ethical considerations made it impossible to exclude pharmacies from the MPS, and so a control group could not be created. In addition, the fact that the Methadone Pilot Project was well established before the Methadone Protocol Scheme was fully introduced meant that the structures and services associated with the MPS were essentially being provided for a proportion of patients in a number of community pharmacies prior to 1 October 1998. This meant that any changes in study findings between Surveys 2 and 3 may not have been exclusively due to the introduction of the scheme. However, given that the introduction of the MPS was the principal overriding policy change affecting pharmacy practice in this field at this time, it can be concluded that the net effects reported here were largely due to its influence.

Community pharmacies not participating in the MPS were not targeted by this study although their involvement could have elucidated issues such as barriers to service provision, and identified attitudinal differences between pharmacists who dispensed

methadone and their non-dispensing colleagues. Some data was already available on Irish non-providers (see Chapter 3), but their inclusion in this survey would have made its findings more complete, and future research initiatives should endeavour to incorporate them.

The proportion of owner respondents was similar to that seen among IPU members at the time that this survey was undertaken (McManus 2001) which suggested that owners and employee pharmacists were fairly well represented by the sample surveyed here. However, data on the gender balance among private pharmacy owners showed that 56% were owned by men (Pharmaceutical Society of Ireland 2001), so data from this study indicated that male owners were more inclined to dispense methadone with the MPS than females owners were. The attitudinal data also indicated that they were more confident in managing their patients on methadone, which suggests that they are a valuable resource in the provision of community-based methadone dispensing services, and their participation in the MPS should be actively promoted.

The gender balance among pharmacy owners who dispensed methadone 1mg/ml was almost identical to that reported by Survey 2 prior to the introduction of the MPS, despite a considerable increase in participant numbers (see Chapter 4). This suggests that steps taken to improve recruitment rates among female pharmacy owners had not been successful in changing participation levels, although they had managed to sustain the gender balance seen earlier. Considering that a sizeable proportion of Irish community pharmacies are owned by female pharmacists (44% according to the Pharmaceutical Society of Ireland 2001), steps must be taken to ensure their continued support and recruitment.

This survey included data on dispensing services for 44% (1,608/3,675) of the patients in methadone treatment and 86.5% (1,608/1,860) of those attending community pharmacies at the time this survey was carried out (CDTL Statistics). Both the total number of patients registered to attend community pharmacies for methadone treatment and the proportion of those registered in methadone treatment that were attending community pharmacies remained almost constant in the course of the study period (CDTL Statistics). This implied that the MPS resulted in little overall change in the volume of patients registered in treatment and the proportion of registered patients who

attended community-based dispensing services. Only the nature of the services provided altered, with significant change centring on the transfer of patients from Physeptone® to methadone 1mg/ml. In March 1999, the proportion of pharmacies dispensing methadone for more than fifty patients (i.e. above the maximum number recommended by guidelines for the MPS) had fallen to less than half that seen in Survey 1, carried out a year earlier (see Chapter 3). This suggested that the MPS had been effective in limiting the numbers of new patients attending individual pharmacies and in reducing the numbers already attending established methadone dispensers. This was in keeping with the explicit aims of the MPS, and should have had a positive impact on pharmacists and on public perception of the impact of the scheme by reducing the concentration of drug misusers around high activity community pharmacies (O'Farrell et al 2000). This should also have helped to normalise their treatment under the MPS by enabling patients to attend more convenience dispensing sites, and continued community pharmacy recruitment should ensure this situation is maintained.

The ability of Irish community pharmacies to facilitate the transfer of patients onto the MPS and to provide methadone treatment services for similar numbers of patients following the introduction of the MPS illustrated the extent to which they co-operated with the scheme, and highlights their vital role in the provision of community-based methadone treatment in Ireland.

The low incidence of the use of written dispensing procedures for methadone dispensing among responding pharmacies suggested that these procedures were still evolving and were relatively ad hoc in nature. However, there is no documented evidence of the use of written dispensing procedures in many aspects of community pharmacy practice in Ireland, so it is possible that their absence in this instance was not a particular facet of the MPS, but relatively standard within the pharmacies involved. However, the finding that many of the dispensing procedures that were in use had been devised by individual pharmacists, rather than by the Pharmaceutical Society of Ireland or by the liaison pharmacist suggested that standard procedures were not applied, and this may have implications for patient care and for those who might want to implement external changes to pharmacy practice in this area. Future research should investigate qualitative aspects of the dispensing procedures currently utilised with a view to developing

standard practices that are implemented by all community pharmacists participating in the MPS.

The use of pharmacy/patient contracts in responding pharmacies had nearly doubled since Survey 1 was carried out, which showed increased community pharmacist co-operation with the Pharmaceutical Society of Ireland's *Policy on Drug Abuse (1996)*. Many community pharmacists had devised individualised contracts, which may reflect the development of locally acceptable agreements between individual pharmacists and their patients. This could be a positive outcome following the introduction of the MPS, as community pharmacists became more flexible in meeting patients' needs. However, data from the qualitative study of service users' views (Chapter 9) and from UISCE (Larkin 2000 & 2001) suggests that patients' views were not considered in the application of pharmacy/patient contracts and that they were not introduced to guarantee appropriate standards of care for patients. This research suggests that their increased use may have been related to community pharmacists' desire to "control" their patients and to protect themselves, in the absence of adequate external support mechanisms. Data from Scotland also identified some pharmacists who provided treatment services essentially against their will (Matheson et al 1999b).

The lack of community pharmacy places for those requiring methadone treatment in Ireland and the ability of pharmacists to write their own pharmacy/patient contracts leaves patients open to manipulation and could lead to inequality of service. Therefore, while the use of pharmacy/patient contracts has value in providing pharmacists with reassurance and protection, and is recommended by the Pharmaceutical Society of Ireland (McDermott 1999) it is essential that the contracts used are fair and reasonably standard in all community pharmacies. A uniform contract could be introduced in all pharmacies, which allowed individual pharmacists a degree of autonomy in some aspects. But given that pharmacists' views regarding their patients' behaviour and their personal security were so strong, it is questionable whether they would be prepared to accept such a contract.

Although not statistically significant, the introduction of the MPS was associated with a rise in community pharmacy participation in the provision of on-site supervised dosing. However, the incidence of the provision of supervised dosing remained lower here than

that reported in Scotland in 2000, where 81% of those who dispensed methadone also supervised doses on-site (Pitcairn et al 2001). Nevertheless, the greater evidence of supervised dosing may have reflected a greater awareness of its value among prescribers, and a higher degree of familiarity with its delivery among community pharmacists. It may also have illustrated an overall policy shift from large volume "takehome" doses to tighter controls on the dispensing of methadone under the MPS.

The absence of significant associations between the demographic characteristics of the respondents surveyed and whether they provided (or were willing to provide) on-site supervision services undermined the anecdotal view that females and older pharmacists were less likely to do so. The "controlling" attitudes associated with pharmacists who supervised methadone consumption may illustrate greater professional involvement, with pharmacists accepting greater responsibility for the safety of their patients and their communities, or may be indicative of less trusting attitudes towards patients in methadone treatment. This aspect of community pharmacists' attitudes is important to their overall relationship with their patients, and merits further investigation.

The expressed willingness of many additional community pharmacists to provide supervision for patients on methadone was a positive finding and should be helpful in further developing community-based methadone dispensing services. The lower willingness to provide supervision services among the EHB respondents not already doing so suggests that the region had saturated its community pharmacy-based on-site supervision services, a situation which needs to be addressed by the liaison pharmacists if community pharmacists are to be able to continue to absorb MPS patients. Further investigation into the qualitative reasons why community pharmacists decide to provide on-site supervision could be useful in exploring this issue.

Given that pharmacists outside the EHB region were more likely to be willing to provide on-site supervision than their EHB colleagues, the reduced incidence of supervision outside the EHB region may highlight a greater degree of stability among patients elsewhere, so that they were less likely to require supervision. It could also show a diminished belief in the value of supervision among ex-EHB prescribers. It may also be due to confidentiality issues, given that in rural areas it could be more difficult to protect the privacy of those in treatment if they were obliged to drink their methadone in a local

pharmacy. Further research is necessary to clarify the issues involved here and provide guidance for those who work to promote the provision of on-site supervision.

The association between respondents' willingness to offer supervision and the receipt of adequate support with their problems suggested that community pharmacists who felt protected and secure within the community-based drug treatment team were more likely to provide supervision. Conversely, the increased feelings of physical vulnerability expressed by respondents who did not provide on-site supervised dosing suggested that better security measures could help to encourage non-providers to offer supervision services. This issue should be addressed by the MPS management, liaison pharmacists and the Gardaí.

Interest in a grant for the modification of their premises to provide a private area for the supervision of methadone on-site was expressed by 44% of respondents who were providing methadone dispensing services in Survey 1 (see Chapter 3). The DOHC consequently offered an initial grant of £2,000 (€2,540) and a subsequent grant of £5,000 (€6,350) for modifications to community pharmacies, yet this survey showed that less than half of those who provided on-site supervision had private areas. In addition, many of the pharmacists who were willing to do supervision already had private areas, so that the provision of a grant was superfluous to their recruitment. Given that many of those who did not provide supervision blamed a lack of a private space for their non-participation, and that the Pharmaceutical Society's Guidelines (McDermott 1999) recommend the provision of privacy in the delivery of on-site supervision services, this issue needs to be further explored in relation to the provision of on-site supervised dosing.

Findings from this survey suggested that the supply of pharmaceutical measures with all multi-dose methadone dispensings continued to be uncommon under the MPS, although there was a reduction in the number of respondents who <u>never</u> supplied them following its introduction (see Chapter 4). It was clear from the data that some community pharmacists had not yet recognised the need to provide pharmaceutical measures to patients with multi-dose methadone dispensings. The increased incidence of supply of pharmaceutical measures by respondents who had attended specialist training suggests that training initiatives may have a role to play in heightening pharmacists' awareness of

the necessity for measures to be provided, and this should be further explored to maximise its potential. In view of the association between the use of babies' bottles in the measurement of methadone and risks to Dublin children (Harkin et al 1999) this message needs to be imparted on them as a matter of urgency.

Most of those participating in the MPS carried only one formulation of methadone, although the number of formulations they stocked increased the longer they had dispensed methadone 1mg/ml. Working with one brand of the 1mg/ml formulation should have simplified controlled drugs storage issues, and the elimination of the 2mg/ml linctus should have reduced the potential for accidents. Pharmacists reported that they "always" complied with prescribers' requirements regarding patients' formulation requirements in a quarter of instances while patients' choice was also an important determinant of the formulation dispensed. This was a positive finding, given the importance patients attached to the taste of their methadone (Neale 1998, Lovell et al 1999, Arts Group 2000, see also Chapter 9).

In accordance with the Misuse of Drugs Regulations, 1988 & 1993 and the Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations, 1993 changes to the methadone dosage and instalment instructions should only be dispensed on foot of new methadone prescriptions. In practice, however, as with the dispensing of all medications, community pharmacists have a responsibility to exercise their professional judgement in deciding whether or not to dispense a prescription. Before deciding not to dispense a prescription, the pharmacist should take all the necessary steps to inform his/her decision such as consulting with the prescriber and the patient. If he/she is not satisfied that it is in the best interests of the patient to dispense a particular medication, then it would appear that they have a professional duty not to do so. Such a decision must be made in the full knowledge that they may be held accountable for any consequences that might arise from such an action (Lynch 2002). This study indicated that many Irish community pharmacists (37%) had used their discretion and withheld methadone doses, where necessary to act in their patients' best interest and protect them from the risk of opiate overdose. Clarification of the role of the community pharmacist in these instances could help to protect pharmacists from a legal perspective. It could also standardise procedures, ultimately reducing conflict between community pharmacists and their patients.

Refusing to dispense methadone was positively related to the provision of on-site supervision and to the length of time respondents had dispensed methadone 1mg/ml, which suggests that experience was an important factor in pharmacists refusals. It may also indicate that those who supervised doses were more likely to refuse to administer them, in cases where they suspected prior intoxication. These findings all point to a cohort of community pharmacists who were fully participating in the treatment of their patients, and were willing and able to withhold a methadone dose in cases where their patients welfare may have been at risk. The lack of an association between respondents' gender and their refusal of a methadone dose shows that female pharmacists were not less likely to confront a patient than their male colleagues, which suggests that female pharmacists felt equally capable of managing conflict within the community pharmacy setting.

Responses to this survey suggested that the liaison pharmacist had had some success in providing the support that was offered to the community pharmacists in Survey 1 (see Chapter 3) particularly in the limitation of the numbers of patients allocated to individual pharmacies. Respondents also saw the role of the liaison pharmacist having two aspects: responsibility for co-ordinating pharmaceutical services under the MPS and the facilitation of methadone prescriber/methadone dispenser relations. As discussed elsewhere (see Chapter 7), it is important that both of these aspects continue to be recognised as the role of the liaison pharmacist evolves and develops.

Specialist training was the service the least number of EHB pharmacists reported receiving from the liaison pharmacists, despite the fact that three evening training sessions were organised by the liaison pharmacists for those EHB community pharmacists during the previous twelve-month period, in preparation for the introduction of the MPS. The majority of respondents reported that they had not had specialist training in the management of drug misusers although it was included in the undergraduate training of all Irish-educated pharmacy graduates. This shortfall should be addressed immediately as the value of training in influencing pharmacists' attitudes has been reported in Scotland (Matheson et al 1999b). Analysis of respondents' qualitative comments suggested various topics of interest, which should be useful for

liaison pharmacists and professional training bodies associated with the continuing education of community pharmacists.

Reports of problems with patients on methadone were similar in frequency to the incidence of service discontinuation due to undesirable incidents seen in Scotland in 1995 (Matheson et al 1999b) although no data were available here on whether these problems had resulted in the discontinuation of patients' treatment. Reports of adequate support in the majority of cases may have helped to reduce the incidence of service discontinuation, although qualitative comments suggested that in many instances the transfer of the patient to an alternative dispensing service due to inappropriate behaviour was the desired support service. Given that statistical analysis showed that the absence of adequate external support in times of crisis was an important factor in determination of pharmacists' attitudes, every effort should be made to facilitate community pharmacists with the problems they encounter in managing patients in the MPS.

Community pharmacists who stated here that they received inadequate support to manage their problems appeared to have primarily depended on methadone prescribers and the Gardaí. These relationships need to be clarified so that pharmacists are familiar with the role of each member of the drug treatment team, and perceived shortfalls in support systems can be avoided. The qualitative feedback on pharmacists' support systems suggested that many community pharmacists had developed their own mechanisms for managing problem patients, possibly by introducing pharmacy/patient contracts. It is important that these contracts continue to provide an outline of service provision as well as a code of conduct for patients. But their use as a tool to ensure unquestioning compliance and total control over patients could undermine patients' rights and should not be encouraged.

Some pharmacists reported feeling physically vulnerable when working with patients on methadone, although feelings of physical vulnerability were much less common here than among respondents to one London study (Sheridan & Barber 1997). Others reported that their patients on methadone were worse than other customers for stealing from their pharmacies, yet they continued to dispense methadone for them. Respondents' qualitative comments also described situations where pharmacists continued to dispense methadone despite considerable personal fears and concerns. It

is questionable whether patients who behaved in this manner should have been considered suitable for community-based methadone dispensing services at all. However, in cases where they were considered suitable, community pharmacists clearly needed much support and back-up in managing their care. This juxtaposition of positive professional involvement and negative personal attitudes has been associated with the stigmatisation of opiate misusers in methadone treatment (Sheridan & Barber 1997), which has been linked to subsequent negative behaviour (Matheson 1998c). This describes a situation where community pharmacists' negative attitudes inadvertently resulted in negative behaviour among their patients, and efforts should be made to address this issue with both service users and service providers.

One could have anticipated a fall in the overall incidence of pharmacist initiated contacts with methadone prescribers following the full introduction of the MPS. But this survey showed that prescription inaccuracies and illegibility were continuing to cause problems six months after its introduction, and pharmacists still reported concerns regarding prescribed methadone doses.

Prescription-related problems can cause delay for patients resulting in conflict in community pharmacies and, if not noticed, they can result in dangerous or inaccurate treatment. The methadone prescription form was designed specifically to simplify prescribing by providing a template that complies with controlled drugs legislation while minimising the hand-writing requirements for the prescriber. If this prescription form continues to give rise to frequent problems it should be reviewed and revised. If, on the other hand, prescriber errors or inaccuracies are the cause of these problems, GP training should address these issues and ensure that prescribers are able to use the form and recognise the legal and practical implications if it is not completed correctly.

Pharmacists' concerns regarding methadone dosages may illustrate a lack of knowledge on their part regarding methadone's therapeutic dose range or dose changes, or these concerns may highlight problems where prescribers deviated from standard dosage norms. Alternatively, they may illustrate a routine double-check system practised in many primary care teams, where the dispensing pharmacist contacts the prescriber to confirm dose changes in all instances where there is a possibility that prescriptions may

have been altered by patients. The data did not clarify the nature of pharmacists' dosage concerns and further research is necessary to investigate it fully.

Although the majority of respondents said they could easily contact methadone prescribers, qualitative feedback on these issues suggested that pharmacists continued to have problems contacting them. Many methadone prescribers do not work fulltime in the field and as the MPS insists that each patient has only one prescriber this can cause difficulties for pharmacists. An inability to contact methadone prescribers may have reduced the extent of pharmacists' input and feedback into community-based drug treatment teams, and may have had a detrimental effect on overall patient care. The issue of prescriber contactability needs to be addressed, with the possibility of the introduction of an on-call service to cover prescribers who cannot be reached.

The high proportion of respondents who said that they would contact the prescriber if they withheld a methadone dose or if their patients presented prescriptions from other doctors for psychoactive medication suggested that these community pharmacists considered themselves members of a community-based drug treatment team, so that their actions were within the confines of patient confidentiality. Alternatively, they may have believed that in these situations they were justified in breaching confidentiality, in the best interest of their patients.

The low percentage of respondents who believed they would be informed if patients used drugs not prescribed by their methadone prescribers suggested that they believed others on the community-based drug treatment team did not regard them as colleagues. While there are confidentiality issues involved here, there are also safety issues, particularly for pharmacists who provided on-site supervised doses. This lack of feedback may have a damaging effect on patient care, pharmacists' self-esteem and on the cohesion of the drug treatment team as a whole, and it raises the risk of accidental overdose. Respondents outlined several justifiable clinical reasons why they require this information, particularly if they supervised methadone consumption at their pharmacies. This issue should be addressed with methadone prescribers at policy level to ensure that pharmacists provide ultimately safe services for their patients.

Respondents to this survey advocated their involvement as equals in the determination and delivery of methadone treatment programmes for their patients. The Pharmacy Guild of Australia has recommended that community pharmacists be involved in case discussions regarding individual patients, particularly during the initiation and stabilisation stages of treatment (Pharmacy Guild of Australia 2000). Policy guidelines on this matter could help to direct community pharmacists towards best practice in this area.

Pharmacists commenced methadone dispensing for a variety of reasons, although the recruitment of pharmacists who had never dispensed Physeptone® was primarily due to the liaison pharmacist. This was an indication of the impact of the liaison pharmacist on the expansion of community pharmacist involvement in methadone dispensing in Ireland immediately prior to and the months following the introduction of the MPS. It also showed the value of prescriber/pharmacist relations in the recruitment of pharmacists to methadone dispensing, as well as the merits of direct patient requests.

Data on the factors that motivated respondents to commence and continue methadone dispensing indicated that respondents believed that pharmacists had a professional responsibility to provide methadone treatment. A similar finding was reported among Scottish pharmacists (85% of Irish respondents held this view compared to 75% of the Scottish community pharmacists as reported by Matheson and colleagues in 1999b). Respondents were also very aware of service users' entitlement to care and that the services they provided were necessary for their local communities. But as described earlier, respondents may have been subject to conflicting professional and personal views regarding their involvement in the MPS, which may have affected the quality of the treatment services that they provided for opiate misusers (Sheridan & Barber 1997).

The pressure on primary carers to provide methadone treatment despite personal reluctance has also been reported in Denmark where many GPs do so out of obligation to their patients and in response to inadequate statutory services (EMCDDA 2000b). External support and encouragement may help them to overcome their personal reservations, but it is difficult to hide fundamental beliefs. Patients in methadone treatment in the UK reported self-selecting their pharmacies on the basis of the attitudes of staff (Roberts 1992) and Irish community pharmacists who were reluctant participants

in the MPS may have had difficulty engaging and interacting with the patients allocated to their care, resulting in poor quality services for those affected. Addressing negative attitudes through training could enhance this process of service delivery (Sheridan et al 1997, Caplehorn et al 1998a, Matheson et al 1999b) and improve retention rates for patients (Caplehorn et al 1998b). Irish undergraduate training includes information on the drugs of abuse and input from pharmacists such as myself who have specialised in the area of Addiction Pharmacy. The final year course also includes a student visit to the National Drug Treatment Centre, where students meet patients and have a first hand experience of a tertiary drug treatment service, and may enhance pharmacy students' understanding of patients in methadone treatment.

The analysis of respondents' views was limited by the absence of significant statistical correlations between the statements investigated. The questionnaire design should have aimed to explored one or two key attitudes, using multiple statements to examine each, but instead it looked at a wide range of separate issues, which were conceptually too diverse to allow in-depth analysis. Nevertheless, the inclusion of a diverse range of statements meant that the data gave some insight into a variety of different aspects of the management of patients on methadone treatment under the MPS from the community pharmacist's perspective.

The majority of those who responded to this study reported that they found it easy to manage their methadone patients, which suggested that the strict constraints enforced by the MPS had reduced the disruption caused by drug misusers and made methadone dispensing easier for community pharmacists. Respondents were also more likely than their Scottish equivalents to believe that community pharmacies were better than tertiary clinics for providing methadone dispensing services. Over two-thirds (67%) of those surveyed here held this view compared to one-third of Scottish respondents (Matheson et al 1999b). This was interesting given that there was greater community pharmacy participation in the provision of methadone treatment in Scotland and an absence of tertiary on-site dispensing services there compared to Ireland. This implied a confidence among Irish community pharmacists in their own ability to provide high quality community-based methadone dispensing services for drug misusers, which may have been due to their undergraduate training in the management of drug misusers. On the other hand, it may have shown an element of disdain among Irish pharmacists towards

Irish tertiary drug services. A more balanced outlook that acknowledged the limitations of community-based methadone dispensing services and the symbiotic relationship between the primary and tertiary care settings may have indicated a better informed, more considered view of the situation in Ireland at that time.

Statistical analysis of the attitudinal data produced two attitudinal features among responding pharmacists: a "confidence" in their ability to manage patients on methadone in the community pharmacy setting and a need to "control" their methadone patients. "Confidence" was associated with pharmacy-ownership and with longer-serving community pharmacists. Conversely, "confidence" was diminished among respondents who had experienced a shortfall in the provision of external support with local problems, and this finding highlights the need for a dedicated and responsive support mechanism for community pharmacists who participate in the MPS. "Controlling" attitudes were also associated with longer-serving community pharmacists and with the provision of on-site supervision. Conversely, "controlling" attitudes were reduced as patient numbers rose, which suggested that pharmacists with higher patient numbers were more trusting of their patients in methadone treatment and/or less concerned about the diversion potential of methadone.

These attitudes may result in healthy pharmacist/patient relationships and professional standards of care for those in treatment under the MPS, as pharmacists confidently managed their patients, while also recognising the need to maintain professional boundaries and ensure the safe dispensing and administration of methadone. Such attitudes should be encouraged, although feedback from service users involved in the qualitative study undertaken as part of this research (see Chapter 9) also highlights the need for more balance in pharmacist/patient power relations.

The consistency in the attitudes held by pharmacists who dispensed methadone in August 1998 (N=99) and March 1999 (N=172) suggests that these views were not affected by the introduction of the MPS. It was not clear from these surveys whether these views were particular to those pharmacists who dispensed methadone 1mg/ml or if they were also held by Irish community pharmacists who did not dispense methadone. Research using a non-dispensing control group could be useful in exploring the factors at play in this situation.

# CHAPTER 6: Longitudinal Analysis of Pharmacy Surveys

A longitudinal analysis of community pharmacy involvement in the provision of methadone dispensing services in the two south sectors of the EHB region from February 1998 to March 1999.

Date	Stage in MPS	Study title	Participants	No. respondents	Location
February 1998	Pilot (MPP) underway	Pharmacy Survey 1	All community pharmacists	201	Southern sectors of the EHB region
August 1998	Interim phase in introduction of MPS	Pharmacy Survey 2	Community pharmacists who dispensed methadone 1mg/ml	99	Nation-wide
March 1999	MPS established	Pharmacy Survey 3	Community pharmacists who dispensed methadone 1mg/ml	153	Nation-wide
after March 1999	MPS established	Longitudinal Study	Community pharmacists who responded to more than one of the above surveys	Varied, as specified in text	Southern sectors of the EHB region
June 1998 to May 1999	Pilot (MPP) & MPS	Liaison Queries	All enquiries received by the liaison pharmacist	848 enquiries	Southern sectors of the EHB region (primarily)
March 1999	MPS established	Patients' Views	Patients in methadone treatment	217	Nation-wide
February 2001	MPS established	Qualitative interviews	Drug misusers, ex- drug misusers, patients in methadone treatment, service providers	15	Three non- prescribing support services

## 6.1. INTRODUCTION

In the 14-month period following February 1998 the delivery of methadone treatment in Ireland changed considerably with the introduction of the MPS. Data available from three surveys of community pharmacies (as outlined earlier in Chapters 3, 4 & 5) presented a way of examining how these changes at national level affected the pharmaceutical services for patients in methadone treatment during that time. These self-completed postal surveys investigated the dispensing services community pharmacists provided for methadone patients. They also examined communication and support between community pharmacists and other members of the community-based drug treatment team as well as aspects of the relationship between community pharmacists and their patients on methadone.

A longitudinal analysis of the findings from these surveys would be useful in illustrating the evolving role of Irish community pharmacists in the provision of methadone treatment during the study period. It would also be used to investigate the net effects of the introduction of the MPS for both community pharmacists and their patients. An interrupted time series study of community pharmacies involved in all three surveys could illustrate specific changes in a subsample of Irish community pharmacies in the course of this 14-month study period. In addition, findings from this study could provide useful guidance for service policy and development and generate ideas for future research in this area.

## Aims

- (1) To establish how the introduction of the MPS on 1 October 1998 affected Irish community pharmacists' involvement in the provision of methadone dispensing services in the southern sectors of the E.H.B. region.
- (2) To investigate how the MPS affected dispensing practice in a sample of community pharmacies surveyed before and after the introduction of the MPS.

#### **Objectives**

(1) To investigate changes in the extent of community pharmacist involvement in the provision of methadone dispensing services between February 1998 and March 1999.

- (2) To look for overall changes in methadone dispensing activity in community pharmacies in the southern sectors of the E.H.B. region following the introduction of the MPS.
- (3) To look at changes in the standards of care provided for patients being dispensed methadone at these community pharmacies.
- (4) To examine the extent of communication between methadone prescribers and community pharmacists.
- (5) To look at the impact of the liaison pharmacist as a source of support and back-up for community pharmacists who dispense methadone.

#### 6.2. METHOD

## 6.2.1. Instrument

The three questionnaires used were designed and piloted under the conditions described previously (see Chapters 3, 4 & 5). Many variables differed from one survey to the next, but variables that were found in more than one survey were identified and analysed, even where the wording used may have varied marginally in the different survey instruments. This was done only where the fundamental meaning of these variables was retained despite variation in the wording. However, where not identical, all versions of the wording used are given in the text for cross-reference purposes. These variables were analysed in the following categories: (a) included in all three surveys, (b) included in Surveys 2 and 3 and (c) included in Surveys 1 and 3.

As well as investigating changes in methadone dispensing activity over the study period and trends in the provision of supervised dosing, this analysis looks at aspects of how methadone doses were dispensed to take home, the use of pharmacy/patient contracts, contact with methadone prescribers and the support services provided by the E.H.B. liaison pharmacists.

## 6.2.2. Samples & Analyses

Details of the survey samples and the variables analysed are given in Tables 6.1 & 6.2. Respondents were allocated an individual code at the outset of Survey 1, which they

retained throughout the three surveys. This facilitated the identification of those who responded to multiple surveys.

Aspects of pharmacy involvement in the dispensing of methadone 1mg/ml were compared as a whole under the Methadone Pilot Project in August 1998 and under the Methadone Protocol Scheme in March 1999 by comparing overall findings from Surveys 2 and 3 (see details in Chapter 5). However, paired data from pharmacies that participated in both Survey 2 and Survey 3 were examined to investigate changes in dispensing practice in this particular group of pharmacies during the study period, and this analysis is carried out below.

The pharmacists included in this analysis represent a highly compliant group, since they were all service providers and all completed questionnaires at six monthly intervals over an 18 month period. This means that their views were likely to be more positive than those of the overall population, so that these findings may not be generalisable. In addition, there were eighteen non-responding methadone dispensers (18/67, 26.9%), who may have had a different perspective and may have been involved in methadone dispensing to a different extent, and their inclusion in the survey would have made the findings more reliable (Sheridan & Strang 1998). Nevertheless, analysis of the data from participants has value due to the longitudinal aspect of this work (Litwin 1995).

Data were compared and analysed using parametric and non-parametric statistical testing methods.

Table 6.1: Analysis samples used in longitudinal study of pharmacy surveys

	Survey 1	Survey 2	Survey 3
Time survey undertaken	February 1998	August 1998	March 1999
Geographical area surveyed	Southern sectors of the E.H.B. region	Nation-wide	Nation-wide
Timing with reference to the MPS	MPP in progress	Interim stage of the introduction of the MPS	MPS in place for 6 months
Target sample	All community pharmacies (N=264)	Community pharmacies in the MPP (N=99)	Community pharmacies in the MPS (N=172)
Response rate within the southern sectors of the E.H.B. region	76%* (201/264)	84%** (56/67)	88% (90/102)

<sup>\* 29% (59/201)</sup> of respondents were dispensing Physeptone®, methadone 1mg/ml or both.

Table 6.2: Variables analysed in longitudinal study of pharmacy surveys

Surveys 1, 2 & 3	Demographic and geographical characteristics of respondents.
	Changes in participation in methadone dispensing over the study period.
	Methadone dispensing activity levels.
	The provision of on-site supervision.
Surveys 2 & 3	How "take-home" methadone doses were dispensed.
Surveys 1 & 3	Incidence of once weekly methadone dispensing.
	Use of pharmacy/patient contracts.
	The role of the liaison pharmacist.

# 6.2.3. Reliability & Validity

Due to the longitudinal aspects of the overall research design test re-testing methods were not employed in these pharmacy surveys to avoid responder fatigue. Instead an external comparator was used to triangulate individual survey findings and assess reliability and comparative data are reported in each chapter as relevant (Healy 1998, see also Chapter 8).

<sup>\*\*</sup> Only pharmacies in the MPS were surveyed, although others may have been dispensing Physeptone®.

Longitudinal analyses, by their very nature, have value in strengthening the validity of the individual study findings. By including all of the pharmacies involved in the MPS in the target area, many of the threats to internal validity were eliminated and longitudinal analyses of these studies will also have improved their individual internal validity. The risks associated with selective non-response among non-compliant community pharmacists were low due to the generally high response rate.

Since many of those surveyed were involved in the MPP and had dispensed methadone 1mg/ml prior to the introduction of the MPS, it cannot be stated conclusively that its introduction caused the effects reported in this study. However, given that it was the only fundamental regulatory change to affect methadone prescribing and dispensing practices in the course of the study period, it can be assumed to have had a significant impact on those involved at that time.

#### 6.3. RESULTS

# 6.3.1. Surveys 1, 2 & 3

#### 6.3.1.1. Demographics

The high response rates to the individual surveys produced a sample of 49 pharmacies for inclusion in this analysis, which represented 73.1% (49/67) of the total possible sample. In each survey, approximately 60% of respondents were the owners of the pharmacies concerned (Survey 1: 67.3%, 33/49; Survey 2: 65.3%, 32/49; Survey 3: 59.2%, 29/49, data were missing on two cases in Survey 3). All of the pharmacies surveyed were in the two southern sectors of the E.H.B. region. Only 8.2% (4/49) of them in Wicklow, the remainder were in Dublin. The majority of those surveyed were located in small groups of local shops (44.9%, 22/49), 34.7% (17/49) were on main shopping streets while 18.4% (9/49) were in shopping centres and one (2.0%) was located in a rural area.

Survey 1 found the provision of methadone treatment services in 85.7% (42/49) of the respondents in this longitudinal study. See Table 6.3 for details of the dispensing status of each participating pharmacy at each survey time point.

Table 6.3: Methadone dispensing status by survey time point

	Survey 1 (%)	Survey 2 (%)	Survey 3 (%)
Methadone 1mg/ml only	13 (26.5)	24 (49.0)	49 (100)
Physeptone® only	9 (18.4)	0	0
Both formulations	21 (42.9)	25 (51.0)	0
None	6 (12.2)	0	0

The reasons the respondents who had commenced methadone dispensing between Surveys 1 and 2 gave for not dispensing methadone when surveyed in February 1998 are listed in Table 6.4.

Table 6.4: Reasons why the six respondents whose pharmacies joined the MPP between February and August 1998 gave for not dispensing methadone in February 1998 (P = pharmacy)

	P1	P2	P3	P4	P5	P6
No request for such a service.	+	+		+	+	+
Security reasons – risk to staff, fear of robbery/hold-up etc.	+		+			
Pharmacy staff feels uncomfortable dealing with drug misusers.		+	+			
Business reasons – other customers may object, shoplifting etc.			+			
Concerns relating to inappropriate prescribing.		+	+			
Pharmacy would be isolated as the only one in the area providing such a service	).	+				
Local opposition to the provision of services for drug misusers.			+			
No support from E.H.B.	+					

## 6.3.1.2. Activity

Details of the numbers of patients attending these community pharmacies at the three survey points are given in Table 6.5. The total number increased between February and August 1998 while the number of pharmacies involved in methadone dispensing also rose. However, with the full introduction of the MPS the overall number of patients being dispensed methadone at these community pharmacies fell by over 12% (109/897). The introduction of the MPS resulted in a fall in the mean and an increase in the median number of patients per community pharmacy in the sample surveyed.

Table 6.5: Patient numbers at each of the three pharmacy survey time points (N=49)

	Sum	Mean	SD	Range	Median
Survey 1	809	16.51	35.67	0 – 190	3
Survey 2	897	18.31	31.43	1 – 175	5
Survey 3	788	16.08	30.08	1 – 195	7

A one-way correlated analysis of variance showed no significant difference in patient numbers at the three survey points ( $F_{1,48}$ =0.03, p=0.86). None of the patient numbers differed from one another with related t-tests when a Bonferroni adjustment was made for the number of comparisons made.

When pharmacies where Physeptone® was dispensed when Survey 1 was carried out were examined by Survey 2, there had been a statistically significant fall in the mean number of patients on Physeptone® per dispensing pharmacy (see Table 6.6.), which was indicative of the shift towards the use of methadone 1mg/ml in anticipation of the introduction of the MPS (t=2.28, df=29, p=0.03).

Table 6.6.: Physeptone® dispensing activity in February & August 1998 (in pharmacies where Physeptone® was being dispensed in February 1998, N=30)

	Sum	Mean	SD	Range	Median
Survey 1	560	18.67	32.15	1 – 127	3.5
Survey 2	252	8.4	15.04	0 - 68	1.5

## 6.3.1.3. Supervision

The proportion and number of pharmacies currently providing on-site supervised dosing increased significantly between February 1998 and August 1998 and again between then and March 1999 (see details in Table 6.7.).

Table 6.7.: Extent of, and increases in the provision of an on-site supervised self-administration service for patients in the MPS

	Supervising (%)	Not supervising (%)	N	$\chi^2$	df	р
Survey 1 (MV=1)	11 (25.6)	31 (72.1)	43*			
Survey 2	18 (36.7)	31 (63.3)	49	19.78	1	<0.01
Survey 3	28 (57.1)	21 (42.9)	49	16.17	1	<0.01

<sup>\*</sup> Six pharmacies that had no patients on methadone were excluded from this analysis.

Despite their expressions of interest, half of the respondents (7/14) who said they were willing to supervise methadone doses in Survey 1 did not report doing so in Survey 3, while 33.3% (5/15) of the respondents who said that they were not willing to supervise in Survey 1 reported supervising methadone doses in Survey 3.

As shown in Table 6.8., the total number of patients drinking methadone on-site in this sample of community pharmacies more than tripled during the study period and the mean number per pharmacy also increased almost threefold.

Table 6.8.: No. patients drinking methadone under supervision at each pharmacy survey time point (N=48, MV=1)

	Sum	Mean	SD	Range	Median	t	df	p
Survey 1	85	2.02	6.17	0 – 30	0			
Survey 2	193	3.94	15.36	0 – 100	0	- 1.51	47	0.14
Survey 3	266	5.43	17.61	0-115	1	- 2.96	47	0.02*

<sup>\*</sup> with Bonferroni adjustment

A one-way correlated analysis of variance showed a significant difference in the number of patients being supervised at the three survey points ( $F_{1,47}$ =4.25, p=0.05). As shown in Table 6.8, subsequent related t-tests indicated that the statistically significant increase in patient numbers took place between Surveys 2 and 3.

# 6.3.2. Survey 2 & Survey 3

A subsample of 73 pharmacists responded to both surveys, which represented an 86.9% (73/84) response rate. As shown in Table 6.9. the supply of measures with multi-dose methadone containers (as opposed to <u>never</u> supplying them) and the use of plastic bottles when dispensing "take-home" methadone doses showed an overall increase following the introduction of the MPS. The number of respondents who reported <u>never</u> supplying methadone in containers with CRCs also fell significantly with the introduction of the MPS.

Table 6.9: Dispensed methadone doses, Surveys 2 & 3

Survey	Ever (%)	Never (%)	Missing cases	$\chi^2$	df	р
2	40 (54.8)	25 (34.2)	8	15.10	1	<0.01
3	63 (86.3)	7 (9.6)	3*			
2	30 (41.1)	39 (53.4)	4	6.76	1	<0.01
3	38 (52.1)	19 (26.0)	16			
2	54 (74.0)	15 (20.5)	4	5.04	1	<0.05
3	59 (80.8)	5 (6.8)	9			
	2 3 2 3 2	2 40 (54.8) 3 63 (86.3) 2 30 (41.1) 3 38 (52.1) 2 54 (74.0)	2 40 (54.8) 25 (34.2) 3 63 (86.3) 7 (9.6) 2 30 (41.1) 39 (53.4) 3 38 (52.1) 19 (26.0) 2 54 (74.0) 15 (20.5)	2 40 (54.8) 25 (34.2) 8 3 63 (86.3) 7 (9.6) 3* 2 30 (41.1) 39 (53.4) 4 3 38 (52.1) 19 (26.0) 16 2 54 (74.0) 15 (20.5) 4	2 40 (54.8) 25 (34.2) 8 15.10 3 63 (86.3) 7 (9.6) 3* 2 30 (41.1) 39 (53.4) 4 6.76 3 38 (52.1) 19 (26.0) 16 2 54 (74.0) 15 (20.5) 4 5.04	2 40 (54.8) 25 (34.2) 8 15.10 1 3 63 (86.3) 7 (9.6) 3* 2 30 (41.1) 39 (53.4) 4 6.76 1 3 38 (52.1) 19 (26.0) 16 2 54 (74.0) 15 (20.5) 4 5.04 1

<sup>\*</sup> none of these currently dispensed multi-dose containers

## 6.3.3. Survey 1 & Survey 3 (N=51)

## 6.3.3.1. Number of patients dispensed their methadone once weekly

The number of patients being dispensed their methadone on a once weekly basis did not change significantly in individual pharmacies between Surveys 1 and 3 (paired sample t-test: t=0.37, df=42, p=0.72). Full details of patient numbers are given in Table 6.10.

Table 6.10.: No. patients who collected their methadone on a once weekly basis

	Sum	% patients	Mean	SD	Range	Median	N
Survey 1	439	54.1	10.21	21.34	0 – 120	3	43*
Survey 3	463	58.4	9.08	14.35	0 - 80	3	51

<sup>\*</sup> Six pharmacies that had no patients on methadone were excluded from this analysis. MV=2

# 6.3.3.2. Pharmacy/patient Contracts

As shown in Table 6.11. the proportion of respondents that reported using pharmacy/patient contracts rose significantly between Surveys 1 and 3 ( $\chi^2$ =6.10, df=1, p=0.01).

Table 6.11.: The use of pharmacy/patient contracts

	Yes (%)	No (%)	N	Missing cases
Survey 1	7 (19.4)	26 (72.2)	36*	3
Survey 3	24 (47.1)	26 (51.0)	51	1

<sup>\*</sup> pharmacies that had no patients on Physeptone® were excluded from this analysis.

# 6.3.3.3. Support from the Liaison Pharmacists

Survey 1 asked respondents if certain services the liaison pharmacists could offer would support their involvement in the MPS or encourage them to get involved if they had not already done so. Following an analysis of the research findings the services that proved most popular in that survey were selected, and Survey 3 asked respondents whether the liaison pharmacists had actually provided them. Table 6.12. shows the initial interest in each service and the extent to which respondents reported it had been provided. Liaison pharmacists appeared to have been most successful in limiting the number of patients allocated to each dispensing pharmacy and in providing written pharmacy/patient contracts, while less than two-fifths of those surveyed said the liaison pharmacists had provided adequate training opportunities for community pharmacists.

Table 6.12.: Support services requested in Survey 1 and their provision by the liaison pharmacists as reported by respondents in Survey 3 (N=51)

		Yes (%)	Don't know*	No (%)	Missing cases
Provide procedures & guidelines	Survey 1	38 (74.5)		9 (17.6)	4
	Survey 3	25 (49.0)	12 (11.8)	10 (19.6)	4
Provide written pharmacy/patient	Survey 1	42 (82.4)		4 (7.8)	5
contracts	Survey 3	28 (54.9)	6 (5.9)	14 (27.5)	3
Organise training in the clinical	Survey 1	40 (78.4)		5 (9.8)	6
aspects of methadone **	Survey 3	20 (39.2)	12 (11.8)	17 (33.3)	2
Limit no. of patients per pharmacy	Survey 1	45 (88.2)		1 (2.0)	5
	Survey 3	35 (68.6)	8 (7.8)	6 (11.8)	2

<sup>\*</sup> this option was not given in Survey 1. \*\* Survey 3 just asked if "training" was provided.

#### 6.4. DISCUSSION

Longitudinal analysis of pre-existing survey data is of proven value in quantitative research (Oppenheim 1992). While the limited geographical area targeted by Survey 1 and the absence of data from community pharmacies not participating in the MPP meant that this longitudinal analysis could not be conclusive regarding all community pharmacy based methadone dispensers at this time, the findings elucidated here provide some insight into the changes in pharmaceutical practice during the study period.

There was a considerable rise in community pharmacy participation in the dispensing of methadone 1mg/ml in the course of the study period, with a number of pharmacists who were not providing methadone dispensing services prior to the introduction of the MPS being prepared to participate in it. This implies that the MPS facilitated a behavioural shift towards service provision by being adequately attractive to community pharmacists, and should be viewed as a positive outcome of its introduction.

The analyses also showed a reduction in the supply of Physeptone®, which was in line with the nation-wide preparations for the introduction of the MPS in October 1998, and illustrated the gradual, but systematic transfer of community-based patients to the 1mg/ml formulation over the preceding months. This was an indication of the cooperation of community pharmacists as they ensured continuity of patient care and facilitated their transfer to the 1mg/ml formulation, in line with national legislative and policy changes. Their help in carrying out this process should be acknowledged and commended.

This analysis showed a relatively stable mean number of patients per pharmacy in this subsample of pharmacies, which suggests that community pharmacies located within a geographical area may reach saturation point, beyond which they are unlikely to expand their treatment services to include additional patients. However, the rise in the median number of patients per pharmacy suggests that the introduction of the MPS resulted in a more even distribution of patients among participating community pharmacies within this locality. These findings indicate that if the MPS is to be able to continue to absorb additional patients into community pharmacy-based methadone dispensing services, more community pharmacists need to be recruited to the scheme. Initiatives such as the appointment of the liaison pharmacists and the provision of funding for pharmacy modifications should help to encourage additional community pharmacists to become involved.

Many respondents commenced the provision of on-site supervision services in the course of the study period, particularly following the introduction of the MPS, which probably reflected the emphasis placed by the MPS on the value of supervised consumption. Assuming that the value of on-site supervision is accepted within the framework of the MPS, the high proportion of respondents who had not commenced providing supervision despite expressing an interest in doing so in earlier surveys illustrates an anomaly in self-report also reported by Backett (1989 & 1992), where participants self-reported views contradict their behaviour. In this instance, while respondents supported the theoretical ideal of on-site supervision, they experienced more difficulty with its ultimate delivery. Considering the high level of support for supervision expressed by this cohort of community pharmacists, MPS organisers, particularly the E.H.B. liaison pharmacists, should maximise their involvement. This

should be done by ensuring methadone prescribers are aware that many additional community pharmacists are prepared to offer on-site supervision, and by offering community pharmacists the support and encouragement necessary for them to translate their positive attitudes into active service provision.

As described earlier, the Pharmaceutical Society of Ireland's *Policy on Drug Abuse* (1996) gave general guidance for community pharmacists who provided methadone treatment services in Ireland. These guidelines were used in examining current practice among pharmacies involved in this longitudinal study. This analysis found that many pharmacists continued to resist the use of plastic bottles when dispensing "take-home" methadone doses. Plastic bottles reduce the risk of breakages, thereby avoiding potential conflict between pharmacists and patients. The absence of stability data on methadone stored in plastic may have made pharmacists opt for glass. Stability testing on methadone stored in plastic should be carried out to improve patient care by ensuring that the potency of methadone is not compromised. If stability testing guaranteed equal potency, it could encourage more pharmacists to use plastic bottles.

Reports of the supply of pharmaceutical measures with every multi-dose methadone container were also low, although there was a fall in the number of respondents who said that they never supplied measures, following the introduction of the MPS. The provision of adequate pharmaceutical measures for patients dispensed multi-dose volumes of methadone should have reduced the need for patients to use babies' bottles when measuring their methadone, a practice that has been associated with child fatalities (Harkin et al 1999). There was also a significant improvement in the provision of child-resistant containers, which should have reduced the risks associated with the storage of methadone in the home.

After this study had been carried out the Pharmaceutical Society of Ireland published practice guidelines (McDermott 1999), to address all aspects of methadone administration and dispensing in Irish community pharmacies and thereby improve standards of care for those in methadone treatment in Ireland. These guidelines, coupled with specialist training should continue to positively influence pharmacists in this regard.

The introduction of the MPS did not reduce the extent of once weekly methadone dispensing. This suggested that in spite of an increased incidence of on-site supervision the volume of methadone dispensed into the wider community continued to be significant under the MPS, which could have safety implications for the community in general regarding accidental overdose in adults and children (Binchy et al 1994, Calman et al 1996, Cairns et al 1996, McCarthy 1997, Harkin et al 1999, Neale 2000).

The use of pharmacy/patient contracts increased significantly in the course of the study period. This may reflect more structure within community-based methadone dispensing services, with pharmacies offering higher and more consistent standards of care. Alternatively, it may reflect a more rigid or punitive attitude to the provision of methadone treatment services, as also described by service users in Chapter 9. While these contracts can help pharmacists to enforce practical limits on patients in methadone treatment and help patients to clarify the services that they can expect to receive, they need to be standardised so that patients are treated in a fair and equitable manner. The Pharmaceutical Society of Ireland has recently published a sample contract (McDermott 1999, see Appendix 1, p.24) which could be used in the majority of situations without undue difficulty.

Although training sessions had been provided for community pharmacists in the course of the study period, less than two-fifths of respondents were satisfied with the training initiatives organised by the liaison pharmacists. It has been suggested that specialist training can positively affect both healthcarers' attitudes and service provision (Sheridan et al 1997, Caplehorn et al 1998a, Matheson et al 1999b). Failure to provide adequate training could have serious immediate and long-term implications for service provision. This self-reported shortfall in respondents' satisfaction with the provision of training highlights the need for an assessment of what respondents want or need from training initiatives, and should be taken as an invitation to provide additional, more accessible training opportunities for community pharmacists. Such training could address many of the practical and attitudinal issues investigated by this survey, with a view to improving clinical practice and increasing overall participation in the MPS. Training with other disciplines, particularly methadone prescribers, could also be helpful in enhancing mutual understanding and establishing better communication channels.

Although these data were self-reported by service providers in one geographical area only, this analysis offers useful direction for service providers charged with planning and developing aspects of pharmaceutical services for opiate misusers in Ireland. It showed increased community pharmacy participation in methadone dispensing and in the provision of on-site supervision following the introduction of the MPS. The data suggest that individual community pharmacies were limited in the number of patients that they could accommodate, so that on-going recruitment is necessary to ensure adequate community-based methadone dispensing services continue to be available. This analysis also identified the safety of "take-home" methadone doses, the standardisation of pharmacy/patient contracts and the provision of specialist training for community pharmacists in the MPS as issues that need the immediate attention of service providers.

# **CHAPTER 7:** Liaison Queries

A study of 848 enquiries received by the EHB Addiction Service liaison pharmacist in the two south sectors of the EHB region June 1998 - May 1999.

Date	Stage in MPS	Study title	Participants	No. respondents	Location
February 1998	Pilot (MPP) underway	Pharmacy Survey 1	All community pharmacists	201	Southern sectors of the EHB region
August 1998	Interim phase in introduction of MPS	Pharmacy Survey 2	Community pharmacists who dispensed methadone 1mg/ml	99	Nation-wide
March 1999	MPS established	Pharmacy Survey 3	Community pharmacists who dispensed methadone 1mg/ml	153	Nation-wide
after March 1999	MPS established	Longitudinal Study	Community pharmacists who responded to more than one of the above surveys	Varied, as specified in text	Southern sectors of the EHB region
June 1998 to May 1999	Pilot (MPP) & MPS	Liaison Queries	All enquiries received by the liaison pharmacist	848 enquiries	Southern sectors of the EHB region (primarily)
March 1999	MPS established	Patients' Views	Patients in methadone treatment	217	Nation-wide
February 2001	MPS established	Qualitative interviews	Drug misusers, ex- drug misusers, patients in methadone treatment, service providers	15	Three non- prescribing support services

### 7.1. INTRODUCTION

From 1992 onwards the E.H.B. Addiction Service worked to expand its tertiary drug treatment services and by July 1999 it had one in-patient detoxification unit, 13 DTCs and 31 satellite services for opiate misusers (CDTL Statistics). In 1996, it undertook a parallel initiative to increase the extent to which primary healthcarers (namely GPs and community pharmacists) were involved in the provision of methadone treatment for opiate misusers. This was done by commencing the Methadone Pilot Project (MPP) and with the subsequent introduction of the MPS in October 1998.

In 1997 the E.H.B.'s Addiction Service recruited two liaison pharmacists to facilitate patient transfers from tertiary to community-based methadone dispensing services and to support the community pharmacists who provided pharmaceutical services for opiate misusers. One liaison pharmacist was responsible for the two southern sectors of the E.H.B. region. There were a total of 1,686 patients registered with the MPS in these sectors in November 1998. Over one-third of these (35.5%, 598/1,684) were attending drug treatment centre pharmacies while the remaining 1,088 (64.5%) were registered to receive methadone at community pharmacies. Of those registered with community pharmacies, 57.1% (621/1,088) were attending GPs in their own surgeries (CDTL Statistics).

Chapters 3 to 6 of this research describe findings from the three self-completed postal surveys that were carried out among community pharmacists from February 1998 and March 1999 and provide quantitative information on pharmaceutical services for those in community pharmacy based methadone treatment during that time. These self-completed postal surveys also asked respondents to report on their relationships with the liaison pharmacists, and to evaluate the pharmacy liaison service's success in providing key support services for them. Some qualitative data were derived from these surveys, but the findings were primarily quantitative in nature.

A survey of community pharmacists in Northern Ireland has indicated that the absence of structured support services poses a barrier to the provision of services for drug misusers there (Fleming et al 2001). This study aimed to investigate the role of the liaison pharmacist in supporting community pharmacists and in facilitating the provision

of community pharmacy based methadone treatment services by examining the enquiries addressed by the liaison service. Findings from this study could provide useful insight into the needs of community pharmacists and the role of specialist support services in meeting these needs. It could also elucidate aspects of how the Irish community pharmacist functioned within the structures of the MPS.

This study was carried out by the liaison pharmacist within the southern sectors of the E.H.B. region and examined the characteristics of a sample of 848 consecutive liaison enquiries received by the liaison pharmacist between June 1998 and May 1999. The study period encompassed the five months immediately prior to the full implementation of the MPS and the first eight months following its introduction.

Results from this piece of work have been published in the peer reviewed International Journal of Pharmacy Practice (see Appendix 1, p.25-30).

## Aims:

- (1) To identify the primary reasons why community pharmacists working with the MPS contacted the E.H.B.'s pharmacy liaison service.
- (2) To investigate the role of the liaison pharmacist in facilitating community pharmacist involvement in the provision of methadone treatment for drug misusers.

## Objectives:

- (1) To identify the primary users of the pharmacy liaison service.
- (2) To look at how service users contacted the pharmacy liaison service.
- (3) To investigate the nature of the enquiries addressed to the liaison pharmacist.
- (4) To examine the pharmacy liaison service's ability to address and answer the enquiries received.

#### 7.2. METHOD

This non-invasive study was a retrospective investigation of the enquiries received by the liaison pharmacist over a one-year period, almost two-thirds of which (161/248 days, 64.9%) was after the MPS had been introduced. Although the pharmacy liaison service

was not formally advertised, the liaison pharmacist contacted all the community pharmacists in south Dublin, Wicklow and Kildare when the service commenced in December 1997. Other pharmacists and members of other professions would have heard about the liaison service primarily through word-of-mouth.

#### 7.2.1. Instrument

In June 1998 a standard enquiry form was introduced for recording liaison enquiries that did not pertain to internal E.H.B. issues. Enquiry forms were stored in the liaison pharmacist's office and in one drug treatment centre pharmacy, where these external enquiries were referred if the liaison pharmacist was not contactable. The liaison pharmacist and drug treatment centre pharmacists completed the forms as enquiries were received. Basic demographic data on enquirers were recorded, along with the nature of their enquiry and/or aspects of the liaison services they required. The dates on which the enquiries were resolved were also recorded.

## 7.2.2. Sample

All of the enquiries addressed by the liaison pharmacy service during the research period from 6 June 1998 to 21 May 1999 that were recorded using the instrument described above were included in this analysis. The enquiries recorded were initiated by service users and so the study sample can be viewed as naturally occurring in both content and frequency.

While all of the enquiries received were included in the study, data derived from enquiries originating from community pharmacists underwent more detailed analysis.

The sample was chosen to gain insight into the situation at the time while minimising the disruption experienced by the healthcare professionals involved. Therefore, while it does give insight into the needs of liaison service users, the retrospective analysis of the enquiries received by the liaison pharmacy service in the course of a one-year period may not be the most accurate or reliable way of investigating the problems encountered by community pharmacists working with the MPS. In addition, had community pharmacists been made aware that a study of their needs was being undertaken or that the pharmacy liaison service was there primarily to support them, rather than to facilitate

patients' methadone treatment, the profile of the enquiries received could have been very different.

Nevertheless, this work provided valuable insight into the needs of those working with the MPS, particularly the community pharmacists involved, and highlights the difficulties they encountered in their day-to-day management of patients in methadone treatment.

#### 7.2.3. Pilot Work

A draft enquiry form was used for a three-month trial period from February to May 1998. The form's content and format were then reviewed and minor alterations were made, following discussions between the liaison pharmacist and other Addiction Service pharmacists. Once the revised enquiry form had been approved by the staff concerned it was introduced in June 1998 (see form in Appendix A.7.1.).

## 7.2.4. Statistical Analysis

Quantitative data derived from the survey were analysed using SPSS Version 9. Where a month and year was given, the median day of that month was used for time analysis purposes. In all other instances missing data were excluded from the analysis.

Qualitative details of the enquiries received were recorded with full idiographic interpretation. This meant that all of the known circumstantial details were also recorded e.g. the enquirer's attitude, the level of urgency of the enquiry, any steps already taken etc. (Robson 1993). Subsequent analysis of the qualitative aspects of the "pharmacy-related" enquiries was carried out by hand.

#### 7.2.5. Reliability

A study of the enquiries addressed by the pharmacy liaison service measured the frequency with which the pharmacy liaison service was used to facilitate the provision of community pharmacy based methadone dispensing services for drug misusers. It was also a reliable method of investigating aspects of pharmacy related questions and problems that arose for other practitioners working with the MPS at this time.

The fact that this study was carried out by the liaison pharmacist who provided this liaison service may have introduced researcher bias during the recording and

interpretative processes. Once recorded, the personal biases of the liaison pharmacist as a female, a pharmacist and an E.H.B. employee may also have played a part in the subsequent analysis of the study findings.

## 7.2.6. Validity

Community pharmacists generally work autonomously, making individual independent decisions. An analysis of the enquiries addressed to an external liaison service established and designed to facilitate their involvement in community-based methadone dispensing initiatives is of value in the identification and exploration of the issues which community pharmacists were unable to manage without seeking external help. The frequency and nature of the enquiries received regarding the facilitation of community pharmacy-based methadone treatment services for drug misusers were accurately recorded using the pharmacy liaison service's enquiry forms.

Methadone prescribers and community pharmacists were not obliged to use the pharmacy liaison service and some may have made their own arrangements for patients commencing methadone treatment. Therefore using enquiries addressed to the pharmacy liaison service during the study period may not provide complete information regarding the numbers of patients that were accepted into community pharmacies during that time, or accurately measure the extent of the problems experienced by the community pharmacists involved. A pharmacy liaison service was established simultaneously in the northern sector of the E.H.B. region. External factors in that sector were similar, but in the absence of data on the enquiries handled by the second liaison pharmacist it was not possible to generalise these findings to the whole E.H.B. region. In addition, these enquiries were received at a particular stage in the introduction of the MPS so it is unlikely that these findings could be replicated at another time. They reflected the situation only in the area and under the particular circumstances that were in place when they were generated, which further limits their generalisability.

## 7.2.7. Ethics & Confidentiality

Although the identity of the enquirers was recorded on the pharmacy liaison service enquiry forms, this information was subsequently excluded from the analytical process, as was information pertaining to individual patients and other healthcare professionals. Those using the liaison pharmacy service were not informed that the data recorded in

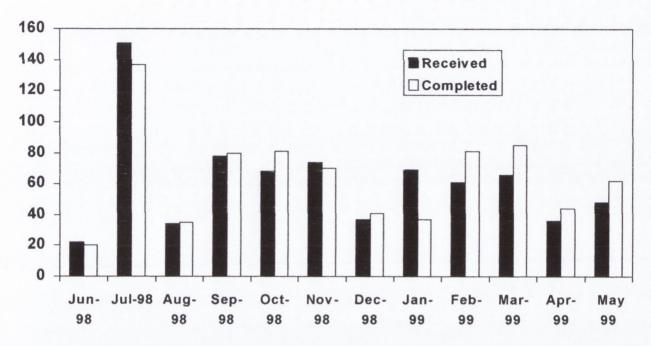
the course of their enquiry would be used for research purposes. But since the data were anonymised prior to analysis, ethical considerations did not require respondents to be informed or give their consent.

#### 7.3. RESULTS

# 7.3.1. Volume of Enquiries

Enquiries were received on more than three-quarters (187/248, 75.4%) of the working days during the study period. A mean of 62.0 enquiries (SD=33.44) were posed per calendar month (range 22-151), with the highest number recorded in July 1998 (N=151), which was when the preliminary or interim phase of the MPS commenced. A mean of 64.4 enquiries (SD=31.73) were answered per calendar month (range 20 - 137). The volume of enquiries handled over time was varied and unpredictable, and no pattern emerged (see Figure 1).

Figure 1: Number of queries received and completed by month of study



#### 7.3.2. Service Users

Over 30% of the enquiries recorded were from pharmacists (268/848, 31.6%) but more than half of them came from doctors (436/848, 51.4%), which was interesting given that they had not been notified of the establishment of the service. The remainder (144/848, 17.0%) of the enquiries recorded came from members of other disciplines. The occupations of the primary sources of enquiries are summarised in Table 7.1. Of the enquiries received from doctors, over ninety percent (393/436, 90.1%) were from doctors employed by the E.H.B.'s Addiction Service (the majority of whom were also GPs), while only 8.7% (38/436) were from GPs and other prescribers operating entirely outside the Addiction Service. Of the enquiries received from pharmacists, 96.6% (259/268) came from community pharmacists, the remaining 3.4% (9/268) from pharmacists working within the E.H.B. Addiction Service.

Table 7.1.: Occupation of the primary sources of enquiries

Occupation of Enquirer	No. enquiries (%)
Addiction Service doctor	393 (46.3)
GP/other prescriber	43 (5.1)
Addiction Service pharmacist	9 (1.1)
Community pharmacist	259 (30.5)
Addiction Service staff (non-doctor, non-pharmacist)	84 (9.9)
Drug Treatment List	45 (5.3)
Other	15 (1.8)

## 7.3.3. Communication methods

Over 70% (71.5%, 606/848) of the enquiries recorded were communicated to the liaison pharmacist by telephone while less than 20% (19.5%, 165/848) were delivered in person. A small minority of enquiries were sent by fax (4.6%, 39/848) and by post (4.5%, 38/848).

Almost all of the enquiries from pharmacists (98.9%, 265/268), more than half of those received from doctors (54.8%, 239/436) and 70.8% (102/144) of the enquiries from members of other disciplines were communicated to the liaison pharmacist by telephone. Only one of the enquiries from pharmacists was delivered in person (0.4%, 1/268), while 30.1% (131/436) of those from doctors and 22.9% (33/144) of those from other disciplines were delivered face-to-face. Of the faxed enquiries, 84.6% (33/39) were sent by doctors.

## 7.3.4. The nature of the enquiries

Enquiries were sorted into two primary categories as determined by whether the liaison service provided was for a patient ("patient related") or a pharmacist ("pharmacy-related"). More than two-thirds (578/848) of all the enquiries recorded were "patient-related" while less than one-third (270/848) were "pharmacy-related". Data on the numbers of enquiries received are given in Table 7.2.

"Patient-related" enquiries were divided into two categories:

- "new dispensing services" those involving the introduction of additional patients into community pharmacy based methadone treatment, and
- "transfers" those that were concerned with the relocation of patients currently in methadone treatment from one community pharmacy to another.

Table 7.2.: Nature of the liaison enquiries recorded (N=848)

Category		Number of queries received			
		N	% of enquiries in	% of all	
			category	enquiries	
Patient-related enquiries (N=578)	New dispensing service	408	70.6	48.1	
	Transfer	170	29.4	20.0	
Pharmacy-related enquiries (N=270)		270	100.0	31.9	

## 7.3.4.1. "Patient related" enquiries

"Patient related" enquiries usually required multiple interagency and interdisciplinary communications. For example, organising community pharmacy based methadone dispensing services for a new patient required contact with the prescriber for details of the methadone dose and dispensing regimen. This was followed by communication with the community pharmacists local to the patient, providing information on the MPS, and possibly a personal visit to the pharmacies. Once dispensing services had been arranged for the patient, the liaison pharmacist communicated the details to the prescriber and the CDTL, and contacted the nominated community pharmacist with the patient's anticipated start date.

Community pharmacy-based methadone dispensing services were organised by the liaison pharmacist for a total of 408 new patients or patients transferring from tertiary drug services to community pharmacies during the period studied. This represented 70% (408/578) of all the "patient-related" enquiries addressed during that time. Seventy two percent (295/408) of these services were organised in response to enquiries from prescribers. The data showed that 22.3% (91/408) of these new services were organised

prior to the introduction of the MPS on 1 October 1998, while the remaining 55.1% (225/408) were organised after its introduction (data were missing on 92 cases). In addition, 170 patients were transferred from one community pharmacy based methadone dispensing service to another during the period studied. The data showed that 54.1% (92/170) of these transfers were organised prior to the introduction of the MPS on 1 October 1998, while the remaining 44.1% (75/170) were carried out after its introduction (data were missing on three cases).

As the facilitation of "patient-related" enquiries was an anticipated role of the liaison pharmacist, and as the majority of the enquiries received were broadly similar, no further qualitative analysis was carried out on them.

## 7.3.4.2. "Pharmacy related" enquiries (see Table 7.3.)

'Pharmacy-related' enquiries were initially divided into four primary categories which were deduced using instinctive impressions gained from working in the field, as well as from the data derived from the quantitative surveys carried out among community pharmacists in the MPS.

As shown in Table 7.3., these four categories were:

- (1) Enquiries relating to problems with patients' treatment cards. These related to instances when patients presented in community pharmacies with valid methadone prescriptions prior to the issue of their methadone treatment cards.
- (2) Enquiries pertaining to problems with methadone prescriptions.
- (3) Requests for the deregistration of patients at community pharmacies due, for example, to unacceptable behaviour, violence or aggression.
- (4) Other pharmacy issues.

Table 7.3.: Initial categorisation of "pharmacy-related" liaison enquiries (N=270)

Enquiry Name	N	% of enquiries in	% of all liaison
		category	enquiries (N=848)
Treatment card problems	41	15.2	4.8
Prescription problems	31	11.5	3.7
Deregistration requests	10	3.7	1.2
Pharmacy issues	188	69.6	22.2

As retrospective analysis took place it transpired that almost 70% (188/270) of the "pharmacy-related" enquiries fell into the category of "other pharmacy issues" which led to a qualitative investigation of these enquiries. All of the enquiries were re-read and listed according to the pharmacy issue involved (see complete list in Appendix A.7.2.). Emergent themes were identified, which were used to group enquiries into the six categories shown in Table 7.4. They could be grouped again into three key roles for the liaison pharmacist: provider of information about drugs and pharmacy regulations, provider of information about drug services in Ireland and facilitator of interdisciplinary communication. Of these, the second role was the most commonly used, accounting for 17.1% (145/848) of all the enquiries recorded.

Table 7.4.: Details of "pharmacy issues" category of 'pharmacy-related' liaison enquiries (N = 188)

Liaison role	Issue	No. of enquiries (%'pharmacy-issues' enquiries, N=188)	% all 'pharmacy- related' enquiries (N=270)	% all enquiries (N=848)
Information on drugs & regulation	Drug information	4 (2.1)	1.5	0.5
	Legal information	9 (4.8)	3.3	1.1
Information on clinical issues and local policy	Clinical policy & procedural issues	45 (23.9)	16.7	5.3
	Information on MPS	80 (42.6)	29.6	9.4
	Aspects of the CDTL	20 (10.6)	7.4	2.4
Interdisciplinary liaison	Interdisciplinary liaison	30 (16.0)	11.1	3.5

Drug information enquiries included requests for information regarding alternatives to methadone in opiate withdrawal (lofexidine, naltrexone etc.). Legal enquiries included contact from a prescriber regarding the procedures necessary to ensure a patient could take his methadone abroad for use during his holidays.

Nearly half of the enquiries requested information about the MPS, including questions about how patients could be transferred from Physeptone® to methadone maintenance,

and questions regarding pharmacy payments. There were also enquiries about the provision of methadone for EU patients visiting or moving to Ireland. Almost one quarter (23.9%, 45/188) of the "pharmacy issues" enquiries related to the clinical policies and procedures required by the MPS, the majority of which related to requests for written information and guidelines. Other procedural enquiries related to the necessity to have treatment cards for patients who were prescribed methadone to manage pain and requests for clinical guidance when patients on methadone missed multiple days' doses. Several enquiries were received regarding the CDTL. Pharmacists were anxious about confidentiality issues, and also wondered what information they could access. One community pharmacist had a patient who worked in a company that produced identification cards similar to the methadone treatment cards, who contacted the liaison pharmacist to ask specific questions about how and where the cards were produced.

An example of interdisciplinary communication facilitated by the liaison pharmacist was the organisation of a drugs worker to accompany a patient to his pharmacy for supervised dosing, when the GP insisted on supervision and the community pharmacist was only prepared to provide this service if the patient was accompanied.

# 7.3.5. Speed of Response

Information was available on the speed of completion for 83.4% (707/848) of the enquiries received. This represented 78.9% (456/578) of the "patient related" enquiries recorded and 93% (251/270) of the "pharmacy-related" enquiries (see Table 7.5.). Of the enquiries where the response rate was known almost a third were answered on the day they were asked and a half of the enquiries studied were answered within two days.

Table 7.5.: Speed of Liaison pharmacist's response

	No. of "patient related"	No. of "pharmacy	Total (%)	Cumulative %
	enquiries (%)	related" enquiries (%)		
Same day	93 (20.4)	157 (62.6)	250 (35.4)	35.4
Next day	115 (25.2)	45 (17.9)	160 (22.6)	58.0
2 – 7 days	108 (23.7)	32 (12.7)	140 (19.8)	77.8
8 - 14 days	45 (9.9)	7 (2.8)	52 (7.4)	85.2
>14 days	95 (20.8)	10 (4.0)	105 (14.8)	100
Total	456	251	707	

## 7.4. DISCUSSION

This study was a useful measure of the extent and nature of the activities carried out by the liaison pharmacist in the two southern sectors of the E.H.B. region over a one-year period during which the MPS was introduced and within 18 months of the establishment of the liaison post.

This study indicates that the primary users of the liaison pharmacist service were Addiction Service prescribers and community pharmacists, with prescribers mainly using the service to request the organisation of community-based methadone dispensing services for their patients. This high demand from tertiary service prescribers could have been anticipated as their patients stabilised and needed to transfer to community pharmacies. But methadone prescribers were not formally notified that the liaison service had been established and it was not designed with their needs in mind. Given the high proportion of the enquiries recorded by this study that was generated by Addiction Service prescribers, it is worth considering their needs in future developments of the liaison pharmacy service.

The low number of enquiries received from Addiction Service pharmacists was indicative of the extent to which primary and tertiary methadone dispensing services function separately, with DTC pharmacists having little involvement in the transfer of patients to primary care. As specialists in the field of Addiction Pharmacy, these pharmacists represent a useful source of information and peer support to their community-based colleagues, which is currently being under-utilised. The potential value of their increased involvement in the transfer and subsequent care of patients stabilised in DTCs merits further exploration.

Research has suggested that active encouragement from local health boards, through the setting up of liaison pharmacist posts, may have a positive effect on pharmacist participation in drug misuse services (Matheson & Bond 1999). Other work has suggested that specialists in the field of drugs and alcohol treatment can provide a useful source of expertise to their generic colleagues (Happell & Taylor 1999) and has advocated greater communication with pharmacists in determining policies applied in the treatment of drug misusers (Peterson 1999). Both liaison pharmacists and DTC

pharmacists have roles to play in the provision of specialist support for their generic colleagues.

The telephone was by far the most popular method of communicating with the liaison pharmacist so it is essential that the liaison pharmacist remain easily contactable by telephone. This was particularly true for community pharmacists. Indeed only one enquiry from a community pharmacist was delivered in person, possibly highlighting their isolation from other members of the healthcare team. Personal visits to community pharmacies may be valuable in creating an informal forum for the dissemination of advice and information. The establishment of a website and email address could also be useful in increasing the accessibility of the liaison service for community pharmacists and other health professionals.

Apart from the exceptionally high number of enquiries received in July 1998, the number of enquiries handled by the liaison pharmacist was relatively constant over time. The volume of requests for new methadone dispensing services remained almost constant over the time period studied, while the number of inter-community pharmacy transfer requests fell following the introduction of the MPS. This showed that patients continued to move from drug treatment centres to community-based dispensing services throughout the study period, which was in accordance with the philosophy of the MPS, while those already placed in community pharmacies were less likely to require a change once the scheme was in place.

Judging from these data it seems likely that the organisation of community-based pharmaceutical services for patients on methadone will continue to be the primary facet of the liaison pharmacist's work. A significant fall in the number of enquiries could have been anticipated once the majority of patients were settled in treatment following the full introduction of the MPS in October 1998. However such a fall was not seen, suggesting that there was a continuing need for the liaison service, even after the MPS was in place for some time.

Analysis of the "pharmacy-related" enquiries received showed that community pharmacists who provided methadone for drug misusers had many and diverse needs. They frequently required expert information, some of which pertained to methadone

treatment *per se* and more which related to the MPS and the Irish drug treatment system itself. In addition, community pharmacists needed a simple way of communicating with tertiary drug services and methadone prescribers when problems or questions arose. Two-thirds of enquiries relating to pharmacy issues were from pharmacists, but significant volumes of these enquiries also came from members of other disciplines, including prescribers, which suggests that members of other disciplines needed more information about what community pharmacists did and how they operated within the MPS.

The analysis of these enquiries provided insight into the problems and needs of community pharmacists working in community-based methadone treatment services. More than a quarter of the enquiries received from community pharmacists related to problems at the prescriber/pharmacist interface i.e. problems with methadone prescriptions or treatment cards. In these instances community pharmacists were vulnerable legally if they decided to dispense the prescribed methadone, but they risked physical or verbal abuse from patients if they refused. Research has suggested that communication between community pharmacists and GPs is usually relatively commonplace (Hughes & McFerran 1996) and the importance of communication at this level for the provision of appropriate pharmaceutical services has also been reported (Cordina et al 1999). These data suggest that additional work is necessary to improve procedures and communication between prescribers and community pharmacists working with the MPS to reduce the incidence of these problems.

Community pharmacists requested that patients be deregistered or transferred to another methadone dispensing service only ten times in the course of the 1-year review period. This incidence was very low considering the frequency of problematic behaviour reported in community pharmacies elsewhere. For example, Smith and Weidner (1996a) reported that a member of the community pharmacy's staff had been threatened in the course of their work in 51% of responding pharmacies and 42% of respondents to one Scottish survey reported the withdrawal of individual patients' methadone dispensing services due to disruptive incidences (Matheson et al 1999b). It was also lower than that reported by community pharmacists in the northern sector of the E.H.B. region in a more recent Irish research study, where 53% of respondents had requested the deregistration of a patient in the MPS (Killen & Zayed 2001). This may indicate that community

pharmacists did not use the pharmacy liaison service to facilitate the discontinuation of patients' treatment in the early stages of the MPS. Alternatively, it may illustrate a more recent increase in the incidence of pharmacists refusing to continue methadone treatment, a trend indicative of reduced pharmacist tolerance or a malfunctioning MPS where inappropriate patients were being allocated to primary care, or where community pharmacists were not receiving adequate support in their management. This, and subsequent findings from Chapter 9 suggest that there is an urgent need for further exploration of this issue.

The speed with which the majority of enquiries were addressed by the liaison pharmacist should have encouraged service users to avail of the service again. In relation to "patient-related" enquiries, this was an indication of the co-operation and support given by community pharmacists, who quickly agreed to provide services for drug misusers when approached by the liaison pharmacist.

Analysis of the "pharmacy-related" enquiries provided insight into the relationship between community pharmacists and the liaison pharmacist, and the expectations of community pharmacists regarding the liaison pharmacy service. The liaison pharmacist post was established primarily to organise the transfer of patients from tertiary to primary methadone dispensing services. But a suitable balance between the provision of "patient-related" services and professional support must be achieved and maintained to ensure that community pharmacists continue to participate in the MPS.

In the wider context of services for drug misusers this shared care, multidisciplinary approach has been recommended in the UK and policy makers there have also noted the importance of communication and support for pharmacists and other healthcare professionals (Nuffield Report 1986, Sheridan et al 1997, Department of Health UK 1999). The quantity and diversity of enquiries received in the course of this study, and the diversity of professionals making those enquiries illustrated the various roles of the liaison pharmacist in facilitating communication and providing support to a variety of disciplines involved in the provision of methadone treatment for opiate misusers. As seen elsewhere (Hevey 1984), this suggests that additional liaison roles evolved over time in response to demands from service users. As community pharmacists' input into

the provision of addiction services continues to develop, these inductive roles may become even more important.

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# **CHAPTER 8:** Survey of Patients' Views

A quantitative investigation into the views of patients on their pharmaceutical services under the Methadone Protocol Scheme (MPS).

Date	Stage in MPS	Study title	Participants	No. respondents	Location
February 1998	Pilot (MPP) underway	Pharmacy Survey 1	All community pharmacists	201	Southern sectors of the EHB region
August 1998	Interim phase in introduction of MPS	Pharmacy Survey 2	Community pharmacists who dispensed methadone 1mg/ml	99	Nation-wide
March 1999	MPS established	Pharmacy Survey 3	Community pharmacists who dispensed methadone 1mg/ml	153	Nation-wide
after March 1999	MPS established	Longitudinal Study	Community pharmacists who responded to more than one of the above surveys	Varied, as specified in text	Southern sectors of the EHB region
June 1998 to May 1999	Pilot (MPP) & MPS	Liaison Queries	All enquiries received by the liaison pharmacist	848 enquiries	Southern sectors of the EHB region (primarily)
March 1999	MPS established	Patients' Views	Patients in methadone treatment	217	Nation-wide
February 2001	MPS established	Qualitative interviews	Drug misusers, ex- drug misusers, patients in methadone treatment, service providers	15	Three non- prescribing support services

#### 8.1. INTRODUCTION

Despite a thorough evaluation of the Methadone Pilot Project (MPP) which initiated radical changes in their treatment services, there was no formal consultation with patients or their representatives prior to its implementation nation-wide as the Methadone Protocol Scheme (MPS) on 1 October 1998. Instead, an Irish edition of *The Methadone Handbook* was published for the use of patients (Preston & O'Connor 1998) in July 1998, to explain the imminent changes and the Department of Health & Children produced a brief patient information leaflet which was distributed via general practitioners and community pharmacists in September 1998.

By the end of March 1999, six months after the MPS was introduced, three quantitative studies had been carried out with Irish community pharmacists to examine the nature and extent of their participation in the provision of methadone dispensing services. To coincide with last of these surveys, in March 1999, a survey was also undertaken to examine pharmaceutical aspects of methadone treatment under the MPS from the patients' perspective. No such survey had previously been undertaken among patients in methadone treatment in Ireland.

As discussed earlier (see Chapter 1), research acknowledges the value of patients' views in designing the delivery and content of their treatment services. Given that the introduction of the MPS resulted in substantial changes to methadone treatment and its delivery, it was important to investigate how the introduction of the MPS had impacted on service users and to examine the nature of their pharmaceutical services under the scheme. In addition, information reported here on the pharmaceutical services provided for patients in the MPS could be collated with findings from Survey 3 carried out simultaneously among community pharmacists, to give better insight into the situation at that time.

This study also examined the provision of methadone for patients who had children, as a contemporary publication emphasised the issue of child safety in homes where methadone was stored (Harkin et al 1999). A cut-off age of 14 years was chosen because earlier work looking at the familial influence of drug taking among Irish parents focussed on children of primary school age (Hogan 1996). Children in this age group

were perceived as more likely to be residing with a parent or parents, resulting in them having a greater impact on the lives of their parents and their ability to comply with the constraints of their methadone treatment programmes. In addition, research investigating drug use among adolescents has traditionally included those aged 14 years old and over (Measham et al 1998), which suggests that by that age children were more knowledgeable about drugs and familiar with their effects and abuse potential. The issue of drug misuse in adolescents was not of concern in this study, which aimed to investigate the exposure of children to methadone primarily from a safety perspective, and so concentrated on children aged under 14 years old.

Insight into the pharmaceutical services provided under the MPS, patients' views on these services and on their service providers, as well as information on the effects (if any) of parenthood on the services they received would be valuable in planning and developing better pharmaceutical services for patients in the MPS.

# Aims:

- (1) To investigate how the introduction of the MPS had affected those in methadone treatment in Ireland.
- (2) To examine the pharmaceutical services patients received under the MPS.
- (3) To establish patients' views and preferences regarding their methadone dispensing services.

## Objectives:

- (1) To establish how the introduction of the MPS had affected those in methadone treatment in Ireland prior to 1 October 1998.
- (2) To investigate patients' views on the MPS as a method of providing their methadone treatment.
- (3) To establish patients' views on the change from Physeptone® to methadone 1mg/ml which coincided with the introduction of the MPS.
- (4) To examine the pharmaceutical services being provided by patients under the MPS.
- (5) To investigate patients' views on their methadone dispensing sites (either community or drug treatment centre pharmacies).
- (6) To examine any service specific trends in the nature of pharmaceutical services being provided to patients under the MPS.

- (7) To identify gender-related trends where evident in the pharmaceutical services being provided to patients under the MPS.
- (8) To investigate how pharmaceutical services were affected by patients' parental status.
- (9) To examine patients' preferences regarding elements of their methadone dispensing services.

### 8.2. METHOD

As a cross-sectional study that employed standardised structured interviewing techniques (Oppenheim 1992), this research was designed to capture information about subjects' views and their pharmaceutical services at one specific time point. As discussed earlier (see Chapter 2), administered patient surveys which employ structured instruments have been shown to produce accurate medical information (Haynes et al 1980) and brief structured interviews using standard questionnaires with consecutive attenders can provide meaningful data on aspects of opiate treatment services (McLellan et al 1992, Tober et al 2000). Darke (1998) has described how self-report can be used as a reliable way of collecting data from drug misusers, a view supported by others working in the field of addiction (Bell 1998, Des Jarlais 1998, Finch & Strang 1998). There are problems associated with the use of retrospective data and researchers were advised of the need to cue participants memories as specifically as possible yet avoid cues which were so specific that they excluded relevant experiences (Shum & Rips 1999). These studies support the research methods employed here to investigate aspects of patients' pharmaceutical services under the MPS.

#### 8.2.1. Instrument

A structured questionnaire was designed for completion by a researcher in the course of private, one-to-one structured interviews with participants (see questionnaire in Appendix A.8.1.). It asked patients about their current pharmaceutical services – their methadone dispensing sites (either community pharmacies or DTC pharmacies), whether they consumed methadone under supervision of a pharmacist and their current attendance frequencies. It also asked patients to describe aspects of their ideal methadone dispensing service. Patients were asked how long it usually took them to

travel to collect their methadone and how long they had to wait for their methadone to be dispensed on arrival. The questionnaire also investigated details of how patients' "takehome" methadone doses were dispensed and whether the pharmacists had ever refused to dispense methadone to them. Participants were asked about the importance of the formulation of methadone they were dispensed and about any adverse effects they may have experienced while in methadone treatment.

Patients were also asked about their interactions with the pharmacists who dispensed their methadone and how the introduction of the MPS had affected them. Their attitudes to several key features of methadone treatment were recorded using a five point Likert Scale. However, constraints on the overall length of the questionnaire meant that only a few attitudinal statements were ultimately included in the survey, which ultimately reduced their value as a measure of internal consistency (Oppenheim 1992).

In order to examine the effect (if any) that having children aged under 14 years old had on the pharmaceutical services provided for patients in the MPS, this study compared services provided for "parents" (i.e. patients with children aged under 14 years old) with those of other patients. It also investigated how patients who were parents were affected by the introduction of the MPS and examined their views and attitudes to their pharmaceutical services and service providers.

Given that the optional responses would be read out in a standardised interview setting, and respondents would have to be able to recall these options in making their choices, the patients' questionnaire used mainly closed questions with a limited number of potential answers. Where patients were likely to give a "yes" or "no" answer rather than expanding on an open theme, a multi-choice question was given first followed by an open-ended question, with researchers having the option of using standard prompts. The use of closed or multi-choice questions with a limited number of possible answers can result in inaccurate data, but the likelihood of this occurring should have been diminished by the extensive pilot work carried out here (as described below) (Oppenheim 1992).

An information leaflet accompanied the questionnaire, which described the nature of and reasons for the study and explained that the survey was anonymous and confidential.

Patients also signed a consent form prior to their inclusion in the study (see leaflet and consent form in Appendix A.8.2.).

# 8.2.2. Pilot & Preparatory Work

Using input from the literature, from a number of key "front-line" indicators (Mayock 2001) and two research pharmacists, a draft questionnaire was drawn up and subsequently distributed to a variety of experts involved in the provision of methadone treatment including a representative of the Department of Health and Children (see Appendix A.8.3. for pilot covering letter).

The draft questionnaire investigated a number of issues that were also examined by the concurrent survey of community pharmacies (see Chapter 5). Had identical research instruments been employed, more findings could have been compared to investigate aspects of community pharmacy-based methadone dispensing services from both the service users and the service providers' perspectives. However, the differing nature of the two target samples meant it was not appropriate to use the same research instrument with patients and community pharmacists. If the identities of patients' pharmacies had been recorded, direct cross-validation could have been undertaken to check for inaccuracies in the precise data reported, which would have improved the validity of the study findings, but was not done here to avoid compromising patient confidentiality.

Two primary changes were made to the draft questionnaire as a result of feedback from the experts involved in the pilot study. Instead of asking respondents how far they travelled to their methadone dispensing service the revised questionnaire asked them how long it took them to travel there. This change was made on the advice of a community welfare officer and was to allow for a variety of modes of transport, and to avoid discrepancies arising from inaccuracies in estimating mileage. In addition, a section on side effects of methadone was included and an attitudinal statement relating to the importance of the taste of methadone was added on the suggestion of a GP coordinator. Other minor suggestions were also implemented regarding the order and wording of the questions.

In February 1999, having incorporated these views and recommendations, the draft questionnaire was piloted among a sample of 20 patients in methadone treatment in Fortune House, an outpatient detoxification centre for opiate misusers in southwest Dublin. The pilot study employed "flash cards" to illustrate the five options on the attitudinal scale. However, pilot interviews indicated that they were unnecessary and appeared to make some respondents embarrassed, possibly by drawing attention to their illiteracy, so they were not used in the final survey.

Following the administration and analysis of the pilot, letters were sent to the research sites identified requesting permission to carry out research on the premises (see sample letter in Appendix A.8.4.). Once permission was granted by the relevant authorities, the survey proper was undertaken in March 1999.

## 8.2.3. Sample

Because of the cross-sectional research strategy employed, the sampling techniques used were crucial if the statistical findings were to be universally applicable. Full numeric details of the patients registered on the Central Drug Treatment List (CDTL) in February 1999 were used in determining the target sample. As this survey aimed to investigate aspects of pharmaceutical services for drug misusers and the relationship between patients and their dispensing pharmacists, all patients being dispensed methadone by pharmacists either in community or drug treatment centre pharmacies at the time of this survey were included in the sampling frame. The target number was set at 200 patients, which represented 6.2% (200/3,208) of the total sample population.

## 8.2.3.1. Sampling Technique

Because of confidentiality issues individual patient names were not available, so the sample could not be selected on a fully randomised basis. But while individual patients were not targeted, quota sampling techniques were applied, with a convenient sample being accessed within each group, so that the ultimate sample was representative of the total number of patients by treatment site and geographical location. On a practical level this meant that a researcher went to each treatment site and interviewed a predefined number of patients without reference to their individual demographic data.

Quota sampling aims to obtain representativeness of a number of elements in the relative proportions in which they occur within a population (Robson 1993). Quota and convenience sampling techniques result in samples that may not be representative and findings that may not have had external validity. Their use here may have resulted in an element of bias in the sample – for example, interviewing at a drug treatment centre at the weekend will access a disproportionately high number of patients who attend the clinic seven days a week. However, detailed comparative research undertaken elsewhere has shown that quota sampling often produces data which is closely comparable to that derived using other representative sampling techniques (Oppenheim 1992).

Careful planning using available data meant that this sample was representative of all those in methadone treatment in number of ways (e.g. the number attending community pharmacies versus drug treatment centre pharmacies), while it ignored other aspects of patient characteristics. For example, all patients surveyed were being prescribed methadone on an outpatient basis, but some were in methadone maintenance while others were in detoxification or stabilisation programmes. Patients were not differentiated on the basis of the nature of methadone treatment they received. Neither was the sample designed to be representative on the basis of the age, sex or parental status of the patients in methadone treatment at the time.

## 8.2.3.2. Selection Criteria

Patients were targeted on the basis of the following criteria:

- dispensing site (i.e. community pharmacy, drug treatment centre)
- prescriber site (i.e. GP surgery, satellite drug service or drug treatment centre)
- geographical location (i.e. health board region, sector within E.H.B. region).

A convenient sample was targeted within each sub-group, the numbers accessed being determined by the original quota sample.

8.2.3.2.1. Dispensing site: Those being dispensed their methadone by drug treatment centre pharmacists represented 42% (1,348/3,208) of all patients receiving methadone from pharmacists at the time. The other 58% (1,860/3,208) of registered patients were attending community pharmacies. Therefore, taking 42% (84/200) of drug treatment

centre based patients and 58% of community pharmacy-based patients (116/200) gave a representative sample by dispensing site.

8.2.3.2.2. Prescriber site: All patients attending drug treatment centres pharmacies were registered with methadone prescribers in those centres, so a 42% (84/200) sample was also representative of the patients attending drug treatment centre doctors. Patients attending community pharmacy-based methadone dispensing services were being prescribed methadone by either a GP in a surgery (53%, 988/1,860) or a doctor based in a satellite drug treatment service (47%, 872/1,860). This led to the targeting of a representative sample of 61 GP surgery/community pharmacy-based patients and 55 satellite service/community pharmacy-based patients.

Note the concurrent survey among community pharmacists (see Chapter 6) revealed a sizeable number of patients in attending community pharmacies who were being prescribed their methadone by doctors based in so-called "scripting clinics" in DTCs. Patients attending these clinics were not targeted by this study as the extent of this practice (which had been established as a short-term solution while the E.H.B.'s GP coordinators worked to recruit community-based GPs to the MPS) was under-estimated by the researcher.

## 8.2.3.2.3. Geographical location: There were four geographical areas involved:

- (1) the south west sector of the E.H.B. region (43% of registered patients, 1,385/3,208)
- (2) the south east sector of the E.H.B. region (15% of registered patients, 482/3,208)
- (3) the north sector of the E.H.B. region (40% of registered patients, 1,295/3,208)
- (4) all other health board regions (2% of registered patients, 46/3,208)

The sample was proportionately divided according to the total population of registered methadone patients within each area. Then it was further divided by prescriber location, so that the final sample was representative of the numbers of patients attending each prescriber site and dispensing service within each geographical area. See Table 8.1. for details.

Table 8.1: Patient numbers in primary prescriber sites by geographical location, February 1999, with associated representative patient sample numbers

	E.H.B.	E.H.B.	E.H.B.	Outside	Total No.
	North sector	West sector	East sector	E.H.B.	Patients
	(%)	(%)	(%)	(%)	
No. patients attending drug	687 (51)	539 (40)	122 (9)		1,348
treatment centres	42	34	8		84
Equivalent sample number					
No. patients attending GP surgeries	325 (33)	418 (42)	203 (21)	42 (4)	988
Equivalent sample number	20	27	11	3	61
No. pts in satellite drug services	283 (32)	428 (49)	157 (18)	4 (0.5)	872
Equivalent sample number	18	25	11	1*	55
TOTAL	1,295 (40)	1,385 (43)	482 (15)	46 (2)	3,208
Equivalent sample	80	86	30	4	200

<sup>\* 0.25</sup> patients

#### 8.2.3.3. Questionnaire administration

Patients were administered questionnaires at their methadone prescribing site i.e. at a drug treatment centre, a satellite drug service or a GP's surgery. Questionnaires were administered by (a) a research pharmacist (53%, 115/217), (b) a psychologist (27.6%, 60/217) and (c) a non-pharmacist member of the patient's healthcare team (19.4%, 42/217).

The use of healthcarers involved in the provision of methadone treatment for some patients may have influenced their responses, but constraints on who could access patients due to confidentiality issues meant it was unavoidable in some instances. In addition, research has shown that interviewer training significantly affects the validity of survey findings (Alterman et al 2001) and several researchers were involved in the administration of this study, each of whom had a different background and experience level. It was not possible to carry out inter-researcher testing (to look for researcher-related bias) because the researchers involved carried out all their interviews at different sites, so that other factors may have affected any biases seen. This limitation should be addressed in future research initiatives by having multiple researchers attend each survey site.

Attempts were made to minimise the extent of these experimenter effects by giving all researchers standard instructions and prompts, and by avoiding the scenario where a patient's questionnaire would be completed by a researcher who had been (or was currently) his methadone dispenser.

Privilege access interviewing (i.e. where the researchers were patients) as used by Griffiths and colleagues (1993) could have helped to overcome this limitation, but practical constraints made it impossible in this instance.

Having set target numbers, visits were scheduled by researchers and questionnaires were administered to consecutive patients on a first-come-first-served basis. Questionnaires were always completed in private, and, in the case of the drug treatment centres, out of earshot of the dispensing pharmacist.

#### 8.2.3.4. Exclusion Criteria

Patients who were being dispensed their methadone by non-pharmacists were excluded from the survey. These represented 13% (467/3,675) of all those registered on the CDTL at that time (CDTL Statistics).

#### 8.2.3.5. Refusals

Participation in the survey was totally voluntary, and no incentives were offered. Patients were made aware verbally that the survey was taking place, and they could present themselves for inclusion if they chose to participate. No information was collected on the extent to which other patients actively avoided participation or refused to take part.

#### 8.2.3.6. Excess Return

An additional 17 questionnaires were included in the survey. This was because the final batch of questionnaires were completed on the same day and returned simultaneously by a number of researchers, making it impossible to ascertain in which order they had been completed, so that those surveyed after the target number was reached could be eliminated.

# 8.2.4. Reliability

Confidence in the value of the findings relates to the quality of the individual responses, and this was of particular significance here. Research has shown that self-report can produce consistent, reliable data among drug misusers (Darke 1998). However, while improving the quality of those responses, with high completion rates and greater accuracy due to the opportunity for explanations or prompts where necessary (Oppenheim 1992), the use of a researcher in the completion of the individual questionnaires may have affected the content of participant responses. Researcher effects and context are among the most likely factors to influence the reliability of self-reported data (Finch & Strang 1998). Inter-researcher reliability could not be tested in this study as different researchers completed all questionnaires at individual research sites, so that possible researcher effects may have been compounded by other external factors. Efforts were made to minimise such external influences by ensuring that questionnaires were completed in private, out of ear shot of the pharmacist in the DTC setting, and at their prescribing site (rather than their dispensing site) for patients attending community pharmacies.

Alternate-form testing was employed to examine patients' views on the value of drug treatment centres and on-site supervised dosing. Respondents were asked separately about their preferences and their attitudes to these aspects of their treatment. There were also opportunities here to examine internal consistency using patients' preferences and their attitudes as measured on a Likert Scale.

Findings from this study could be triangulated with those of respondents to Survey 3 of the community pharmacists involved in the MPS.

#### 8.2.5. Validity

#### 8.2.5.1. Internal validity

Methods used to ensure that a representative sample was accessed improved the internal validity in this study. But its internal validity may have been threatened by maturation issues, where other aspects of participants' lives affected the changes seen in the course of the time period studied. Causal relationships associated with the introduction of the methadone cannot be conclusively identified in the absence of a control group. In addition, given that no data was recorded regarding patients who

avoided or refused to participate in this study, the possibility of selective nonparticipation among patients who held "unacceptable" views, who were non-compliant or who were dissatisfied with their treatment services cannot be ignored.

## 8.2.5.2. Face validity:

Using feedback from respondents on a variety of aspects of their methadone dispensing services was a valid way of establishing the nature of their pharmaceutical services under the MPS. The aspects of pharmacy services chosen for inclusion were determined using good practice guidelines published in the Pharmaceutical Society of Ireland's *Policy on Drug Abuse* in October 1996.

## 8.2.5.3. Content validity:

The issues explored by this study were identified through an exhaustive literature review, following dialogue with field workers and peer researchers and after a pilot among 20 patients in methadone treatment. They also related to the earlier and concurrent surveys carried out among Irish community pharmacists who dispensed methadone (see Chapters 3 – 6 inclusive).

# 8.2.5.4. External validity (generalisability):

While the sample chosen may have been representative of those in methadone treatment in Ireland when this study was carried out, many of the patients involved were experiencing relatively new phenomena during the study period due to its timing relative to the introduction of the MPS. Therefore, it is unlikely that its findings could be reproduced under other circumstances. However, given that this study specifically aimed to investigate patients' pharmaceutical services under the newly established MPS, and considering that all patients in methadone treatment in Ireland at this time were subject to the same regulatory changes, these findings may be regarded as representative of their experiences as a whole population.

#### 8.2.6. Ethics & Confidentiality

Ethical considerations were paramount in accessing patients in methadone treatment. All relevant committees and authorities were consulted and informed in advance of this study, and their views were incorporated in the ultimate instrument employed.

Patient names and other confidential details held on the CDTL were not used when sampling for this study. Only gross numeric data were utilised, which protected patients' identities. Participants were supplied with verbal and written information about the nature and purpose of the study in advance of their involvement. It was clarified to them that their input was voluntary, anonymous and confidential, and that none of the information given would be associated with them as individuals. A written consent form was signed by patients prior to their inclusion in the study. Having agreed to participate, patients' personal details were related to their completed responses by code only.

# 8.2.7. Statistical Analysis

Data were analysed using SPSS Version 9. Details of prescribing and dispensing sites, attendance and supervised dosing regimens were entered directly, as were patient demographics. Information given regarding time was recorded as the number of months to the higher month. Responses to open-ended questions were coded retrospectively, and then grouped on the basis of the primary emergent themes.

Parametric and non-parametric statistical tests of difference were carried out on the survey findings, to identify statistically significant associations. In addition, a correlation coefficient in the form of Cronbach's Alpha was used to investigate internal reliability in the five point Likert scale used to measure respondents' views on a variety of attitudinal statements.

#### 8.3. RESULTS

#### 8.3.1. Demographics

#### 8.3.1.1. Sample

Nearly seven percent (6.8%, 217/3,208) of patients being dispensed methadone by pharmacists in February 1999 responded to this study (see full study findings in Appendix A.8.5.). This represented 108.5% (217/200) of the original design sample. As shown in Table 8.2. patients attending community pharmacies were marginally under surveyed (98.3%, 114/116) while those attending drug treatment centres were over represented (122.6%, 103/84). As shown in Table 8.3. the overall return was low from E.H.B. north sector (88.8%, 71/80) and high from the south-east sector (160%, 48/30).

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Patients were surveyed in six GPs' surgeries, nine satellite drug treatment services and thirteen drug treatment centres in the E.H.B. region, as well as at four sites in other health boards. Because of problems accessing prescribers to arrange visits, GPs in the north sector of the E.H.B. and satellite drug services in Tallaght were under represented, as was the Southern Health Board, but all other target specifications were met.

Table 8.2.: Patient Returns Summary by Prescribing Service site

	Sample	Returned	Difference	% of registered
				patients surveyed
GPs surgeries	61	54	-7	5.5
Satellite drug services	55	60	+ 5	6.9
Drug treatment centres	84	103	+ 19	7.6
Total	200	217	+ 17	

Table 8.3.: Patient Returns Summary by Service Location

	Sample	Returned	Difference	% registered patients
				surveyed
E.H.B. north	80	71	- 9	5.5
E.H.B. west	86	94	+ 8	6.8
E.H.B. east	30	48	+ 18	10.0
Outside E.H.B. region	4	4	0	8.7
Total	200	217	+ 17	

## 8.3.1.2. Sample Characteristics

Almost two-thirds of those surveyed were male (65%, 141/217) and 34.6% (75/217) were female (data were missing on one case). Almost three-fifths (57.6%, 125/217) of those surveyed were parents (as defined as having at least one child aged under 14 years old) and between them the parents surveyed had a total of 212 children under 14 years old (mean = 1.7 children per patient family, SD=0.94, range=1-5). More than half of the parents surveyed (55.2%, 69/125) had one child, 27.2% (34/125) had two children and 17.6% (22/125) had three or more children.

Table 8.4. gives demographic details pertaining to participants' ages, with the mean male age being significantly higher than that of females (t=4.056, df=186.13, p<0.01).

Table 8.4.: Mean Patient Ages in years (N=217)

	Mean	SD	Range
Overall sample	28.12	7.12	18 - 51
Male	29.43	7.46	18 - 51
Female	25.71	5.78	18 – 46

As shown in Table 8.5., almost one quarter (23.4%, 33/141) of the males surveyed were 35 years old or older, while only 8% (6/75) of the females surveyed were over 34 years old. When patients aged over 34 years were excluded, males continued to be significantly older than females (t=2.58, df=175, p<0.05. Males: mean=26.04 years, SD=4.1, N=108. Females: mean=24.43 years, SD=3.9, N=69).

Table 8.5.: Patient Age Groups (N=217)

	No. patients (%)
Up to 15 years old	*******
15 - 19 years old	10 (4.6)
20 - 24 years old	68 (31.3)
25 - 29 years old	65 (30.0)
30 - 34 years old	35 (16.1)
35 - 39 years old	22 (10.1)
40 + years old	17 (7.8)

## 8.3.1.3. Treatment History

In Table 8.6. the lengths of time patients had been in methadone treatment were analysed in blocks of six-month periods. As the MPS had been introduced approximately six months prior to this survey, the most recent six-month period was called the 'post-MPS' period.

Although their treatment may not have been continuous, the mean length of time since respondents were first prescribed methadone was 58.32 months (SD=59.35 months, range=1–300 months, N=213 patients). Almost 10% (9.7%, 21/217) of them had been prescribed methadone for the first time during the post-MPS period while over three-fifths (61.3%, 133/217) had first been prescribed methadone more than two years earlier (data were missing on four cases).

The mean length of time respondents were in their current treatment programmes (i.e. with the same methadone prescriber and dispenser) was 17.68 months (SD=25.29 months, range=1–204 months, N=216 patients). Approximately one-third of respondents (36.4%, 79/217) had commenced their current treatment programmes during the post-MPS period (data were missing on one case).

Almost one-third (30.4%, 66/217) of respondents had remained in the same treatment programmes since they first commenced methadone treatment.

Table 8.6.: Duration of respondents' methadone treatment (months)

	Time since first prescribed methadone	Time in current treatment programme*
Post-MPS (preceding 6 mths)	21 (9.7)	79 (36.4)
7 – 12 months	30 (13.8)	66 (30.4)
13 – 24 months	29 (13.4)	33 (15.2)
25 - 60 months	70 (32.3)	26 (12.0)
> 5 years	63 (29.0)	12 (5.5)
MV	4	1

<sup>\*</sup>defined as having the same methadone prescriber and dispenser

Analysis showed no relationship between patient gender and the length of time that patients were in their current treatment programmes (t=0.24, df=213, p=0.81). Males had been an average of 17.99 months in their current programmes (SD=27.93 months, N=140) compared to females' average of 17.11 months (SD=19.8 months, N=75) (data were missing on one case).

Over one quarter (26.9%, 21/79) of the patients who had joined their current programmes post-MPS were prescribed methadone for the <u>first time</u> ever during that

period, and two-thirds of these respondents (14/21, 66.7%) were attending community pharmacies. Over half of those who commenced methadone treatment more than five years previously were currently attending DTC pharmacies (70/138, 50.7%), while seven of the twelve patients (58.3%) who were in their current programmes for more than five years were attending DTC pharmacies.

#### 8.3.2. Treatment Services

# 8.3.2.1. Dispensing Service Site

Some participants (13.8%, 30/217) had never been dispensed their methadone at a community pharmacy, and others (15.7%, 34/217) had never attended a DTC. Of those surveyed, 70.5% (153/217) had previously experienced methadone dispensing services at both community and DTC pharmacies.

Over half (51.8%, 73/141) of the males and 48% (36/75) of the females surveyed were dispensed their methadone at community pharmacies ( $\chi^2$ =0.28, df=1, p=0.6). Similarly, almost half (46.4%, 58/125) of the parents surveyed and 55.4% (551/92) of other patients attended community pharmacies ( $\chi^2$ =1.73, df=1, p=0.19).

A relationship was not found between patient age and current methadone dispensing site (t=1.22, df=215, p=0.22), with the mean age of participants in community pharmacies being 28.71 years (SD=7.56, N=109) and those in DTC pharmacies 27.53 years old (SD=6.64, N=108).

#### 8.3.2.2. Attendance Frequency

The mean attendance frequency for the sample surveyed was 4.63 days per week (SD=2.43, median=6). As shown in Table 8.7., participants' mean attendance frequency was associated with their dispensing site (t= -12.0, df=187.69, p<0.01) and prescribing site (KW  $\chi^2$ =90.45, df=2, p<0.01). Participants who attended community pharmacies and those who attended GPs' surgeries were dispensed their methadone least frequently.

The frequency of attendance did not appear to be related to participants' parental status (t=1.33, df=189.14, p=0.19), with parents attending their methadone dispensing sites a mean of 4.82 days per week (SD=2.36, N=125) and other patients a mean of 4.37 days per week (SD=2.51, N=92).

Table 8.7.: Statistical relationships between participants' current attendance frequencies and their current methadone dispensing and prescribing sites.

		Attendance	SD	N
		Mean no. days/week		
Dispensing site	Community pharmacy	3.1	2.23	109
	DTC pharmacy	6.17	1.48	108
Prescribing site	GP's surgery	2.7	2.19	54
	Satellite drug service	3.78	2.33	60
	DTC	6.13	1.5	103

# 8.3.2.3. On-site supervised self-administration

When asked if they had ever consumed a methadone dose under the supervision of a pharmacist 86.6% (188/217) of patients said they had. When asked about their current level of supervised dosing, patients gave details as outlined in Table 8.8. The mean frequency of supervision was 4.21 days per week (SD=2.88, range=0-7, N=217). Over three-quarters (76%, 165/217) of participants currently drank at least one supervised methadone dose each week.

Table 8.8.: Number of patients' methadone doses currently supervised by a pharmacist each week (N=217)

No. daily doses supervised per week	No. patients (%)
None	52 (24.0)
1- 2 days	20 (9.2)
3 – 4 days	17 (7.8)
5 days	20 (9.2)
6 days	29 (13.4)
7 days	79 (36.4)

As shown in Table 8.9. the frequency with which participants' currently drank their methadone under supervision was negatively correlated to both the length of time since they were first prescribed methadone and the duration of their current treatment programmes. This indicated that patients who had been in methadone treatment over a

longer period of time, and those that had been retained longer by their current treatment programmes were drinking significantly fewer methadone doses under supervision.

Table 8.9.: Correlations between the frequency of on-site supervised methadone dosing and time (months) since methadone treatment initiated and time (months) in current treatment programmes (data were missing on one case).

	r	df	р
No. months since methadone treatment first initiated	- 0.20	211	<0.01
No. months in current treatment programme	- 0.16	214	0.02

Patients received significantly more supervised doses at DTC pharmacies than at community pharmacies (t = -13.54, df=170.96, p<0.01). Participants reported a mean of 2.28 supervised doses per week in community pharmacies (SD=2.61, N=109) compared to a mean of 6.17 supervised doses per week in DTC pharmacies (SD=1.48, N=108). Details are shown in Table 8.10.

Table 8.10: Number of supervised doses each week by methadone dispensing site

	No. patients in community pharmacies (%)	No. patients in drug treatment centres (%)
None	52 (47.7)	0
1 day	4 (3.7)	1 (0.9)
2, 3, 4 days	21 (19.3)	11 (10.2)
5 days	1 (0.9)	19 (17.6)
6 days	29 (26.6)	0
7 days	2 (1.8)	77 (71.3)

When data from respondents who were currently supervised six or seven days per week were analysed, they showed that 9.3% (10/108) were being treated with methadone for the first time in the post-MPS period and 21.3% (23/108) would have chosen to drink all of their methadone doses on-site. Over half (57.4%, 31/54) of the participants who were prescribed their methadone by GPs in their own surgeries were not consuming any methadone under supervision.

Parental status did not appear to be associated with the frequency of supervised dosing (t = -1.17, df=215, p=0.24). Parents reported drinking a mean of 4.41 supervised doses per week (SD=2.82, N=125) and other patients reported drinking a mean of 3.95 supervised doses per week (SD=2.95, N=92).

## 8.3.2.4. Accessibility of Methadone Dispensing Services

When asked how long it took them to travel (from their usual starting point) to their methadone dispensing service, participants reported a mean travel time of 18.33 minutes (SD=17.64, range=1-120, N=215). Travel times were not dependent on the dispensing site that respondents attended (t= -0.77, df=213, p=0.44), with participants who attended community pharmacies reporting a mean travel time of 17.4 minutes (SD=17.81, N=107) and those in DTC pharmacies reporting a mean travel time of 19.26 minutes (SD=17.5, N=108).

Forty-five percent (98/217) of respondents reported travelling for ten minutes or less, while almost three quarters (73.3%, 159/217) of those surveyed said that they reached their methadone dispensing service in 20 minutes or less (data were missing on two cases). As shown in Table 8.11. over one quarter (25.3%, 20/79) of those who attended their methadone dispensing services every day spent more than 20 minutes travelling to their dispensing site. It is possible that the high travel times seen here were linked to participants travelling from their place of work to methadone dispensing services that were located near their homes, although this could not be confirmed as no data was recorded on participants' employment status.

Table 8.11.: Travel time for respondents who attended their methadone dispensing service every day (N=79)

	No notionto (0/)
	No. patients (%)
1 - 5 minutes	27 (34.2)
6 – 10 minutes	11 (13.9)
11 – 20 minutes	21 (26.6)
> 20 minutes	20 (25.3)

In order to assess the extent to which attendance obligations disrupted the everyday lives of participants, data on attendance frequencies and travel times were combined to

produce a "weekly travel time" (no. days attendance per week x one way travel time). Note that as respondents were only asked to report their travel times to their dispensing service, no assumptions can be made about the length of time patients spent travelling back from their services. This analysis indicated that participants in DTC pharmacies had significantly longer "weekly travel times" than those attending community pharmacies (t= -4.65, df=202.16, p<0.01), with participants attending DTC pharmacies travelling for a mean of 114.96 minutes per week (SD=107.6, N=108) compared to a mean of 53.78 minutes per week for those in community pharmacies (SD=84.18, N=107, MV=2). When respondents with total travel times of over four hours per week (N=14) were excluded, this association remained highly statistically significant (t= -6.19, df=162.87, p<0.01. DTC: mean=86.39 mins/week, SD=59.38, N=97. CP: mean=42.35 mins/week, SD=38.56, N=104).

Ideally DTCs should only provide services for patients who reside locally, when even high attendance frequencies would not cause undue disruption as travel times would be low. But this data suggested that participants in DTCs were likely to experience more disruption than those in community pharmacies as their attendance frequencies were higher and their travel times were not significantly lower. This was important given that many patients in DTCs were trying to stabilise their lives and control their drug use, and may have been experiencing enough difficulties without the added disruption associated with high "weekly travel times".

In addition "weekly travel times" were not significantly different for parents and other patients (t=1.147, df=213, p=0.25). Parents had a mean "weekly travel time" of 91.22 minutes (SD=109.51, N=125) compared to a mean of 75.19 minutes (SD=88.09, N=90, MV=2) for non-parents, which suggested that patients' parental status did not affect the attendance regimens allocated to them. This may have had childcare and cost implications for both parents and service providers.

#### 8.3.2.5. Methadone dispensing – patient waiting times

When asked how long they usually waited for their methadone to be dispensed after their arrival at their methadone dispensing service, nearly half (48.4%, 105/217) of participants said they waited for less than five minutes for their methadone to be dispensed. Almost four-fifths (78.4%, 170/217) of the respondents had their doses

dispensed within 10 minutes and only 8.3% (18/217) reported waiting for more than 15 minutes (see additional details in Appendix A.8.5.). There was no significant difference in the length of time patients waited for their methadone to be dispensed in community pharmacies as compared with DTC pharmacies ( $\chi^2$  =0.92, df=3, p=0.82). In addition, statistical analysis found no relationship between the length of time respondents waited for their methadone to be dispensed and their parental status ( $\chi^2$  =0.88, df=3, p=0.83), which may also have implications in relation to childcare, both on-site in DTCs and in homes where parents were absent.

#### 8.3.2.6. "Take-home" methadone doses

Details of how their "take-home" methadone doses were dispensed were recorded in Table 8.12. for the 138 participants (64%, 138/217) who did not currently consume all of their methadone on-site, as related to their current methadone dispensing sites. Patients reported that CRCs were "always" supplied to almost four-fifths of respondents (78.9%, 109/138) (data were missing on four cases). Almost all of the respondents who attended DTC pharmacies reported their methadone was dispensed in plastic, child-resistant containers. When examined for participants who were dispensed multi-dose methadone containers, the supply of measures was uncommon, with only 7.6% of patients (8/106) reporting "always" being given one (data were missing on 31 cases).

The data on the supply of CRCs, plastic bottles and individual containers were grouped by computing their individual scores to give one total "good practice" variable. Further analysis indicated that patients attending DTC pharmacies were significantly more likely to report "good practice" than those attending community pharmacies (MW U=179.0, p<0.01. CP mean=7.9, SD=2.1, N=69. DTC mean=4.27, SD=179.0, N=30). As shown in Table 8.12., participants attending DTC pharmacies were significantly more likely to report being supplied "take-home" methadone in plastic, child-resistant, individual dose containers, but the use of CRCs was high in both dispensing sites and the supply of pharmaceutical measures was equally common in both.

Table 8.13. shows details of how "take-home" methadone doses were dispensed for <u>parents</u> who did not drink all of their methadone on-site as compared to other patients who were not fully supervised. Only the incidence of the use of CRCs differed significantly between parents and non-parents. Participants were significantly more likely

to report being dispensed their methadone in child-resistant containers if they were parents, but the similar mean values for parents and non-parents, coupled with high standard deviation values suggest that the difference was not discernible in practice.

## 8.3.2.7. Measuring Methadone

Almost three-quarters of the patients surveyed (74.2%, 161/217) said they had previously measured a volume of methadone. When asked to list all of the instruments they had used to measure it, 82% (132/161) said they had used a pharmaceutical measure (132/157) and 28.6% (46/161) said they had previously used a baby's bottle. Twenty-one patients (13%) said that they had never used anything other than a baby's bottle to measure methadone. Other measuring instruments reported were a spoon (N=2), an empty syringe (N=1), a glass cylinder (N=1) and a bottle previously used to supply a "take-home" dose of methadone (N=1) (data were missing on four cases).

No significant relationship was found between the lifetime use of babies' bottles and participants' parental status ( $\chi^2$ =0.03, df=1, p=0.87). Over one fifth of the parents surveyed (20.8%, 26/125) and 21.7% (20/92) of other participants had previously used a baby's bottle to measure methadone.

#### 8.3.2.8. Refused Methadone doses

Over seventeen percent of patients (17.5%, 38/217) said that a pharmacist had refused to dispense a prescribed dose of methadone to them. When asked why their pharmacists had withheld their methadone, most participants reported that pharmacists had done so due to prescription related problems (55.2%, 21/38). The second reason why patients believed doses were with-held was because pharmacists thought the patients were under the influence of drugs or alcohol (15.8%, 6/38). One (2.6%, 1/38) respondent did not know why the pharmacist had refused to dispense his methadone.

Respondents who were parents were significantly more likely to have been refused a dose of methadone than other participants ( $\chi^2$ =4.88, df=1, p=0.03). Over one fifth (22.4%, 28/125) of parents had previously been refused a methadone dose compared to 10.9% (10/92) of other participants.

Table 8.12.: Pharmaceutical practices regarding dispensed methadone doses, as related to their methadone dispensing sites (scale: "always" = 1, "usually" = 2, "sometimes" = 3 and "never" = 4)

		Community	mmunity DTC		р	Comn	nunity	DT	ГС	N
			Pharmacy			pharr	nacy	pharr	macy	(%)
		(%)	(%)			Mean	SD	Mean	SD	
Plastic	Always	35 (32.7)	31 (100.0)	542.5	<0.01	2.7	1.37	1.0	0	66 (47.8)
Bottles	Usually	7 (6.5)	0							7 (5.1)
(MV=7)	Sometimes	11 (10.3)	0							11 (8.0)
	Never	47 (43.9)	0							47 (34.1)
CRCs	Always	79 (73.8)	30 (96.7)	1185.0	<0.01	1.53	1.03	1.0	0	109 (78.9)
(MV=4)	Usually	7 (6.5)	0							7 (5.1)
	Sometimes	6 (5.6)	0							6 (4.3)
	Never	12 (11.2)	0							12 (8.7)
Measures	Always	7 (9.5)	1 (3.2)	438.5	0.59	3.53	1.49	3.2	0.86	8 (7.6)
(N=105*)	Usually	2 (2.7)	1 (3.2)							3 (2.9)
(MV=31)	Sometimes	25 (33.8)	7 (22.6)							32 (30.5)
	Never	13 (17.6)	7 (22.6)							20 (19.1)
	Had own measure**	11 (14.9)								11 (10.5)
Individual do	seAlways	9 (11.5)	15 (48.4)	513.0	<0.01	3.56	1.03	2.27	1.36	24 (22.0)
containers	Usually	2 (2.6)	1 (3.2)							3 (3.0)
(N=109***)	Sometimes	1 (1.3)	5 (16.1)							6 (5.5)
(MV=7)	Never	60 (76.9)	9 (29.0)							69 (63.3)

<sup>\*</sup> Respondents who drank 6 - 7 doses on-site and those who were always dispensed their methadone in individual dose containers were excluded.

<sup>\*\*</sup> This response was not listed. Respondents volunteered this information. \*\*\* Respondents who drank 6 – 7 doses on-site were excluded.

Table 8.13.: Pharmaceutical practices regarding dispensed methadone doses, as related to parental status (scale: "always" = 1, "usually" = 2, "sometimes" = 3 and "never" = 4)

		Parents	Others	MW U	р	Pare	Parents		ers
		(%)	(%)			Mean	SD	Mean	SD
Plastic	Always	39 (51.3)	27 (43.5)	1925.5	0.31	2.19	1.38	2.42	1.42
bottles	Usually	3 (3.9))	4 (6.6)						
	Sometimes	7 (9.2)	4 (6.6)						
	Never	23 (30.3)	24 (38.7)						
CRCs	Always	66 (86.8)	43 (56.6)	1878.5	0.03	1.27	0.78	1.59	1.08
(MV=4)	Usually	2 (2.6)	5 (6.6)						
	Sometimes	3 (3.9)	3 (3.9)						
	Never	4 (5.3)	8 (10.5)						
Measures	Always	4 (6.8)	4 (8.7)	372.5	0.14	3.14	0.9	2.81	0.98
(N=105*)	Usually	0	3 (6.5)						
(MV=31)	Sometimes	19 (32.2)	13 (28.3)						
	Never	13 (22.0)	7 (15.2)						
	Had own measure**	5 (8.5)	6 (15.2)						
Individual dos	seAlways	13 (17.1)	11 (17.7)	260.0	0.85	3.19	1.27	3.16	1.3
containers	Usually	2 (2.6)	1 (1.6)						
(N=109***)	Sometimes	3 (3.9)	3 (4.8)						
(MV=7)	Never	39 (51.3)	30 (48.4)						

<sup>\*</sup> Respondents who drank 6 – 7 doses on-site and those who were always dispensed their methadone in individual dose containers were excluded.

<sup>\*\*</sup> This response was not listed. Respondents volunteered this information.

<sup>\*\*\*</sup> Respondents who drank 6 - 7 doses on-site were excluded.

#### 8.3.3. Patients' Views

## 8.3.3.1. Patients' general views

Patients were asked for their views on a selection of attitudinal statements, which were coded using a five point Likert Scale. Their responses are given in Table 8.14.

Table 8.14.: Patients' responses to listed attitudinal statements.

	Strongly Agree (%)	Agree (%)	Neither Agree nor Disagree (%)	Disagree (%)	Strongly Disagree (%)	MV
I am happy with the way my methadone is dispensed at the moment.	50 (23.0)	117 (53.9)	11 (5.1)	21 (9.7)	18 (8.3)	
It is a good idea to have special clinics where drug misusers are dispensed their methadone.	84 (38.7)	99 (45.6)	14 (6.5)	14 (6.5)	5 (2.3)	1
I have enough privacy if (when) I drink my methadone in front of the pharmacist.	29 (13.4)	93 (42.9)	9 (4.1)	50 (23.0)	23 (10.6)	13*
I (would) feel embarrassed drinking methadone in the chemist.	67 (30.9)	86 (31.3)	6 (2.8)	60 (27.6)	14 (6.5)	2**
I have a good relationship with the pharmacist who dispenses my methadone.	87 (40.1)	116 (53.5)	5 (2.3)	5 (2.3)	2 (0.9)	2
It is difficult for me to get to the chemist/clinic in time to get my methadone.	25 (11.5)	51 (23.5)	10 (4.6)	103 (47.5)	27 (12.4)	1
The brand of the methadone is very important to me.	44 (20.3)	93 (42.9)	24 (11.1)	42 (19.4)	9 (4.1)	5
I worry about being registered on a central treatment list.	39 (18.0)	49 (22.6)	13 (6.0)	100 (46.1)	16 (7.4)	

<sup>\*</sup> responses were missing from thirteen participants, nine of whom had never been supervised

Over three-quarters of respondents "agreed" or "strongly agreed" that they were happy with their current methadone dispensing service (76.9%, 167/217) and almost all participants reported good relationships with the pharmacists who dispensed their methadone (93.6%). Over four-fifths (84.3%) of participants "agreed" or "strongly agreed" that special methadone dispensing clinics were a good idea, with positive views being significantly more likely among parents (MW U=4427.0, p<0.01. Parents: mean=1.71, SD=0.84, N=124. Others: mean=2.1, SD=1.05, N=92).

<sup>\*\*</sup> no responses from two patients who had never been supervised

More than half of those surveyed (56.3%) "agreed" or "strongly agreed" that they had (or would have) enough privacy when drinking methadone on-site at a community pharmacy, but over three-fifths of them also associated feelings of embarrassment with drinking methadone in a community pharmacy. This suggested that embarrassment related to drinking methadone at a community pharmacy could be separated from the issue of privacy, and may be an indication of the perceived stigmatisation of those on methadone treatment by community pharmacists and other pharmacy staff.

Over one-third of respondents (35%) reported difficulty with their methadone dispensing service's opening hours. When the views of those who had attended both community pharmacies and DTC pharmacies were examined, participants who were currently in DTC pharmacies were significantly more likely to report difficulty with their pharmacies' opening hours than those attending community pharmacies (MW U=1375.0, p<0.01. CP: mean=3.83, SD=1.07, N=72. DTC: mean=2.65, SD=1.37, N=72). This finding indicated that DTC pharmacy opening hours caused problems for patients in methadone treatment, while community pharmacies offered a more flexible and accessible dispensing service. This was particularly important given that earlier data indicated that patients in DTCs were also attending more frequently than those at community pharmacies, which increased the frequency with which they were subjected to the stress associated with these limited opening hours.

Almost two-thirds of participants (63.1%) "agreed" or "strongly agreed" that the formulation of their methadone was very important to them, which may have been related to the incidence of side effects reported below. Due to anecdotal evidence of wide-spread confusion among those in methadone treatment under the MPS regarding the formulations of methadone 1mg/ml available, individual patients were not asked for the name of their methadone's manufacturer, which meant that these data could not be related to individual formulations of methadone 1mg/ml.

In the concurrent survey of community pharmacies (see Chapter 5) two-thirds of respondents said they stocked only one formulation of methadone 1mg/ml, and patient preference "always" determined the formulation of methadone that was supplied in 13.7% of the community pharmacies surveyed.

Over two-fifths of respondents "agreed" or "strongly agreed" that they were worried about being registered on the CDTL (40.6%, 88/217). Worrying was not associated with parenthood (MW U=5623.0, p=0.77. Parents: mean=2.99, SD=1.39, N=125. Others: mean=3.07, SD=1.19, N=92) but female respondents were significantly more likely to report being worried about being registered on the CDTL than males were (MW U=4065.0, p<0.01. Males: mean=3.21, SD=1.25, N=141. Females: mean=2.65, SD=1.34, N=75). Although a sizeable minority of participants (particularly females) expressed concern regarding their inclusion in the CDTL, these data suggested that participants believed that their inclusion on the list would not compromise their position as parents.

# 8.3.3.2. Alpha reliability analysis

As described earlier in Chapter 5 (Pharmacy Survey 3), Cronbach's Alpha co-efficient is used as an indicator of internal reliability, with a value of 0.7 or greater indicating that respondents held consistent views towards a number of different attitudinal statements. In that instance, participants' responses to individual statements can be added together to create a new "attitude" variable, which can then be used in subsequent analyses to identify relationships between patients' "attitude" and key predictor variables.

As they were conceptually distinct from the remaining six attitude variables, two of the statements examined in the course of this research ("It is a good idea to have special clinics where drug misusers are dispensed their methadone" and "The brand of the methadone is very important to me.") were removed from the Alpha analysis of these data. In spite of this, subsequent analysis found the alpha-reliability co-efficient for the remaining six item scale was 0.36, which indicated that it had poor internal reliability. This meant that individual responses could not be summed to provide a 'score' variable to represent respondents' overall "attitude" in subsequent analyses.

Although additional attitudinal statements were deliberately removed from the questionnaire during the piloting stage to reduce its overall length and minimise respondent fatigue, a more in-depth analysis at that stage could have helped to identify attitude statements which could have been used to form a scale which could ultimately have produced a reliable "attitude" score for each respondent (Oppenheim 1992).

## 8.3.3.3. Factor Analysis

Since Cronbach's alpha was too low to allow the development of a single "attitude" variable in this instance, factor analysis was undertaken to look for relationships between individual attitudes reported. Factor analysis allows multiple responses to be grouped to create a smaller number of "attitude" variables, which simplifies further analytical processes.

When factor analysis was conducted on the six remaining attitude variables, three factors were initially extracted with Eigenvalues equal to or greater than 1.00 (see details in Table 8.15., see correlation matrix in Appendix A.8.6.). The first factor accounted for 24% of the variance in respondents' attitudes (Eigenvalue=1.4), and seemed to relate to respondents' views on the suitability of community pharmacies for the provision of onsite supervision. Factor scores were used to create a new variable called "suitable". Respondents with lower scores in this variable appeared to believe that community pharmacies were more "suitable" in that they agreed that community pharmacists were able to manage the provision of on-site supervision services and could provide adequate privacy with little cause for embarrassment during on-site supervision.

The second factor identified which accounted for a further 22% of the variance (Eigenvalue=1.3) appeared to relate to respondents' satisfaction with current dispensing services and was associated with the accessibility of these services as illustrated by their opening hours. It indicated that participants who were happy with their pharmacy opening hours were happy with their overall methadone dispensing services, which suggested that opening hours are a crucial aspect of the methadone dispensing service. Factor scores were used to create a new variable, which was called "happy", with lower scores indicating higher agreement with this view.

The third factor showed an association between participants worrying about being registered on the CDTL and the extent to which they reported "good" relationships with their dispensing pharmacists. It accounted for 19% of the variance (Eigenvalue=1.1). The resultant variable was called "tension" as it implied an association between respondents' faith in the MPS and their relationship with their pharmacist, with higher numerical scores being indicative of poorer pharmacist/patient relations and higher levels of worry.

As the new attitude variables had similar and relatively low Eigenvalues, and as the data were essentially being paired, new "attitude" scores were computed by adding the original attitude scores together, rather than using the computer-generated "factor" scores.

Table 8.15.: Eigenvalues for factor analysis of six attitudinal statements (promax rotation)

	Fastand	F10	F4 0
	Factor 1	Factor 2	Factor 3
	Suitable	Нарру	Tension
I have enough privacy if (when) I drink my methadone in front of the pharmacist.	0.81	- 0.12	0.17
I (would) feel embarrassed drinking methadone in the chemist. (reversed)	0.79	- 0.01	- 0.11
It is difficult for me to get to the chemist/clinic in time to get my methadone. (reversed)	- 0.10	0.78	- 0.23
I am happy with the way my methadone is dispensed at the moment.	- 0.04	0.80	0.34
I have a good relationship with the pharmacist who dispenses my methadone.	0.18	0.21	0.79
I worry about being registered on a central treatment list. (reversed)	0.27	0.27	- 0.59

## 8.3.3.4. Univariate Analysis

A number of key respondent characteristics were selected as possible predictors of patient attitude, and these were analysed with the new attitude variables. The characteristics selected were:

- (a) Respondent gender
- (b) Respondent age
- (c) Parental status
- (d) Time since first prescribed methadone
- (e) Time in current treatment programme

- (f) Ever drank a supervised methadone dose
- (g) Current methadone dispensing site (community pharmacy or DTC)
- (h) Current attendance frequency
- (i) Current supervision frequency

A study of the relevant box and scatterplots helped in the interpretation of the data, and a univariate analysis was subsequently carried out (see results in Tables 8.16. & 8.17.). Both prior experience of supervised dosing and their current dispensing site were statistically significant predictors of patients' attitudes towards the "suitability" of the community pharmacy as an on-site supervision site and their reported "happiness" with their current arrangements. Those who had previously drunk a supervised dose were significantly more likely to report that the community pharmacy was "suitable" for on-site supervision and that they were "happy" with their current arrangements. Those who were currently attending a DTC pharmacy were significantly more likely to report that the community pharmacy was "suitable" for on-site supervision, while they were significantly less likely to report being "happy" with their current dispensing arrangements. Female respondents reported significantly more "tension" in the pharmacist/patient relationship than males did, although the mean values for these groups and their related standard deviations suggested that this finding was not significant in practice.

An examination of the scatterplots and subsequent analysis found no statistically significant correlations between any attitudinal variable and respondent age or the length of time since they were first prescribed methadone. However, their current attendance frequency and their current on-site supervision frequency were both statistically significant predictors of their responses to the "suitability" and "happiness" factors. The reported "suitability" of the community pharmacy increased as respondents' current attendance frequency and their current frequency of on-site supervision increased, while their reported "happiness" fell as these predictors rose. There was a statistically significant relationship between the number of months respondents had been in their current treatment programmes and their responses to the "tension" attitudinal variable, with reported "tension" falling as time in their current programmes rose.

Table 8.16.: Statistical results of univariate analysis on attitudinal factors "suitable", "happy" and "tension" versus key categorical predictors

Attitudinal factor	Predictor variable	t	df	р		Mean	SD	N
Suitable	Sex	0.40	199	0.69	Male	6.27	2.13	128
					Female	6.14	2.26	73
	Parental status	- 1.12	200	0.26	Yes	6.08	2.23	117
					No	6.42	2.08	85
	Previously supervised	-6.74	29.58	<0.01	Yes	6.01	2.14	183
					Never	8.26	1.28	19
	Current dispensing site	4.51	200	<0.01	CP	6.91	2.17	97
					DTC	5.59	1.98	105
Нарру	Sex	0.61	213	0.54	Male	5.05	1.91	141
					Female	4.88	2.04	74
	Parental status	- 0.45	214	0.65	Yes	4.94	2.01	125
					No	5.07	1.88	91
	Previously supervised	6.76	58.61	<0.01	Yes	5.22	1.95	187
					Never	3.52	1.12	29
	Current dispensing site	- 3.85	214	<0.01	CP	4.50	1.78	109
					DTC	5.50	2.00	107
Tension	Sex	- 2.29	212	0.02	Male	4.52	1.39	139
					Female	4.99	1.50	75
	Parental status	0.54	213	0.61	Yes	4.72	1.61	124
					No	4.62	1.19	91
	Previously supervised	1.32	213	0.19	Yes	4.73	1.41	186
					Never	4.34	1.63	29
	Current dispensing site	0.52	213	0.61	CP	4.72	1.51	109
					DTC	4.62	1.38	106

Table 8.17.: Statistical results of univariate analysis on attitudinal factors "suitable", "happy" and "tension" versus key parametric predictors

Attitudinal factor	Predictor	Pearson's Correlation	р	N
Suitable	Patient age	0.09	0.20	202
	No. months since initial methadone treatment	0.09	0.21	198
	No. months in this treatment programme	0.06	0.42	201
	Current attendance frequency (days/week)	- 0.31	<0.01	202
	Current supervision frequency (days/week)	- 0.38	<0.01	202
Нарру	Patient age	- 0.11	0.11	216
	No. months since initial methadone treatment	- 0.01	0.86	212
	No. months in this treatment programme	- 0.11	0.12	215
	Current attendance frequency (days/week)	0.22	<0.01	216
	Current supervision frequency (days/week)	0.24	<0.01	216
Tension	Patient age	- 0.20	0.73	215
	No. months since initial methadone treatment	- 0.10	0.13	211
	No. months in this treatment programme	- 0.14	0.04	214
	Current attendance frequency (days/week)	- 0.04	0.57	215
	Current supervision frequency (days/week)	- 0.05	0.51	215

## 8.3.3.5. Multiple Regression Analysis

Following from this exploratory univariate analysis, a multiple regression analysis was undertaken to establish which predictor variables were most significant in the determination of respondents' attitudes. As discussed earlier, variables that predict more than 10-15% of the variance seen are regarded are useful in the study of social science.

A multiple regression analysis of the attitudinal factor "suitability" and the independent variables listed above indicated that these variables accounted for 13.7% of the attitudinal variance seen ( $F_{9,187}$ =4.45, p<0.01). But the analysis indicated when examined together only respondents' current frequency of supervised dosing was a statistically useful predictor of their views on the "suitability" of community pharmacies for the provision of this service (see details in Table 8.18), with those with higher frequencies viewing the community pharmacy as more "suitable" than other respondents.

Similar analysis on the attitudinal factor "happy" showed that the independent variables listed above accounted for only 9.1% of the attitudinal variance seen (F<sub>9,201</sub>=3.35, p<0.01). The analysis indicated that both their prior experience of on-site supervision and their current methadone dispensing site were statistically useful in predicting responses to the attitudinal variable "happy" (see details in Table 8.19.). Respondents who had previously drank methadone under supervision were significantly more likely to report current "happy" attitudes, as were respondents who were currently attending community pharmacies.

Multiple regression analysis indicated that the independent variables examined accounted for only 2.4% of the variance in the third attitudinal factor "tension" ( $F_{9,200}$ =1.57, p=0.13). Statistical details are given in Table 8.20. The data showed that not having consumed methadone under the supervision of a pharmacist was associated with more "tension".

Table 8.18. Multiple regression analysis of attitudinal factor "suitability" and key predictor variables.

	В	Standard error b	t	Significance of t
Respondent gender	0.08	0.32	0.25	0.81
Parental status	0.28	0.31	0.9	0.37
Previously drank a supervised methadone dose	- 1.0	0.61	- 1.65	0.1
Current methadone dispensing site	- 0.35	0.39	- 0.91	0.37
Respondent age	0.01	0.03	0.01	0.99
No. months since methadone treatment initiated	0.01	0.01	0.26	0.79
No. months in this treatment programme	0.01	0.01	0.17	0.87
No. days attendance per week	0.18	0.17	1.08	0.28
No. days supervised per week	- 0.34	0.16	- 2.11	0.04

Table 8.19. Multiple regression analysis of attitudinal factor "happy" and key predictor variables.

	В	Standard error b	t	Significance of t
Respondent gender	- 0.21	0.29	- 0.73	0.47
Parental status	0.05	0.27	- 0.20	0.85
Previously drank a supervised methadone dose	1.25	0.49	2.56	0.01
Current methadone dispensing site	0.68	0.35	1.95	0.05
Respondent age	- 0.02	0.02	- 1.15	0.25
No. months since methadone treatment initiated	0.01	0.01	1.21	0.23
No. months in this treatment programme	- 0.01	0.01	- 0.65	0.52
No. days attendance per week	- 0.03	0.16	- 0.20	0.84
No. days supervised per week	0.02	0.15	0.16	0.88

Table 8.20. Multiple regression analysis of attitudinal factor "tension" and key predictor variables.

	В	Standard error b	t	Significance of t
Respondent gender	0.04	0.22	1.85	0.07
Parental status	- 0.17	0.21	- 0.08	0.41
Previously drank a supervised methadone dose	0.72	0.37	1.94	0.05
Current methadone dispensing site	0.0.6	0.27	0.23	0.82
Respondent age	0.02	0.02	0.97	0.33
No. months since methadone treatment initiated	- 0.01	0.01	- 0.74	0.46
No. months in this treatment programme	- 0.01	0.01	- 1.47	0.14
No. days attendance per week	0.06	0.12	0.48	0.63
No. days supervised per week	- 0.14	0.11	- 1.26	0.21

## 8.3.4. The effects of the introduction of the Methadone Protocol Scheme

The effects that the introduction of the MPS had on participants were recorded qualitatively, and classified retrospectively as "positive", "negative" or "mixed", depending on how their impact was interpreted by the researcher. Details of participants' responses are given in Table 8.21.

Table 8.21.: Overall effects of the introduction of the MPS (N=217, MV=12)

	No. patients (%)
Positive	71 (32.7)
Negative	25 (11.5)
Mixed	15 (6.9)
Unaffected	77 (35.5)*
New to treatment	17 (7.8)

<sup>\*</sup> equivalent to 38.5% (77/200) of participants who were in treatment pre-MPS

Three-quarters of the parents surveyed (40/53) reported "positive" outcomes compared to 72.1% (31/43) of other participants ( $\chi^2$  =0.14, df=1, p=0.71). Over four-fifths (81.4%, 35/43) of those attending community pharmacies reported "positive" outcomes compared to 67.9% (36/53) of those in DTC pharmacies ( $\chi^2$  = 2.24, df=1, p=0.14).

Respondents who had reported "positive" or "negative" effects were asked to describe the effects they had experienced. Where respondents were reticent or vague researchers used these standard prompts: "treatment options, financially, standards of care, unaware – no difference". As shown in Table 8.22. over one-third of respondents (34.2%) said they were better off financially since the MPS was introduced while 32.4% said they now had better standards of care. The "negative" effects most commonly reported related to increased difficulty in gaining access to methadone treatment (also described in relation to longer waiting lists) (18.9%), the transition from Physeptone® to methadone 1mg/ml (8.1%) and experiencing more difficulty with attendance regimens under the MPS (12.6%). Additional details are given in Appendix A.8.7.

Table 8.22.: Grouped effects of the introduction of the MPS (N=111, multiple responses accepted)

	No. patients (%)
Financially better off	38 (34.2)
Better standards of care	36 (32.4)
Better treatment options	26 (23.4)
Improved or stabilised health/drug use	20 (18.0)
Tighter controls in place (good)	16 (14.4)
More difficult to access treatment	21 (18.9)
More difficult attendance regimen	14 (12.6)
Preferred Physeptone®	9 (8.1)

#### 8.3.5. Side-effects associated with methadone treatment

Participants were asked whether they had ever experienced adverse effects that they associated with their methadone, and were prompted with the possible side effects of "nausea, diarrhoea, constipation and drowsiness". Ninety-six respondents reported that they had experienced side effects while on methadone treatment (44.2%). Of these, 55 patients (57.3%, 55/96) said that they continued to experience these side effects. This represented 25.3% (55/217) of the total sample surveyed.

When those who reported having experienced side effects were asked to describe them, 44.8% (43/96) reported constipation, 36.5% (35/96) reported nausea and 15.6% (15/96) had experienced excessive sweating. Eleven patients (11.5%) reported drowsiness as a side effect of their methadone treatment. (Full details are given in Appendix A.8.8.).

#### 8.3.6. Respondents preferences

#### 8.3.6.1. Choice of dispensing site

Thirteen percent (20/153) of the respondents who had experienced both a community pharmacy and a DTC pharmacy service expressed no preference for one dispensing service above the other. But 70.6% (108/153) of respondents said they would prefer to attend a community pharmacy and 16.3% (25/153) would choose to attend a DTC pharmacy. Only 3% (2/66) of the respondents currently in community pharmacies who had attended both sites and expressed a preference chose to attend a DTC pharmacy but 65.7% (44/67) of those currently attending DTC pharmacies who stated a preference

wanted to transfer to community pharmacy-based methadone dispensing services. Qualitative reasons for participants' choice of dispensing site are listed in Appendix A.8.9.

Respondents who were currently attending DTC pharmacies who had experienced both sites and expressed a preference for attending a community pharmacy were more likely to "agree" or "strongly agree" that they had difficulty with their dispensing hours (MW U=313.0, p=0.01. Stay mean=3.17, SD=1.4, N=23. Move mean=2.26, SD=1.25, N=42).

# 8.3.6.2. Choice of attendance frequency

When asked how often they would choose to attend their methadone dispensing service, 60.4% of patients (131/217) said they would choose to attend one day per week. Sixtyone patients (28.1%) said they would prefer to attend their methadone dispensing service twice or three times a week, and 25 patients (11.5%) said they would choose to attend four days a week or more. Qualitative reasons for participants' chosen attendance frequencies are listed in Appendix A.8.10. A summary of the difference between patients' current regimens and their attendance preferences are given in Table 8.23.

Table 8.23.: Summary of respondents' chosen attendance regimens versus their current attendance frequencies (N = 217)

	No. patients (%)
Chose current regimen	63 (29.0)
Preferred less frequent attendance	152 (70.1)
Preferred more frequent attendance	2 (0.9)

A total of 177 patients gave reasons for their chosen attendance preferences (MV = 40). Most selected low frequency attendance regimens but others expressed a preference for high frequency regimens. Full details of these reasons are given in Tables 8.24. & 8.25. The most common reasons patients gave for low frequency attendance regimens were convenience (19.8%), work commitments (17.1%) and reduced travelling (14.3%). The most common reasons why participants chose high frequency attendance regimens were a preference or need for frequent psychological or medical support (5.1%) and fear of not being able to manage their own methadone doses (3.7%).

Table 8.24.: Reasons why participants chose low (or reduced) frequency attendance regimens

	No. patients (%)
Less hassle (convenience)	43 (19.8)
Working	37 (17.1)
Less travelling	31 (14.3)
Saves time	11 (5.1)
I want to have a normal life	9 (4.1)
Can take dose when I want it	9 (4.1)
Privacy issues	7 (3.2)
Can avoid dealers	6 (2.8)
Not physically well enough to attend	5 (2.3)
I wouldn't want to bring kids there (DTC)	5 (2.3)
Can reduce/control my own dose	4 (1.8)
Reduce problems with travelling – due to work	4 (1.8)
It's difficult to get to the chemist on time	4 (1.8)
It's embarrassing	4 (1.8)
I would like a sleep in	3 (1.4)
I would like to be able to work	3 (1.4)
Shows trust	2 (0.9)
Less work for the pharmacist	1 (0.5)
Pharmacy staff make me feel unwanted (stigma)	1 (0.5)
I have a child at home	1 (0.5)
I could reduce the cost of taxis/buses	1 (0.5)
I could reduce my dose and sell my methadone	1 (0.5)

Table 8.25.: Reasons why participants chose high frequency attendance regimens

	No. patients (%)
I like/ need support or medical care (+/- urinalysis)	11 (5.1)
Afraid of not managing my methadone dose	8 (3.7)
It's nice to get out of the house	6 (2.8)
Can't say you're selling methadone	1 (0.5)
Would be asked to sell my methadone	1 (0.5)
I'd be going to the chemist anyway for other medicines	1 (0.5)

# 8.3.7. Respondents' current supervision levels and their attitudes to on-site supervision

When asked where they would choose to drink their methadone, 71.4% of patients (155/217) said they would choose to drink it at home every day. Thirty-four patients (15.7%, 34/217) said they would prefer some level of supervised dosing, and 25 patients (11.5%, 25/217) opted to drink all of their methadone doses under the supervision of the pharmacist. The remaining 1.4% (3/217) said they had no preference as to where they consumed their methadone.

Details of respondents' chosen levels of supervision compared to their current levels are given in Table 8.26. All of the patients who had never previously had a supervised dose chose to take all of their methadone at home (29/29), while only 67% (126/188) of those who had experienced supervision requested none here. This suggested that exposure to on-site supervised dosing improved the acceptability of this procedure for patients in methadone treatment. It may also indicate that patients who had experienced on-site supervision recognised its value in relation to their own health, and were more willing to allow pharmacists to help them to comply with prescribed daily dosage regimens.

Table 8.26.: Preferred supervision level compared to current supervision level (N=217)

No. patients (%)
70 (32.3)
120 (55.3)
6 (2.8)
18 (8.3)
3 (1.4)

The reasons for patients' choices are given in full in Appendix A.8.11. Privacy (27.2%, 59/217), convenience (22.1%, 48/217) and reduced contact with the drug scene (20.3%, 44/217) were the most commonly cited reasons for patients' decisions (data were missing on 37 cases).

When examined in relation to the level of supervision requested, 36.8% (57/155) of respondents who chose no supervision said such a service was better for them because of privacy issues and that it reduced their contact with the drug scene (24.5%, 38/155)

(data were missing on 15 cases). Less than thirty percent (45/153) of those who had previously had a supervised dose of methadone cited privacy as a determining factor in their choice of supervision level compared to 51.9% (14/27) of those who had never consumed a dose under supervision ( $\chi^2$  =5.25, df=1, p=0.02). Of those who requested full supervision, 52.0% (13/25) said they preferred it because it reduced the temptation to misuse or sell their methadone, and the risk of robbery (data were missing on seven cases).

Patients who currently had no supervised doses were significantly more positive about their current methadone dispensing arrangements than other patients (MW U=2866.0, p<0.01. No Sn mean=1.77, SD=0.88, N=52. Sn mean=2.38, SD=1.23, N=154. 1="strongly agree" ... 5="strongly disagree").

#### 8.4. DISCUSSION

This survey was the first one to be undertaken among patients participating in the MPS, to examine their views on pharmaceutical aspects of their treatment. Findings from this study were essential in developing a picture of how those in methadone treatment in Ireland were affected by the introduction of the MPS and in examining the nature of the dispensing services being provided for them.

Study findings indicated that the introduction of the MPS had resulted in a methadone treatment system that was tightly controlled and enforced strict limits on participants. Most participants were happy with how their methadone was dispensed and reported good relationships with their dispensing pharmacists, although many participants worried about being registered on the CDTL, and many side-effects were associated with the long-term use of methadone. Participants described high-frequency attendance and on-site supervision regimens and recognised the value of these services for patients in methadone treatment. They reported reasonably short travel times, minimal waiting times and "take-home" methadone doses that were not uniformly dispensed in accordance with good practice guidelines (McDermott 1999). Many participants' pharmacists had refused them a dose of methadone but most understood why this had happened. Community pharmacies were more popular than DTC pharmacies although

privacy in the course of on-site dosing in the community pharmacy was an important issue, as distinct from that of patient embarrassment during the supervision process.

These findings highlighted aspects of the MPS' pharmaceutical services that were positively regarded by service users. It also helped to identify issues that were unacceptable or difficult for them, which may have undermined patient progress or created barriers to treatment participation. Overall, the data indicated that the introduction of the MPS had a positive impact on most of those whom it affected.

While the sample taken was relatively small, and did not include the minority of patients attending DTC "scripting clinics", it was designed to be representative of all other patients registered in methadone treatment in February 1999 by geographical area, dispensing service and prescribing service. The sample surveyed was similar in age and gender balance to those registered on the CDTL at the time (CDTL Statistics). When patients' ages were compared with the national contact statistics for 1998 (O'Brien et al 2000) patients aged under 20 years old were under-represented while those in the older ages groups were over-represented. The lower number of younger patients is to be expected given the limited number of patients aged under 18 years old who were being prescribed methadone at the time the survey was carried out. The gender balance in this survey was also within 5% of that recorded both nationally and within the E.H.B. region in 1998 (O'Brien et al 2000). These findings suggested that this sample of patients was representative of problem opiate users and of those in methadone treatment at the time this survey was undertaken which meant that these data may be generalisable when examining this population as a whole (CDTL Statistics, see HRB data in Appendix A.8.12.).

The majority of those who participated in this study were parents of children aged under 14 years old, but there were no published data on the incidence of parenthood among Irish patients in methadone treatment which could be used to establish whether this proportion was mirrored in the population as a whole.

The categorisation as "parents" of respondents who had children aged under 14 years old in these analyses was supported by recent Irish research, which has shown that beyond the age of 14 or 15 years children were vulnerable to the initiation of drug use

(Mayock 2000) and by Scottish research which showed that drug use among children aged under 14 years old rarely involved opiates (Forsyth & Barnard 1999).

Governmental guidelines indicate that drug misusers' children should not automatically be taken into care (ACMD 1988, DOHC 1989) and a six-year follow-up study of 45 pregnant patients in methadone treatment in Dublin showed that the majority of them had retained custody of their children (Keenan et al 1993). However, despite these guidelines, one Irish publication argued that value judgements were being applied to mothers in methadone treatment prior to the introduction of the MPS (Butler 1993).

There were no discernible differences in the attendance or supervision frequencies of participants who were parents and other patients, which suggests that having children aged less than 14 years did not affect patients' ability to access "take-home" methadone doses. This may indicate that value judgements previously applied to parents in Irish drug treatment services (Keenan et al 1993, Butler 1993) had dissipated under the MPS. This implied a change in staff attitudes towards a more inclusive, less moralistic approach, which should have helped to create more user-friendly treatment services. The absence of a significant association between parenthood and worry about registration on the CDTL also supports this suggestion. Such an attitudinal shift should have had a positive impact on the uptake of methadone services by parents and should be supported and encouraged by MPS management and policy makers.

However, this finding also had negative connotations in as far as it suggested that no concessions were being made or special precautions taken for patients who were responsible for children. MPS patients who were parents and were attempting to comply with their methadone treatment regimens may also have had to manage "take-home" methadone doses, while caring for young children. Treatment services should consider these factors in the determination of patients' attendance regimens, as treatment outcomes may be adversely affected by the application of unnecessarily strict conditions or the supply of unsafe "take-home" methadone doses.

Further research into the social responsibilities of patients in methadone treatment could be useful in designing pharmaceutical services that better meet their needs, both in terms of convenience and accessibility and in relation to the safety of patients and those with whom they live. Pharmacists may also benefit from information regarding the risks associated with methadone in the home, and training in the safe supply of "take-home" methadone doses.

In the absence of longitudinal data from the pre-MPS period it was not possible to establish what proportion of the patients who had commenced methadone treatment had been retained throughout the introductory period. Nevertheless, this study showed that many patients had been retained by their first treatment programmes, which suggested good retention rates despite the period of disruption and change during the introduction of the MPS. This was a positive finding as retention in continuous methadone treatment has been shown to be of benefit to opiate misusers (Smith 1990, Gelbhart 1994, Dore et al 1999, Gossop et al 1999a).

Government-led protocols such as the MPS should ideally include feasibility studies, which also follow-up patients who drop out of treatment to investigate why they were lost from treatment. While this study identified a number of negative outcomes following the introduction of the MPS, they were reported by patients who continued to participate in the programme. A study among opiate misusers who were in methadone treatment prior to the introduction of the MPS, but did not continue after its introduction could help to pinpoint these issues, thereby enabling service providers to identify and address these barriers to service participation.

The attendance frequencies and incidence of on-site supervised dosing reported here were generally high, and were higher than those reported in the concurrent survey of community pharmacies (see Chapter 5), as patients in DTC pharmacies attended more frequently than their peers in community-based services. The high overall rate of on-site supervision should have decreased the volume of methadone available for diversion, thereby reducing associated risks to children (Binchy et al 1994, Calman et al 1996) and adults (Cairns et al 1996, McCarthy 1997). This should have had a positive impact on the community in general and resulted in public support for the MPS. Participant preferences for relatively frequent attendance regimens and on-site supervision were similar to findings in the UK (Neale 1999, Luger et al 2000) and indicated that Irish patients were also aware of the difficulties in managing their own methadone, and were

prepared to use the support mechanisms available to reduce the volumes of methadone they took off site.

Patients who expressed a preference for more frequent attendance and on-site supervision chose intensive, structured support services offered by the most rigorous methadone treatment programmes. It was not clear whether these patients were motivated by physical or psychological needs, but their needs may have prevented them from transferring to community-based treatment programmes where daily supervision was less common and less private, and support from other disciplines (such as counsellors and community care workers) was less accessible. This has long-term implications for drug treatment service providers, and particularly for tertiary service pharmacies, in terms of efficiency and cost. It is possible that the expansion of on-site supervision services in community pharmacies, and more privacy during the provision of these services, could enable these patients to be managed within a non-specialist environment.

Participants who preferred to attend methadone dispensing services less frequently and wanted to take their methadone at home showed more independence and wanted more control over their own treatment. These patients most commonly cited their work as the main external factor limiting their attendance at their methadone dispensing services, with participants who worked experiencing difficulty in complying with stringent attendance regimens. Although no data were recorded in this study regarding the employment status of participants, the recent increased level of employment among Irish patients in methadone treatment has been documented elsewhere (Farrell et al 2000), and the value of employment as a stabilising influence should be acknowledged in the determination of patients' attendance regimens. In light of the social and personal benefits associated with being employed, service providers should consider using patients' efforts to gain or maintain employment as an alternative measure of progress during their methadone treatment, and include this criteria in determining aspects of their treatment programmes.

Further research into the characteristics of patients in methadone treatment could offer service providers useful insight into the needs and preferences of those in methadone treatment. Perhaps an easier transfer process would encourage patients who prefer high

support services to try community-based methadone, safe in the knowledge that they could move back to tertiary care should the need arise.

The provision of "take-home" doses of methadone is generally controlled due to service providers' fears of accidental overdose, abuse or diversion of prescribed doses (Binchy et al 1994, Calman et al 1996, Cairns et al 1996, McCarthy 1997, Harkin et al 1999, Neale 2000). Despite the implicit risks, this survey found that many Irish patients were regularly being dispensed methadone to "take-home". This survey also found that CRCs were widely, but not exclusively used when dispensing methadone. The respondents who were attending community pharmacies reported a greater incidence of the use of CRCs than that reported by community pharmacists participating in Survey 3 (see Chapter 5). The use of CRCs on dispensed methadone doses is recommended by the Pharmaceutical Society of Ireland (McDermott 1999) and by the Pharmaceutical Society of Great Britain (1991) as they are essential in reducing the risk of accidental overdoses among children of patients in methadone treatment. The more frequent provision of child-resistant containers reported by parents suggests that the pharmacists dispensing their methadone recognised the dangers associated with "take-home" methadone doses. Pharmacist involvement in the determination of patients' attendance and supervision regimens could ensure that this issue was taken into consideration in the management of patients who are parents.

The reported supply of measures with multi-dose methadone dispensings was low and was no more common among patients who were parents. This was of particular concern in light of the reported level of use of babies' bottles to measure methadone. This did not appear to have been affected by the introduction of the MPS or the documented association between their use and child fatalities (Harkin et al 1999). A more concerted effort is required to ensure that the health promotion message regarding the relationship between the use of babies' bottles and child overdose reaches both community pharmacists and patients in methadone treatment.

When examined in relation to patients' current dispensing sites, DTC pharmacies complied with good practice guidelines more often than community pharmacies. This suggested that the implementation of good practice guidelines was an issue for the Pharmaceutical Society of Ireland (in conjunction with the Irish Pharmaceutical Union

and the Department of Health & Children) rather than for the E.H.B.'s Addiction Service, and should be addressed urgently to promote better standards of care.

While most respondents recognised the value of tertiary methadone treatment services, the majority of the patients surveyed expressed a preference for being dispensed their methadone at community pharmacies and those currently attending community pharmacies were generally "happier" than those in DTC pharmacies. Patients' attitudes towards community pharmacies appeared to become more positive as their current regimens became more tightly controlled within a tertiary drug treatment setting. This suggests that it is possible that their preference for community-based methadone treatment was related to a belief that it would be less strict. This has implications for community pharmacists, who may have to deliver strict dispensing regimens to patients with expectations such as these and may resent this level of structure in their treatment programmes. Efforts should be made to clarify the role of community and tertiary methadone dispensing services, so that patients understand the value of both treatment sites.

This study found that difficulty with DTC pharmacies' opening hours was associated with a patient preference for attending community pharmacies. Other factors (for example, the location of the DTC or the assumption that patients in community pharmacies attend less frequently) may also have affected this finding. However, it suggests that the extension of opening hours at DTC pharmacies is one of the ways in which tertiary methadone treatment services could be made more attractive to patients. In particular, DTCs that offered methadone dispensing services outside office hours could facilitate the attendance of patients who worked.

Lack of privacy in the community pharmacy setting discouraged patients from drinking methadone on-site, and the provision of adequate privacy is a major challenge to pharmacists who provide this service. A survey carried out in Glasgow suggested that more patients would accept or even welcome supervised dosing if their privacy was protected (Neale 1999). Patients on methadone in the UK also complained about a lack of privacy (Matheson 1998a, Luger et al 2000) as did one Australian study (Ezard et al 1999). Community pharmacists should be encouraged to improve the level of privacy they offer to patients who drink methadone on-site, to protect the confidentiality of their

patients on methadone. The provision of DOHC grants for the modification of pharmacy premises to create private areas for the on-site supervision of methadone was one pragmatic approach to this issue, although many community pharmacies did not avail of them. Further research into patients' needs and expectations could be helpful in determining the ways that community pharmacists could facilitate them.

Some patients who reported adequate privacy in the community pharmacy also reported feelings of embarrassment, which suggested that their embarrassment was separate to their need for privacy. Embarrassment that is unrelated to privacy may be due to perceived negative attitudes among dispensing pharmacists or other pharmacy staff, which can result in stigmatisation (Sheridan & Barber 1996). These feelings of stigmatisation have been associated with negative behaviour among drug misusers (Matheson 1998c) and should be addressed to avoid confrontation in community pharmacies. Community pharmacists and other pharmacy staff should be trained to accept and respect their patients on methadone, and should be encouraged to use the provision of supervision as an opportunity to support and advise patients. This would make the supervision process more therapeutic and beneficial for patients and could reduce the incidence of conflict between them and the pharmacists who supervise them.

These findings highlight the need to make tertiary care methadone dispensing services more attractive to patients in the MPS by addressing key issues such as their opening hours. The MPS must also endeavour to recruit additional community pharmacists to meet the need for primary-care based services for those in methadone treatment. In addition, the MPS must ensure that community pharmacists participating in the MPS afford their patients full privacy in the course of their treatment, and that these community pharmacists hold positive attitudes towards their patients, thereby avoiding feelings of stigmatisation, and encouraging patients to participate fully in their methadone treatment programmes.

Convenience is very important to patients and needs to be maximised if treatment services are to be user-friendly and accessible. Convenience was the primary reason cited for their choice of methadone dispensing service by patients in one London study (Lovell et al 1999). The time patients spend travelling to their methadone dispensing service is one indicator of service convenience, and short travel times were reported as

a positive aspect of community-based methadone dispensing services by participants in one UK study (Luger et al 2000). This survey found patients had an average of almost twenty minutes one-way travel time, which, while comparable with travel times reported in one Australian study (Ezard et al 1999), may indicate that their attendance at methadone treatment caused considerable disruption to their lives.

The allocation of patients to pharmacies which resulted in them travelling for considerable lengths of time, particularly during the initiation of methadone treatment or during periods of change or instability when their attendance frequencies were high, reduced service convenience and may have been a barrier to participation in methadone treatment. One study carried out in Dublin suggested that the commencement of a treatment programme resulted in a state of vulnerability for parents and their children of primary school age equal to that experienced when parents engaged in high frequency heroin use (Hogan & Higgins 2001), and treatment regimens should try to avoid causing additional stress at that time.

At the moment patients in the MPS are allocated to a community pharmacy near their registered residence, but with increasing levels of employment among patients in methadone treatment (Farrell et al 2000), it is possible that this approach is not the most efficient. While the recruitment of community pharmacies to the MPS is essential to ensure that community-based methadone dispensing services are geographically adequate to meet patient demand, this finding may also justify a review of the process involved in the nomination of pharmacies for individual patients.

Patients surveyed here reported short pharmacy waiting times, which were comparable with those associated with improved systems in hospital outpatient pharmacies. For example, an intervention by O'Malley (1990) reduced average waits from 5-43 minutes to 9-13 minutes, Webb and colleagues (1995) reduced patient waiting times from 40 minutes to 4 minutes and Boyce and O'Hare (1998) increased the percentage of prescriptions dispensed within 10 minutes from 12% to 26%. Shorter waits for those in methadone treatment may reduce patients' exposure to other drug misusers and the drug scene. Waiting times were no different for parents, which highlighted the need for crèches and other child care facilities, particularly at DTCs. Yet while participants waited relatively short periods for their methadone to be dispensed, researchers reported that

this was not universally perceived in a positive light. The issue of patient waiting times was not explored in a qualitative manner in this study, and should be investigated more thoroughly to gain insight into the factors involved.

This survey revealed that pharmacists had refused to dispense methadone to a number of respondents for a variety of reasons. Prescription problems were the most frequently reported reason respondents believed pharmacists had refused to dispense their methadone, which highlighted a lack of cohesion and co-operation within community-based methadone treatment services. Since this issue directly affected patient care, it should be addressed and resolved by organising training initiatives for methadone prescribers and encouraging team building efforts to strengthen relationships between the primary carers working together in the MPS.

The second most commonly reported reason for pharmacists refusing to dispense their methadone related to the pharmacists' belief that patients were intoxicated. It could not be ascertained whether respondents had actually been under the influence of drugs or alcohol in these instances, but assuming that they were, pharmacists' refusals showed confidence in their own ability to recognise the signs and symptoms of intoxication. It also showed that they were aware of potential overdose situations and safety issues for their patients. In addition, it showed their confidence in their ability to manage conflict situations with their patients. Training in recognising the signs and symptoms of intoxication and clearer guidelines on how to manage intoxicated patients could be helpful for pharmacists who dispense methadone. Such guidelines could also help to standardise the procedures followed, and make the process more transparent and predictable for the patients involved.

Despite the strict regimens enforced by the MPS, with limited methadone dispensing hours and reports of pharmacists refusing to dispense methadone doses, inadequate privacy and patient embarrassment in community pharmacies, almost all participants indicated that they had "good" relationships with the pharmacists that dispensed their methadone. Positive attitudes towards pharmacists who dispensed methadone were also reported by one UK study (Sheridan & Barber 1996). The extent to which pharmacists participating in Survey 3 (see Chapter 5) also reported that patients on methadone were easy to manage suggested that the MPS had established a workable

structure which facilitated both service providers and service users. These findings suggested that the level of control that had been enforced by the MPS had provided adequate structure to allow both pharmacists and patients to operate comfortably at this stage. However, analysis of attitudinal data suggested that there was an element of "tension" in the pharmacist/patient relationship, which merits further investigation.

Research has shown that community pharmacists can positively influence patients in smoking cessation programmes (Maguire et al 2001) and that the provision of structured pharmaceutical support mechanisms can increase patient satisfaction (Bernsten et al 2001). Further qualitative insight into the relationship between community pharmacists and patients in the MPS could help to clarify the role of the community pharmacist from the patient's perspective, and could be useful in planning future developments in this role. Further investigations could also help to identify the criteria that determined participants' overall satisfaction with their dispensing services and in exploring the nature of the pharmacist/patient relationship.

Despite high patient satisfaction with how their methadone was dispensed, methadone 1mg/ml was frequently associated with a number of self-reported side effects. As seen elsewhere (Zule & Desmond 1998), many of these side effects continued to affect patients throughout their time in treatment. Many patients had experienced long-term side effects while in methadone treatment, including constipation, nausea and drowsiness, all of which are generally related to methadone (Preston 1996) and excessive sweating, weight-gain and dental decay, which have also been associated with methadone 1mg/ml in Ireland (Larkin 1999).

The incidence of methadone-related adverse effects suggested that those endeavouring to treat Irish opiate misusers should consider making an alternative opiate substitute available. For example, buprenorphine is widely used elsewhere (EMCDDA 2000a) and is of proven value in the treatment of opiate addiction (Schottenfeld 1997, Fischer et al 1999b, Duburcq et al 2000), although evidence-based research is limited compared to that supporting the use of methadone.

In addition, pharmacists working with patients on methadone should be aware of the side effects patients are likely to experience, be able to advise patients on their severity

and duration, and recommend practical measures to alleviate them. Specialist training should be provided for community pharmacists imparting this information under the MPS. Written documentation such as "The Methadone Handbook" (Preston & O'Connor 1998), which was revised for Irish patients prior to the introduction of the MPS, should also be utilised in explaining the properties of methadone to those participating in the scheme.

The formulation of their methadone was also important for most respondents, yet Survey 3 carried out concurrently among community pharmacies in the MPS (see Chapter 5) reported that most of them stocked only one formulation of methadone 1mg/ml and only a minority "always" dispensed the formulation of methadone chosen by their patients. In addition, their transfer from Physeptone® to methadone 1mg/ml was among the negative effects participants associated with the introduction of the MPS. This issue may have been a source of conflict between pharmacists and patients in the MPS, resulting in ongoing physical and psychological distress.

This phenomenon has also been documented elsewhere, with methadone's formulation reported to be important to those in methadone treatment in the UK (Neale 1998, Lovell et al 1999) and resistance to formulation change also reported among patients in methadone treatment (Steels et al 1992, Silver & Shaffer 1996). Pharmacists should be more sensitive to patients' views on the formulation of their methadone. Qualitative research that provided a clearer understanding of patients' perceptions of their methadone formulation might help methadone manufacturers and service providers to better meet patients' needs.

The introduction of the MPS in October 1998 affected over half of this cohort of drug misusers, almost two-thirds of whom reported positive outcomes. The fact that the introduction of the MPS did not disrupt many patients' treatment services was probably due to the establishment of numerous services under the MPP, as these services retained their patients following the introduction of the MPS. Nevertheless, the high incidence of positive outcomes among those affected supports the original hypothesis of this research, that the MPS would have a positive impact on patients in methadone treatment in Ireland.

The provision of free methadone treatment under the MPS was a commonly reported positive outcome and may have made methadone treatment more accessible to hidden drug misusers as well as improving retention rates (Wells et al 1995, Kwiatkowski et al 2000). It may also have reduced the incidence of conflict between patients and community pharmacists because Australian research suggests that payment is a primary reason for argument in the pharmacy (Muhleisen et al 1998). These data suggest that the MPS is an accessible, user-friendly way of providing methadone treatment for Irish opiate misusers.

However, the tightening of access to methadone treatment and the restrictions imposed on those participating in the scheme did cause problems for patients. Irish drug treatment services have historically struggled with the need to balance treatment controls with patient care (Butler 1991). But in spite of this, service providers must strive for a balance between maintaining control over the supply of methadone and allowing for the individualisation of treatment programmes, which may ultimately produce better treatment outcomes, and mechanisms that facilitate such a balance should be investigated and implemented.

# CHAPTER 9: Qualitative investigation of Service Users' Views

A qualitative investigation into the views of patients and others on key aspects of pharmaceutical services provided under the MPS.

Date	Stage in MPS	Study title	Participants	No. respondents	Southern sectors of the EHB region		
February 1998	Pilot (MPP) underway	Pharmacy Survey 1	All community pharmacists	201			
August 1998	Interim phase in introduction of MPS	Pharmacy Survey 2	Community pharmacists who dispensed methadone 1mg/ml	99	Nation-wide		
March 1999	MPS established	Pharmacy Survey 3	Community pharmacists who dispensed methadone 1mg/ml	153	Nation-wide		
after March 1999	MPS established	Longitudinal Study	Community pharmacists who responded to more than one of the above surveys	Varied, as specified in text	Southern sectors of the EHB region		
June 1998 to May 1999	Pilot (MPP) & MPS	Liaison Queries	All enquiries received by the liaison pharmacist	848 enquiries	Southern sectors of the EHB region (primarily)		
March 1999	MPS established	Patients' Views	Patients in methadone treatment	217	Nation-wide		
February 2001	MPS established	Qualitative interviews	Drug misusers, ex- drug misusers, patients in methadone treatment, service providers	15	Three non- prescribing support service		

#### 9.1. INTRODUCTION

A number of issues described in the earlier quantitative studies of patients' view on pharmaceutical services under the MPS required more in-depth investigation, which could be best carried out using qualitative interviewing techniques, because of the recognised limitations of quantitative surveys (Bryman & Bulmer 1988, Davies 1989, Oppenheim 1992, McKeganey 1995). In addition to its own intrinsic value, data derived from this qualitative study carried out more than two years after the original quantitative work could be compared with findings from the earlier survey of patients' views (see Chapter 8) to validate them and facilitate their interpretation (Denzin 1970, Bryman & Bulmer 1988, Brannen 1992, Robson 1993, O'Muircheartaigh 1999, Schwartz & Sprangers 1999). As the researcher resigned from the E.H.B. after the quantitative studies were carried out, this qualitative work was not compromised by bias associated with the researcher's status as an E.H.B. employee.

# Aim:

To investigate, in a qualitative manner, aspects of pharmaceutical services for those in methadone treatment in Ireland under the MPS.

#### Objectives:

- To investigate key aspects of pharmaceutical services for patients in the MPS.
- (2) To explore aspects of methadone dosing under the MPS.
- (3) To examine patients' views on methadone as a medicine used as a substitute for heroin in the treatment of opiate addiction.
- (4) To explore the relationship between service users and the pharmacists who dispensed methadone under the MPS.

#### 9.2. METHOD

The purpose of these exploratory interviews was to collect qualitative data on a number of key ideas and hypotheses that emerged from the previous quantitative work with patients participating in the MPS. These data had identified key areas where further

exploration and interpretation was necessary to gain better insight and full clarification of respondents' views.

Four aspects of the pharmaceutical services provided for patients in methadone treatment under the MPS were identified for exploration. The quantitative survey (see Chapter 8) suggested that patients regarded their waiting times (i.e. how long patients waited for their methadone to be dispensed) and their dispensing sites (i.e. community pharmacies or DTC pharmacies) as important aspects of their pharmaceutical services, so they were explored in more detail here. In addition, work carried out in the UK had suggested that privacy and stigmatisation were two important elements in the provision of community pharmacy-based methadone dispensing services (Sheridan & Barber 1996 & 1997, Matheson 1998a, 1998b, 1998c) and they were also examined by this qualitative study. These interviews also examined the process of methadone dosing, characteristics associated with methadone as a medicine and the nature of the pharmacist/patient relationship.

In addition to the exploratory nature of this qualitative work, the time lag between the quantitative survey and this qualitative work meant that this study had a longitudinal aspect, looking at changes in patients' views during that two year period. Longitudinal data has intrinsic value in reducing threats to validity (Litwin 1995).

Mixing research methods can enhance the overall value of a study by cross-validating findings or by excavating or interpreting new phenomena (Denzin 1970, Bryman & Bulmer 1988, Brannen 1992, Robson 1993). In addition, the literature suggests that more complex or in-depth information is best derived using qualitative research techniques (Caplehorn & Saunders 1993, Chernomas 1997, Maher et al 1999, Schwartz & Sprangers 1999) and has also indicated that self-report can produce useful, reliable data from drug misusing populations (Darke 1998).

The researcher aimed to investigate previously identified issues by carrying out semiinductive, exploratory interviews with a purposeful sample of key individuals. Semistructured interviewing techniques that were influenced by feminist theory were used to introduce key topics as unobtrusively as possible (Robson 1993). Otherwise the researcher allowed the interviews to develop deductively, using findings from the earlier quantitative survey of patients' views as a framework to examine interviewees' views and attitudes (see discussion topics in Appendix A.9.1.). Themes that emerged from early interviews were actively introduced in subsequent interviews, which improved internal validity of this study (Huberman & Miles 1998). This approach has also been used elsewhere to explore sensitive issues with patients undergoing medical treatment (Chernomas 1997).

## 9.2.1. Sample

A purposive sample of fifteen current or ex-opiate users and other key individuals was selected via personal contacts and using "snowballing" techniques, without input from or contact with any methadone dispensing service.

Purposive sampling involves guiding the selection of subjects according to the specific needs of the project, and is commonly used in case studies (Robson 1993). "Snowballing" techniques use initial subjects as informants to access populations of interest, and can be seen as a particular type of purposive sampling. More systematic and rigorous methods could have resulted in a more representative sample (McKeganey 1995) but purposive sampling and "snowballing" techniques are often preferred when there is difficulty in identifying and accessing members of the population of interest (Lee 1993, Robson 1993) and have been found effective in investigating illicit activities (Biernacki & Waldorf 1981, Power 1989).

Individuals who had not experienced methadone treatment under the MPS, but who were in direct contact with the drug using community were also included as "front-line" indicators of prevalent views and opinions (Mayock 2001). Although one GP was used as a source of interviewees, accessing potential interviewees via contacts at methadone services was generally avoided to reduce external bias due to respondents' hopes or fears that their treatment could be affected by their participation in the study or the views that they expressed. In addition, in an effort to gain a broad impression of the views of drug misusers on the pharmaceutical aspects of methadone treatment, this study also contacted people who had never or were not currently participating in such treatment programmes, but who had close ties with drug misusers and methadone treatment services.

As the study aimed to amass views on pharmaceutical services, particularly in the community pharmacy setting, those who held firm views on this subject were positively sought out for inclusion in the study, while the participation of those who had more limited experience of methadone treatment or less well-formed views on its pharmaceutical aspects was not followed up to the same extent. In addition, participants were chosen to be socially representative by including people who were likely to hold a range of diverse and sometimes opposing views (O'Muircheartaigh 1999).

Since purposive samples do not meet requirements of probability sampling, statistical assumptions about sampling errors and the establishment of population parameters did not apply. Nevertheless, the researcher attempted to access respondents with a broad range of characteristics, views and experiences of the pharmaceutical aspects of methadone treatment. The researcher aimed to access interviewees with differing drug use histories and whose methadone treatment histories included the following:

- (i) Problem opiate users, never prescribed methadone.
- (ii) Never treated under the MPS, previously prescribed Physeptone®.
- (iii) Previously treated under the MPS, not currently in methadone treatment.
- (iv) Currently participating in the MPS, previously prescribed Physeptone®.
- (v) Closely connected to drug misusers or methadone treatment services, never prescribed methadone.

Interviewees were contacted on a one-off basis and no records were retained regarding their names or contact details. This meant that the data could not be proofed by participants prior to their inclusion in the study, which left them open to potential misinterpretation by the researcher. Nevertheless, the value of anonymised data such as these in the investigation of sensitive topics is supported by the literature (Walton et al 1999).

### 9.2.2. Interview Locations

Interviews were carried out at three different sites to facilitate access to a broad variety of interviewee characteristics. No interviews were carried out at a methadone prescribing or dispensing site.

The original sites targeted by the researcher were:

- (1) UISCE: Union for Improved Services, Communication and Education, an organisation established and run by current and ex-drug misusers to represent the interests of themselves and their peers.
- (2) An inner-city needle exchange service with a drop-in centre used by drug misusers from all parts of Ireland.
- (3) A GP's surgery in a south west Dublin suburb.

Staff at UISCE co-operated fully with the research initiative, with the project manager facilitating the participation of several interviewees by organising meetings and providing a suitable venue for these meetings. The venue provided was the service's drop-in facility, which was accessible to all service users. Interviews were organised for off-peak times so that the drop-in was relatively quiet, to facilitate privacy and better sound quality during taped interviews. Five people were interviewed at this location.

Following repeated contacts with management at the inner-city needle exchange and drop-in, it transpired that there were practical difficulties in gaining direct access to its patients. However, when the researcher visited the project, staff suggested that the research could be undertaken at a local back-to-work initiative, TURAS, as there was a high overlap in the clientele. TURAS is a state-funded employment initiative for people living in the Dublin 8 area of south central Dublin. The management at TURAS were subsequently approached and they were prepared to allow their service to be used as an alternative access point. The project manager organised a date for the interviewer to attend the service. She informed service users in advance that the researcher would be on-site that day, and facilitated the participation of those willing to get involved by providing a private room on-site where the interviews could take place. Four people volunteered to get involved and were included in the study at this location.

The GP who participated in the study wrote to a cross-section of his patients on the MPS (12/45) and asked them if they were interested in participating in an independent research initiative looking at pharmaceutical aspects of their methadone treatment. Two patients responded and the GP put them in direct telephone contact with the researcher. One patient contacted the researcher but subsequently failed to attend a pre-arranged interview. The second patient arranged to meet the researcher at *Pathways*, a back-to-

work programme for ex-prisoners, which is located in north Dublin city centre. When the researcher attended *Pathways* to carry out this interview, the interviewee spontaneously encouraged others to get involved, thereby becoming a primary informant in accessing people attending an inner-city post-prison programme. "Snowballing" resulted in two additional individual interviews and one group interview at the *Pathways* project.

# 9.2.3. Pilot & preparatory work

As it evolved from the findings of a full quantitative investigation of patients' views, this qualitative study of their views was not piloted. Instead, key findings from the quantitative work were used as a deductive guide for the interviews, and interim analysis of findings from early interviews helped to further refine the issues and in adapting the techniques employed in subsequent encounters. Issues to be investigated were also discussed in advance with a service provider who was a GP co-ordinator and methadone prescriber (Dr John O'Grady) and one patient representative (Mr Tommy Larkin, co-ordinator of UISCE). The study aimed to investigate and explain the relationships between data in a set of conceptually specific analytical categories, while also allowing theory to emerge inductively from the data.

The study protocol was written and initial contacts were made with management at the interview sites in January 2001, with interviews taking place in February and March of that year.

### 9.2.4. Interviewing Techniques

Drug misusers can be problematic to access and engage, and it can be difficult to develop a rapport with them, thereby ensuring honesty and full disclosure. In an effort to make the interviews more honest, morally sound and reliable, a post-positivist paradigm which was influenced by feminist-based theory was employed i.e. empathy and emotional engagement were used to develop a trusting relationship between the interviewer and the subject (Robson 1993). This was in contrast to the scientific, positivist approach, which frowns on interviewer involvement, and emphasises the value of detachment and role differentiation between interviewer and subject (Denzin & Lincoln 1998).

The researcher was experienced in working with drug misusers and had lived in Dublin for a number of years, which enabled her to use and understand the language and culture of those interviewed. Non-verbal and visual elements were also addressed (Denzin & Lincoln 1998) in an effort to improve the spontaneity of the responses, as self-reported qualitative research is intrinsically more susceptible to reactivity and to demand characteristics than quantitative study, and responses can be influenced by the presentation of interview themes and questions (Schwartz & Sprangers 1999). All research topics were introduced with interviewees but they were encouraged to focus on the issues that were of most importance to them. This meant that every issue was not discussed to the same extent during every interview. Care was also taken in exploring retrospective events as research has shown that memory is related to a number of cues, which must be specific enough to trigger recall yet general enough to avoid excluding vital data (Shum & Rips 1999).

Most of the interviews were carried out spontaneously, with only two being carried out at a pre-arranged time and place. Some people who expressed an interest in participating in this study failed to attend pre-arranged interviews and their views were not collected. These instances could be construed as refusals to participate, although no data was available as to why they did not present for interview. Interviews were held in private and at the convenience of the interviewees. Participants themselves decided whether they were interviewed individually or as part of a group of their peers. Each was read an introductory statement prior to their participation in the project (see statement in Appendix A.9.2.).

Group interviews were carried out with participants and researcher seated around tables, with all participants being equally able to make eye-contact with the interviewer. The interviewer introduced key topics (see Appendix A.9.1. for details), initiated debate between participants and then remained relatively silent, so that the issues were discussed without external interruption or direction, making them essentially similar to group discussions. However, care was taken to ensure that individuals did not dominate the group forum, and the researcher elicited the views of less forthcoming participants in instances where they appeared to be overshadowed or in the minority within the group setting.

# 9.2.5. Ethics & Confidentiality

Ethical considerations were of primary importance when undertaking this qualitative study as the issues involved were sensitive and personal in nature. Potential conflict between service users and service providers was avoided by undertaking the study in non-prescribing service sites. But this also had ethical implications as the identification of an individual as someone who is (or was) familiar with methadone treatment by their inclusion in this research study could have far-reaching social and personal implications for them.

Therefore, to avoid their identification as current or ex-opiate users, or as patients in methadone treatment, the researcher did not directly approach potential interviewees. Instead, a number of alternative approaches were used to overcome this ethical dilemma. In UISCE the project co-ordinator introduced the researcher to a number of people whom he knew to have views on pharmaceutical services for those on methadone. A GP asked a subset of his patients if they were interested in participating in the study, before putting them in direct contact with the researcher. In *Pathways*, an interviewee identified via this GP, informed his peers about the study, resulting in their subsequent participation. In TURAS the project manager informed all service users that the study was taking place and facilitated their voluntary participation by allowing the interviews to be carried out on-site.

The protocol for this study included an introductory statement, which was read and explained to participants on an individual basis prior to their interviews (see Appendix A.9.2.). Those who participated in the study did so on a voluntary basis and no incentives were given. As interviews were not held on premises with methadone prescribing or dispensing services, these aspects of interviewees' lives remained totally confidential and unaffected by their participation in the study.

Interviewees were afforded the maximum possible privacy during interviews. Participants were also free to determine whether they were interviewed individually or as groups. Once participants' verbal consent was given, a dictaphone was used to tape the interviews and it remained visible to participants at all times.

Interviewees were contacted as described above, with most being accessed via their peers using "snowballing" techniques, without formal introductions being made. Given that participation was voluntary, there were no incentives and subjects were totally anonymous, it was felt that the introduction of a written consent form might create a sense of officialdom, which might alienate subjects and become a barrier to participation. Robson (1993) cites instances including researching sensitive topics such as drug abuse, where an informal approach and verbal agreement are regarded as more appropriate than asking for written consent.

Therefore, given the limited demographic and medical details necessary for the purposes of the study and in order to avoid confrontation and potential refusals, it was decided to forego requesting written consent from participating individuals. Instead, the agencies where research was undertaken provided informed written consent. In addition, potential participants were informed of the nature and purpose of the research and the procedures involved ,should they agree to participate. They were advised that the content of their interviews with the researcher was totally anonymous and confidential, and that it would be recorded on tape using a dictaphone. Potential participants were also guaranteed that the content of the tapes would not be linked to them as individuals or to their methadone treatment services and that the tapes would be destroyed within two months of the interview date. Having been informed of the purpose of the study and the process involved should they agree to participate, the researcher accepted verbal consent as adequate for their inclusion in the study.

### 9.2.6. Analysis

As agreed in advance with interviewees and with the written consent from interview site managers (see consent forms, Appendix A.9.3.), all interviews were recorded on tape using a small, unobtrusive dictaphone. Each interview was fully transcribed using Microsoft Word and documents were coded manually into broad themes during the data management stage. The transcripts were subsequently imported into QSR N5 for more detailed analysis.

QSR N5 is a computer software package previously known as NUD\*IST, an acronym for Non-numerical Unstructured Data Indexing Searching and Theorising. It is designed to facilitate the analysis of responses to open-ended questions. QSR N5 allows the

researcher to code interview transcripts and subsequently analyse and explore that coding, regardless of the research methods or philosophies employed. It can manage data which are both sensitive and complex, and can separate individual ideas while also grouping them into general themes. This is done using the QSR N5 "node" system, which stores data in an easily accessible manner. Memos were written throughout the analytical process, both manually and using the QSR N5 package, to facilitate easy access and recall of new and emergent themes (Miles & Huberman 1994, Gahan & Hannibal 1998).

Although the interviews were concerned with a number of predefined themes, QSR N5 also enabled the researcher to identify additional emergent themes and sub-themes. The analysis resulted in the data being initially grouped into a number of broad themes, which were each subsequently subdivided into several related categories or sub-themes. These categories evolved inductively through a study of the data via repeated reading of the interview transcripts (Bernard 2000). QSR N5 allowed the study findings to be recorded inductively and the findings were then analysed retrospectively in light of the original themes being explored. Emergent themes and patterns were recorded and verified retrospectively by carrying out comparisons between portions of the data.

Individual coded categories were examined to assess internal consistency. Divergence within these categories was also noted and negative instances were recorded. These analyses resulted in the development of a number of central issues, on which respondents held a variety of (sometimes conflicting) views. The number of respondents that held each view was also noted. The analysis recorded generally accepted and deviant views, as analysis of these deviant views was useful in refining the ultimate study findings (McKeganey 1995). The quantification of commonly held views and the presentation of negative evidence helps to avoid anecdotalism and improve internal validity (Lincoln & Guba 1985, Seale 1999).

Due to the volume of data collected, all of the themes discussed could not be reported here. Therefore, the analytical process assessed the relevance of the data to the research project as a whole, and included only that which was most pertinent to the overall study aims. Some of the responses collected in the course of this study were quoted in the text to illustrate the themes and views that emerged and ensure that

respondents' views were represented accurately. All participant names have been changed to protect their anonymity. A full audit trail is available on this study, which can be used to confirm its credibility (Lincoln & Guba 1985).

## 9.2.7. Reliability & Validity

Since qualitative studies aim to explore issues within an identified community, rather than to quantify characteristics of a general population, authenticity is a more important feature than either reliability or validity (Lincoln & Guba 1985). As discussed earlier, self-report among drug misusers has been shown to produce reliable data (Adair et al 1995 & 1996, Darke 1998). Although self-report is not without its limitations (May & Foxcroft 1995, McKeganey 1995), all efforts were made in the course of this research to minimise these limitations and produce authentic data.

The researcher attempted to establish a balance of power with interviewees by using their terminology, dressing in their style of clothing and interrupting their responses as little as possible. Facilitation of the group interviews was unobtrusive, with the researcher intervening only to introduce new topics and to clarify confused or contradictory comments. The low level of researcher involvement in all interviews resulted in diffuse power relations and enabled participants to develop issues according to their own views rather than in response to direct questions or externally imposed criteria (May & Foxcroft 1995).

When targeting subjects for inclusion in this study, efforts were made to avoid direct contact or association with any pharmacist or pharmacy involved in the provision of methadone under the MPS. Interviews were carried out at neutral venues rather than at methadone prescribing agencies. Although the sample was not intended to be representative, attempts were made to include a diverse group of participants by using a number of different research sites which had different purposes and were located in different geographical areas (McKeganey 1995).

In addition, all interviews were carried out by the same researcher, who was a pharmacist, but was not employed by the E.H.B. and had never dispensed methadone to any of the participants.

These aspects of the research methods should have improved the authenticity of the findings by diminishing sources of external, researcher and subject bias. This approach also overcame limitations of the earlier quantitative survey of patients' views (see Chapter 8) where many respondents were interviewed on-site at their methadone dispensing services and a number of researchers were involved, some of whom were pharmacists who had previously dispensed methadone to interviewees.

Test-retest reliability measures were not attempted here as interviewees had agreed to participate in the study on the understanding that they could remain anonymous and untraceable. In addition, the rapid changes taking place during this period could have resulted in significantly different responses to similar enquiries even using relatively close time points (Litwin 1995). While replication was impossible here, the study could theoretically have been repeated using another purposive sample, although many argue that this is not an issue when assessing the value of findings from qualitative studies as the findings do not purport to have external generalisability (Bryman & Bulmer 1988, Robson 1993, Seale 1999).

This study used a small, purposive sample designed to provide feedback on a number of key pharmaceutical issues as identified by the earlier quantitative survey of a sample of patients in methadone treatment under the MPS (see Chapter 8). The use of a sole researcher, while encouraging unstructured, inductive research, may have reduced the potential generalisability of study findings, as they cannot be validated by data from other researchers in the same team (Bryman & Bulmer 1988). In addition, the interpretation of participants' response may have been biased by the researcher, thereby affecting study findings. Second coding of the data by another researcher could also have strengthened the validity of the study findings.

The interpretative approach used in this study, by focussing solely on the pharmaceutical aspects of people's methadone programmes, risks highlighting issues which, although important within this framework, were actually relatively inconsequential in respondents' overall impression of methadone treatment. The use of a broader, more inductive interviewing technique could have identified different issues than those emphasised in this study. The absence of data from such interviews may undermine the validity of these study findings. However, internal validity will have been improved by

using findings from an interim analysis of data from early patient interviews in adapting the approach adopted in later interviews (Litwin 1995, Huberman & Miles 1998). In addition, three totally different research locations were used to access potential participants, which will also have strengthened the validity of the study findings.

#### 9.3. RESULTS

## 9.3.1. Demographics

To avoid resistance from participants and to ensure total anonymity, little demographic data were requested. Table 9.1. gives details of the data that were known, with age groups being estimated by the researcher. Pseudonyms have been given to participants to facilitate differentiation and association of views.

Table 9.1: Demographic information on participants (N=15).

	Derry	John	Ray	David	Richie	Tom	Terry	Elaine	Kate	Charlie	Lisa	Jim	Mick	Dave	Peter
Gender	M	M	M	М	M	M	M	F	F	M	F	М	M	M	M
On methadone	Υ	Y	N	N	N	Υ	N	N	N	Υ	Υ	Υ	Υ	Y	Υ
Previously prescribed Physeptone®	Υ	Υ	Υ	N	Υ	Υ	Υ	Ν	N	?	?	?	Υ	?	Υ
Ever in DTC?	Υ	Υ	Υ	N/A	Υ	Υ	Υ	N/A	N/A	Υ	Υ	Υ	Υ	N	Υ
Ever in CP?	Υ	Υ	Υ	N/A	Υ	Υ	Υ	N/A	N/A	N	Ν	Ν	Υ	Υ	Υ
Where now?	CP	CP	N/A	N/A	N/A	DTC	N/A	N/A	N/A	DTC	DTC	DTC	CP	CP	CP
Interview site	P	P	Р	Р	Р	P	U	U	U	U	U	Т	Т	Т	Т
Age*	40's	20's	20's	30's	20's	40's	40's	30's	20's	40's	20's	20's	20's	20's	20's
I/G**	1	G	G	G	1	1	1	1	1	1	1	1	G	G	1

<sup>\*</sup> estimated by the researcher

Six of those interviewed were not currently on methadone, although at least three of these had previously been prescribed methadone (methadone 1mg/ml, Physeptone® or both) and one other participant had previously acquired illicit supplies. Over half (8/15) of those interviewed had been prescribed Physeptone® prior to the introduction of the MPS. David had never been prescribed methadone but he had bought and taken black-

<sup>\*\*</sup> G = group interview, I = individual interview

market Physeptone®. Both Ray and Richie had been prescribed methadone 1mg/ml but were not currently in methadone treatment.

Twenty percent (3/15) of those who participated in this study were female, but only one of them was currently in methadone treatment. Nine of those interviewed were estimated to be aged between 20 – 29 years old, two were in their 30's and four had an estimated age of 40 years or older. Of those who were currently on methadone, six were aged 20 – 29 years old and three were aged 40 years or older.

Eleven participants (11/15) had previously attended a drug treatment centre and three of those who had been prescribed methadone had never had their methadone dispensed at a community pharmacy. Of those who were currently participating in the MPS, five were attending community pharmacies and four people had their methadone dispensed at drug treatment centres.

# 9.3.2. Key aspects of pharmaceutical services under the MPS

The earlier survey of patients' views (see Chapter 8) reported that patients were not obliged to wait very long for their methadone to be dispensed, but it appeared to the researchers that this speedy service was not always regarded favourably by the patients involved. As the wait for methadone to be dispensed is an ongoing condition of methadone treatment it is important that service providers, particularly pharmacists, gain an understanding of the processes involved from the patients' perspective. Therefore this qualitative survey undertook to identify the key issues and to examine how patients were affected by the speed of their dispensing service.

It appeared that this issue was quite complex, with several aspects involved. There seemed to be a fine line between serving patients too quickly and leaving them waiting too long, both of which were perceived as disrespectful. Patients seem to want to be served reasonably quickly but they did not want to be served out of turn as they saw this as stigmatising them, and believed it was done with people who misbehaved or were not trusted in the pharmacy.

**John:** Yeah, there's an awful lot of robbery to go with it (dispensing methadone) ...I think that's why they get rid of them ones (patients on methadone) first, 'cos they don't want bag men (shoplifters) hanging around. But I don't look like that (a drug misuser) – I really don't – now I know that

myself. I have noticed people that come in that are like kinda' like – they look the part – they're in and out – which I'm not. I just go in and sit down. I'd say hello and that and just sit and look at the people coming and going and the aftershaves, perfumes for her (partner) or whatever...

Researcher: But do you not mind them keeping you waiting?

**John:** Yeah, sure I was there a while, but I'm glad they don't treat me like the others.

Some participants had experienced or witnessed prolonged delays, some of which they felt were unnecessary, and contrived by dispensing pharmacists as a way of punishing patients. Many complained that these delays disrupted other aspects of their lives, particularly their jobs.

**Derry:** I can think of one (pharmacist) in particular and he does loads of methadone prescriptions. And on the particular mornings you'd have to go in and the methadone would be all ready. And still the pharmacist would say to a couple of them (patients) "it's not ready, come back later". And the person who he's saying it to would know full well that it's ready but for one reason or another the pharmacist would have had a run in with them or he didn't like them and he'd make them come back. So I'm just making the point that there is some pharmacists that can make things difficult for people.

**Dave:** Well, what I don't like about it is — say last week I went in there (community pharmacy) about half 10 and there was two people in there before me. So I walked out, went in and got a paper, and when I came back in I was waiting for your one (pharmacist). And your woman says "I'll be with you there in a minute" and the people that came in behind me were all served first, right. So it was 11 o'clock when I came in here (work). So I was left waiting nearly 40 minutes — and that's happened a few times.

The data suggested, however, that where patients had a good relationship with the pharmacist, their methadone could be dispensed after any time interval without the pharmacist's motives being misconstrued or upsetting patients (Derry, Richie, John, Peter).

**Derry:** Obviously if there's people there before me, they look after the people, like, you know - no jumping queues or anything. There was a couple of times when I got called before people that was actually in there. But that wasn't - how can I say this - I wasn't being treated any differently, like, "better get him out quickly". It just so happened that those times would be weeks when I had left in my script so it would have been ready, do you know what I mean...

**Peter:** He (community pharmacist) will deal with his customers first, you know, but I don't mind that. But there's a team of them there, like there's loads of them. So he just tells one of them to work on it (methadone), get it and measure it out and that.

Some participants had developed various strategies for ensuring that they were dispensed their methadone at a time that suited them:

**Mick:** See I do go in early in the morning, you know, like, so the chances of the chemist being packed is slim. Now some mornings it does be, but I'd hand in the prescription and I know them that well now that, you know what I mean. And I'd walk off and say I'll come back in 10 minutes and I mean like they'd have it ready for me when I come back, you know what I mean. And they'd just hand it to me then, like.

Richie: There was one place that the (DTC) originally sent me to and that was (named pharmacy) and he wanted me in after 6 o'clock, and I didn't want that so they changed me to (other pharmacy).

There appeared to be two aspects to the issue of privacy during the dispensing of methadone in community pharmacies. The first related primarily to the discretion of dispensing staff, with two participants describing how community pharmacists could do more to maximise patients' privacy, if they were sensitive and co-operative.

**Mick:** I'd be getting it (methadone) in a bottle. But she'd walk out with the bottle, like, in her hand and then put it in a bag at the front counter, you know what I mean. I don't know why she can't put it in a bag in the back.

**Elaine:** The thing is the blatancy with which the methadone is handed over. There doesn't seem to be any kind of confidentiality and stuff, you know, you have to drink it right there, and it's very awkward for people, they're often very uncomfortable with that.

Two participants described how patients could devise methods of communicating with understanding community pharmacists so that they could tell if a patient wanted to delay methodone dispensing to afford him greater privacy (Dave, Terry).

**Dave:** But if I was embarrassed I'd give (pharmacist's name) a sign (wink), say yeah, you know, kind of like, and he'd know, ...

The other issue regarding privacy during methadone dispensing related to the provision of special private areas for people who were drinking their methadone on-site at community pharmacies. Seven interviewees described the value of such areas in protecting the privacy of patients and the sensibilities of other customers (John, Mick, Richie, Peter, Terry, Derry, Terry).

**John:** I think it would be better (to use a private area for supervision) because at least the ordinary people ... I think they would be a bit afraid. Because some of them (patients on methadone) really do look strung out.

**Derry:** See you have to take the day's dose (under supervision) - you know what I mean...and they call you into a room at the side, and you sign your prescription and you get the rest. And I don't know if they do it (supervise) with any other medication, but I never seen people looking at each other as if to say "Jesus, what's he doing up there?"

**Terry:** If people have a fairly decent relationship with their chemist it's OK, if they're drinking it when there's nobody watching and I know some of them (community pharmacies) have little places where you can go around the side where people don't see you.

Richie: ... to provide somewhere a little bit private in the place, not only for the addict, but for their customers as well, you know their regular customers.

While one interviewee said he knew that the use of such an area in itself could have identified him as a patient in methadone treatment, he still preferred to have it.

**Peter:** Down there he has a room, like, he brings you in the back room, like. It's a big chemist see. But (named community pharmacy) and all haven't - they just hand it to you over the counter... I think it is better if you can go into the back. Because you don't want every one knowing, even though if they see you going in the back room so they probably know anyway, you know like, it's the same thing, but still, you know...

One participant described how the lack of privacy in community pharmacies could prevent drug misusers from seeking methadone treatment and two others outlined how it could breach confidentiality for patients in methadone treatment:

Mick: I know this girl and she's really in the abyss and she will not go into the chemist for fear of the embarrassment if her mother was to walk by or because her mother's friends'd find out. And I said you'll just have to put that behind you. It's a case of needing treatment — I mean sometimes it is embarrassing but you just have to...

Terry: Say if you're going to your local chemist (for methadone) really the rest of the neighbourhood shouldn't know anything about you... Some people don't care who knows - if they have pretty chaotic lifestyles people know anyway. But for people who are trying to keep it low key, you know, particularly people who say, you know, have young kids who are going to school... and still people associate HIV and hepatitis and all with addicts. So if they know that you are an addict then they probably assume that you might be HIV and then they worry about letting their kids play with your kids. And o'course they also assume that crime goes hand in hand with addiction. So like say the women have these rooms where they hang out in schools and they leave their bags and that, and then all of a sudden they know that

someone is an addict and the bag moves closer in ... And people feel that... And then it goes on an'on, yeah...

Peter: But the thing in (named community pharmacy, not the one he attends), that's just a counter, and he hands it (methadone) to you waiting at the counter in front of everyone in the shop and all. See they're not big chemists, there just corner chemists, they're small enough. But most people don't really mind drinking it there. But then again it's letting other people know - people you don't need to know, and you don't want to know. And they'll say see young Kavanagh up there, drinking his Phy and I didn't know he was getting it, you know what I mean ... that sort of thing. Because it's local and they all know you...

When participants discussed the level of respect with which they were treated at their dispensing sites, participants described feeling vulnerable because of their own insecurities and dehumanised by pharmacy staff. One interviewee said he initially felt exposed in the community pharmacy setting because his treatment revealed that he had previously used drugs.

**Derry:** When I started going to the chemist first I was uncomfortable. But that wasn't all to do with the fact that you're going to a chemist. The prescription's for Physeptone® so they (pharmacy staff/pharmacist) know straightaway that you're an ex-user, and you know the way there's a stigma attached to people who used drugs and all that - even people who're stable. Their defences come up immediately, and they're watching you and that.

Three participants described how patients in methadone treatment were discriminated against and received an inferior service in community pharmacies (Charlie, Kate, Peter).

Charlie: They (community pharmacists) just couldn't care less about you. Basically, you're a nuisance to them, you know. It's just a business thing to them - they've no real interest in your health or whatever. You're more or less just money in their pocket to them, you know, you're buying a product, you're being dispensed a product. The fact that they want you to leave that chemist, and come back in if you want to buy something else apart from that, it shows they're actually looking at you differently when you go in. You're not the same as someone else going in and buying, you know. You're a kind of second class citizen.

**Kate:** It's the most blatant form of segregation you've ever seen written (the pharmacy/patient contract) - apart from something that came out of South Africa, do you know what I'm saying! Say if you're going in to collect your methadone and you're menstruating, you can't even buy a packet of pads or a packet of Disprin® as a painkiller to ease the cramps. You can't do that, you have to collect your methadone, go out and then maybe come back or else go somewhere else. It's unbelievable! And it doesn't seem to consider the person

that's going in to avail of the service. Because that's what you're doing - no matter what you're going in for! And they just seem to be saying, right we'll give this quality of service to these people, but this is the quality of service we're giving to these other people, because you're ... on this form of treatment.

**Peter:** There's a bench and you're sitting on the bench and right beside it, at eye level, there's a camera pointing right at it. And I couldn't see why it's there. Because it's not anti-theft or anything because it's pointing at a wall with a bench, you know what I mean, there's nothing there that you could steal. So I think it's just there to monitor who ever sitting on that bench ... make sure you don't get up to anything. It's a bit weird alright.

Conversely, two other interviewees reported being treated with the same degree of respect as other customers, which made them feel valued at their community pharmacies.

**John:** In the chemist there's a little area to sit down, and if you're sitting there a while and they know you they make you a cup a tea!

David: And is there a different seating area for people on methadone?

**John:** No, no. I think they want to serve them (drug misusers) first. But I don't look like (a drug misuser) – now I know that myself – I've noticed now when the other people come in they're in and out. I'm not.

Richie: No matter if there was any amount of people I was never told to go and come back or anything like that.

In the course of these semi-structured interviews, participants described a number of significant differences between community pharmacies and DTC pharmacies from the service user's perspective, yet both services had a role to play in meeting the needs of different people at different stages in their treatment (Dave, David, Derry, Richie, Terry, Charlie):

**David:** I think both of them (DTC & CP) work a treat. When you first go on in the clinic and you're still trying to get used to the methadone, you need time for it to go into your body. You're still missing the gear and the needle and the whole lot. So you're vulnerable and you're better off going to the clinic every day and they can keep an eye on you as well.

Participants displayed a familiarity with the clinical progression and the procedural steps involved in the allocation of patients to primary or tertiary dispensing services (Derry, Charlie, Richie, Dave).

Charlie: See the way they work is when you're starting you give a urine once a week, maybe twice a week, and if that's clean say after a couple of months they might give you a takeaway twice a week, or three times

a week, say you go in Monday, Wednesday and Friday. Now if you're going in another couple of months again, then they might bring it down again. If you continue to keep it clean they give you what they call weekly takeaways, you go in once in the week. And if you can get that far, then ... they move you off to a chemist...

Participants appeared to accept this process and the restrictions it imposed, although some complained about its impact on patients who had work commitments (Charlie, Peter).

**Peter:** Some people have to go to clinics every day and you couldn't have a job or anything, you know. I mean you couldn't be telling your boss you've to go down and get your Phy every day. And some of them have to go down between 2 and 4, you know what I mean, so they couldn't go on their lunch. There's no way you could have a job.

Two interviewees described how the speed of the process was determined by their own progress, as measured by their urinalysis results and externally by the judgement of their prescribers.

**John:** Scripted off (i.e. attending community pharmacy) is much better, but you have to really work at it to be scripted off. They won't script you off unless you prove yourself.

**Lisa:** Your doctor decides. You just go up to your doctor and you say look I'm on the clinic long enough and I don't like to be coming down because...

While the 1999 survey of patients' views found the majority (70%) favoured community pharmacy-based methadone dispensing services (see Chapter 8), this qualitative study noted more balanced views, with participants describing advantages and disadvantages associated with both. When participants' responses were examined to explore the reasons why they expressed a preference for one dispensing services site above the other, a number of key issues emerged.

Firstly, participants reported higher levels of support for patients in DTCs compared to those attending community pharmacies, to an extent where some of those previously transferred to community pharmacies were actively seeking to return to tertiary care.

**Charlie:** A lot of them that's after going onto the chemists are trying to get back on the clinics. Because say if you've a problem at home, and you're going though a bad time, in the clinics maybe you can talk to the doctor or

there's always someone there you can talk to. Whereas in the chemist, they don't want to know your troubles.

This was true for patients who were unstable or who had high support needs but it was also true for some patients who were doing relatively well.

Terry: ... he'd been on methadone for about 30 years at this stage, and he had a grand relationship (with staff) when he was in (DTC). He only had to go in and see a doctor once a week and then he'd get his week's supply. Now he was probably on about 60mg or so, but what he would do is take only maybe 20 everyday and take the bulk of it on the Saturday. And the nature of his work - he'd be fitting out hotels and things like that, down the country. So it was great for him that he had his Phy to take-away. And if he couldn't make it in his wife would go in and collect it for him, and everything was OK because they knew him for so long. And then he got farmed out to a GP and a pharmacist. And of course the GP doesn't have the same relationship with him, and insists on him drinking it everyday - won't allow his wife to collect or anything like that. So now he can't fiddle his dose like he used to, and he's compensating with alcohol and benzos. But as well, he's having major problems with the job... so the pressure is coming from every side. And basically what's he's saying is he has no-one to talk to now. He has no relationship with his GP, whereas he could've gone into them in the clinic - but now they're saying to him "Oh, no, you're out now...".

Conversely, many participants cited exposure to other drug misusers, dealers or the general drug scene as reasons why patients chose to have their methadone dispensed at community pharmacies (Derry, Richie, Kate, Peter). This finding was also reported by the earlier survey of patients' views (see Chapter 8) and supports the Methadone Protocol Scheme's efforts to limit patient numbers in individual community pharmacies.

**Derry:** Oh I'd prefer going to the chemist, because ... you can imagine the atmosphere in the waiting room (in DTC), with everyone shouting at each other, talking about this and about that. No, I'd be happy where I am, keep it at the chemist.

**Richie:** There are too many of your own kind there (at DTC) – the old culture, the old ways, all there again.

Peter: See most of them you have people hanging around selling tablets and what have you. I was only 17 when I went to Trinity Court and they won't take you without an adult so I got me auntie along. And we were walking in and this bloke was asking her did she want to buy tablets and all... she was sick, she was. She never went with me after that, so I had to get someone else along with me. You'd never get that outside the chemist now, because it's just a high street chemist, you know, they don't hang around outside it, you know.

The hours that dispensing services were open was also important in determining preferred methadone dispensing service sites for many participants. As described earlier, limited opening hours were a source of conflict in the DTC setting. They were also associated with one participant expressing a preference for having his methadone dispensed at a community pharmacy, a trend also seen in a quantitative survey of patients' views (see Chapter 8).

Jim: I'd like to go to the chemist because my clinic is only open from 10 to 12. Like say if I didn't get there before 12 they'd say come back at 2 o'clock. And even then they only give you half your dosage! It's like being back a school kid and if you're late you get punished for it! My ideal set up would be the chemist because at least I'd be able to go there at different times.

To summarise, participants reported that patients were very sensitive to any perceived differentiation between them and other customers in the community pharmacy setting, and regarded being served out of turn or afforded inadequate privacy as a pharmacist's way of belittling patients or displaying his/her power by controlling or punishing them. This theory was refined by the negative cases that indicated that any waiting time and any level of privacy were acceptable where there was a healthy pharmacist/patient relationship. This discriminatory behaviour was perceived as stigmatising, regardless of mitigating factors and participants displayed little insight into the motives of community pharmacists who behaved in this way.

Attending a community pharmacy continued to be regarded as a sign of greater stability and trust and attending tertiary treatment services was perceived as more supportive and more controlling. Findings suggest that once transferred to primary care, patients were left largely to their own devices, with greatly reduced input and limited (and sometimes inadequate) support. Participants in this study displayed little resistance to the allocation and progression structures as determined by the MPS (i.e. stabilise in tertiary care before transferring to community pharmacy) which suggests that they had accepted the confines and limitations of the MPS.

## 9.3.3. Aspects of methadone dosing under the MPS

The earlier survey of patients' views (see Chapter 8) indicated that individual patients had specific preferences regarding methadone dosing, and this study aimed to explore

the rationales that affected their choices. This study differentiated between methadone doses that were administered under professional supervision on-site at methadone dispensing sites and doses that were dispensed for patients to "take-home".

When asked about the value of on-site supervision, participants identified a number of advantages and disadvantages. Some people thought that being able to drink their methadone at the pharmacy was more convenient for patients than carrying it on their person and made life simpler for them (Derry, Jim, Elaine), while others believed that on-site supervision helped patients to stabilise in the early stages of methadone treatment and helped them to conform with treatment regulations at other times (Richie, John, Charlie, Mick).

**Derry:** No I've no problem with it (supervision). Like when I leave the pharmacy I have to take today's (methadone dose) anyway. So it's better for me 'cos it means when I come in here (work) I don't have to fiddle around with it (methadone) and go down the toilet and take today's.

**John:** Ah yeah, you have to (be supervised) – ah yeah, everyone does, everyone has to start off that way, drinking every day. I suppose like you have to because like we are junkies and liars, do you get me, and sometimes you can't be very disciplined.

**Mick:** I didn't mind (being supervised), I have to say. The way I looked at it is if someone had a different illness and they had to take their medication in the chemist, it's a case of having to, you know what I mean. It's a case of needing treatment — I mean sometimes it is embarrassing but you just have to... you know what I mean like, you just have to do it.

Three participants also explained how some patients did not want the responsibility of "take-home" doses as they would be asked to sell them or unable to manage their daily doses (Jim, Richie, Elaine).

**Jim:** Having takeaways during the week you're just putting pressure on yourself like. I wouldn't be into that. And there's loads of people who'd be annoying you to sell it.

One participant said that having to attend his methadone dispensing service gave structure to his day and ensured that he made it to work on time and fulfilled other personal commitments.

Jim: If I didn't have to go to the clinic first I'd probably stay in bed an extra half an hour and I'd be a bit late coming to work then. And at the weekends I'd be just as glad getting up early because I'd be going up to see me kid anyway.

While participants identified these positive aspects of on-site supervised dosing, it also had a number of negative connotations. One interviewee described how it had a negative impact on patients by affirming their identity as "addicts" and two participants described how it reduced patients' freedom by limiting their ability to travel, change their routine or make long-term plans:

**Terry:** It affirms their addiction, people going through the same routine every day, it just confirms the importance of the methadone in their lives and reduces their freedom. Giving people take home doses gives them a bit more freedom of movement...

Charlie: It contains your life (daily supervision). You have no life. You have to be there at a certain time every day and if you're not you get docked on your methadone. So you can't make plans for say the likes of holiday time with your kids. So they have that grip over you you're locked into a kind of wheel you know what I mean.

One participant (John) stated plainly that the obligation to attend his methadone dispensing service to drink his methadone on a daily basis was "a pain in the-what-do-you-call-it", while two others outlined how it prevented some people from working.

**Charlie:** (The clinic) only opens at half nine so you get in and the hatches... and you have to queue up... So I can't see any form of work that's going to let you off for them hours.

The physical problems associated with consuming methadone on-site (e.g. vomiting) and the issue of privacy are discussed elsewhere in this chapter.

Participants were asked about the methadone that was dispensed to patients to take away from their methadone dispensing sites. Two participants described taking their daily methadone dose in accordance with their prescribers' instructions (Tom, Derry) while three other interviewees reported less rigorous compliance with methadone prescribing regimens. One participant regularly took less than his prescribed dose (John) and three others described how patients temporarily discontinued dosing, then binged to derive methadone's euphoric effects (Elaine, Richie, Terry).

**Derry:** I just pour it (methadone) in and I'd know just where 45 is, and I stop just before that, and it always works out. And the length of time that I was supposed to have it for, it would always work out that I'd have it that way. And to me, that meant that I was doing it right, you know what I mean.

**Richie:** Some days I just wasn't bothered to take it at all. But then what I was doing was I was leaving it for three days and then I was taking the 30mls together to get a kick out of it.

**John:** I get 80 (mg of methadone) off her (GP) but see I'm only taking 55. And when I'm down to 50 I will ask her to cut me from 80 to 60, do you know what I mean? So I'll still have the bit of leeway there and if I feel like I'm pushing it a bit much I can still take 60.

**Elaine:** I know people who are still doing that (bingeing) who will actually go without for a few days. Or, when they have nothing, they go and try to score again or they will top it up with a few days of really, really heavy benzo use...

Interviewees were asked to discuss any problems that could occur when methadone was taken home. They listed vomited doses and broken methadone bottles that were not re-dispensed as the most common problems (Mick, Dave, Terry, Elaine, Kate).

**Mick:** You nearly have to walk back in with the sick in a bag, you know, to prove to him you're after being sick, you know.

**Dave:** If you were to smash your bottle of methadone, you walk out of the chemist and that bottle of methadone gets smashed, that's tough shite – who's going to believe you? You sold that bottle of methadone!

The robbery of methadone supplies was reported as a relatively uncommon occurrence. Instead, interviewees appeared to differentiate between methadone being stolen and some of it being "taken" by someone they knew, who was in a similar position to themselves (Charlie, Mick, Terry, Peter). This was common and regarded as almost acceptable in some instances. In fact it was to be expected if people did not take proper precautions, and little sympathy was expressed for those who lost methadone in this way.

Charlie: You wouldn't be mugged as such because most people know people... But if you left it out of sight for a second it'd be gone, you know, and that'd be the people who'd just been talking to, you know. They'd just whip it, because they're just going to be as sick as you, you know what I mean.

**Mick:** Once you get your methadone it's your own responsibility, you know what I mean. It's like money in your pocket, so you have to watch it. So if someone was genuinely robbed or something I would sympathise, but if somebody lets their methadone out of their sight, with somebody in their

own home, well ...

The issue of child safety when methadone was stored in the home was also explored by one parent who described how his daughter discovered his "take-home" methadone supply in its hiding place, which prompted him to lock it in a cupboard in his bedroom.

**John:** One day my (5 year old) daughter pulled (my methadone) from behind the chair. I always thought she never knew it was there... And she found it there! I'm telling you I lost it that day... and now I keep my methadone locked in a high cabinet in my bedroom.

To summarise participants believed that many patients would prefer to have their methadone doses supervised for a variety of personal and psychosocial reasons, a belief which supported findings from the earlier quantitative survey among patients in methadone treatment, when a minority of patients expressed a preference for on-site supervision as their ideal dispensing arrangement (see Chapter 8). But obligatory supervised dosing could undermine patients' progress from addiction to independence and jeopardise employment opportunities, and should be enforced with reference to the broader social context of their lives. Allowing patients to take their methadone without supervision gave them more freedom and more control over their methadone treatment and their lives in general. But those who took their methadone at home had to accept full responsibility for the methadone dispensed to them and participants recognised that service providers dispensed methadone on this basis. Participants knew that service providers would not help them even if they ran into genuine difficulties in managing their methadone.

#### 9.3.4. Methadone as a Medicine

Following the high incidence of methadone related side effects and the importance of formulation among patients reported by the earlier study of patients' views (see Chapter 8), this study explored the importance and acceptability of methadone to patients in the MPS and investigated the impact of the change from Physeptone® to methadone 1mg/ml following the introduction of the MPS.

Much "street-lore" surrounded the use of methadone as a substitute for heroin, with a number of themes emerging in the course of the interviews. Methadone appeared to play a pivotal role in patients' lives, and was associated with a number of positive and

negative attributes. Participants expected methadone to "hold" them i.e. they wanted it to prevent them from experiencing opiate withdrawal symptoms. But many expressed a desire for more of an effect than this, and their dissatisfaction with methadone treatment often stemmed from an absence of any additional effect beyond this physical level.

**Kate:** People feel like they're just being held, and it's up to them how they fall asleep at night or how they deal with what's going on in their lives, which is grand in one way. But if you've nothing going on in your life and you're not getting any support it doesn't work.

Charlie: I think most people that are going for methadone are looking for some type of kick. It doesn't have to be a massive kick, just something to get them through the day, right. But ... to give them a green Physeptone (methadone 1mg/ml) that's just like drinking water - it's all it does is basically stops you getting sick, there's nothing else off it, you know, the way they see it (service providers), their attitude is they're not there to give you a kick. But they have to realise that that's what they (service users) are looking for. And if you don't give it to them in some safe form or other, they're going to get it themselves, right.

Many participants also associated a number of side effects with the use of methadone. The effects reported were very diverse and participants did not differentiate between those associated with methadone itself and those associated with its withdrawal.

**Terry:** People are talking about obesity, flatulence, diarrhoea, depression, sweating - people did sweat with the brown too, but they seem to believe they sweat a lot more now. I always thought it was the sugar in the brown that did that, but obviously not.

**Peter:** Sweating... and yawning and tiredness, with your eyes watering and that if you haven't got it. Sometimes I'd forget to take it - and you haven't got it all day and then you start yawning and that and tears in your eyes and then you just cop - God I didn't take me Phy (methadone 1mg/ml) today, you know.

**Lisa:** Pains in the back of me muscles and me back, headaches and all.

**Jim:** Just getting sick and that, in the beginning, my stomach churning and that. And terrible headaches in the beginning. But that was all. It was only when I started that I used to get them.

Dave: A good buzz and bad teeth!

**Richie:** A cousin of mine has to sit in the clinic from 9 o'clock in the morning and can't leave the place until half 11. She has to take two tablets to ease her stomach, and then she's to sit there 'cos she can't take the whole lot (dose of methadone) at once because it's coming back up out of her.

Two participants associated flatulence with the use of methadone 1mg/ml, saying it was a major problem that was under-reported because of patient embarrassment. This side effect may have been related to the use of artificial sugars and/or glycerine in the sugar-free methadone formulations.

Charlie: I'd say the main side effect, the biggest side effect – and no one likes to complain about it, is a build up of wind. There's a gigantic build up of wind, and if you try hold it, it causes severe pain. It's not normal I think you'd be passing it about 100 times more than the average person. And it can get embarrassing at times, you know, say like, if you're sitting on a bus...

**Derry:** I have a big big problem with that (flatulence), now I mean it's a massive problem. Jesus, anybody in the centre will tell you, even at home.

Participants were also concerned about the addictive nature of methadone, both in physical and psychological terms:

Charlie: The withdrawal off the methadone is much more severe than heroin even it takes a lot longer to come off it. Like if you go through cold turkey from heroin you'd be over the worst in say 7 to 10 days. If you're to go through the withdrawals off methadone you're talking about 6 months. The withdrawals are much more severe than the heroin you were on in the first place you know.

**Tom:** When I see ... clinic opening up in the morning it's almost like "Medication Time! Medication Time!" And you see the children that are descending on that clinic, now I mean 16 year olds, and they're on maintenance methadone programmes, maintenance in other words they are on that now for life!

Participants in this study suggested that aspects of the methadone's formulation including its taste, smell, consistency and volume affected its acceptability (Dave, Tom, Derry, Peter).

**Dave:** The brown (Physeptone®), I bleedin' hated it. Ah jazus, it was horrible, I can't even smell the thing. I hated it. It was disgusting.

**Tom:** That (Physeptone®) was a different methadone, it was nicer methadone, it was a sweeter methadone. It was like - I don't know - there was even a sensation like... you could almost feel a sense of well-being on it... green methadone is absolutely horrible — it's like thick jelly. I don't even like the taste of it, do you know what I mean.

**Peter:** Some people say they'd prefer the brown, but I think the green is way better. Well, the old brown used to taste like (brand of cough bottle),

you know what I mean, and you could feel it warming your chest up when you drank it. And people felt they could feel it taking effect straight away, whereas it wasn't, it was just that burning feeling in your throat and in your chest. But it still took four hours or so to get into you, but people thought that it kicked in quicker because they could feel it doing down their throat.

Three manufacturers were marketing versions of methadone 1mg/ml when this study was carried out, which produced copious "street-lore" and resulted in general confusion among participants. Even where participants understood the pharmaceutical aspects of formulating methadone, they still expressed preferences for one product about another and were not convinced that they were equally useful.

**Mick:** There's this myth out, like I don't believe it, but certain people reckon that Phymet® is stronger than the Pinadone, you know, like, and whatever.

Dave: It is, it holds you longer.

**Mick:** But like if you look at the bottle, though, every bottle has 5mg is the same as 5ml, whatever, five is the same as five, 1mg is the same as 1ml, whatever it works out, you know. So I can't really see the difference, you know. The only hassle I'd have is if they're giving me that thick stuff...

**Derry:** There was a story going around that it was some Irish crowd making new Physeptone® and it was supposed to be given out in (DTC). It was supposed to be from this company and people were saying it wouldn't hold a mouse. Now I don't know how true that is, but that's what they were saying.

Much of the discussion around participants' views on their methadone's formulation centred on the transition from Physeptone® to methadone 1mg/ml. Some interviewees accepted the change (Derry, Elaine) but others (Terry, Tom, Charlie) were opposed to it and expressed difficulty in making the transition. Their resistance to the formulation change appeared to be linked to a lack of faith in the decision-makers:

**Derry:** It's better in that (it is sugar-free) and it's better in the fact that it's a small amount, and to me it's not as difficult to take. And for me, because I'm on a relatively low level, I don't be struggling knocking it back. So, no I think it was a good move, from the brown to the green.

**Terry:** People don't know what's going on – a lot of them believe that they are being used as guinea pigs and they don't know if they are getting placebo or the real thing or what. I suppose everybody assumed there must be a catch, you know, they're not doing it for our benefit!

**Tom:** Sometimes I feel are they almost ripping us off here – is it really methadone in it – you know, is that the drug methadone?

Other participants said that they did not believe that methadone 1mg/ml was as strong as Physeptone®. This was related to the length of time that methadone 1mg/ml "held" them i.e. prevented the manifestation of physical withdrawal symptoms (Mick, Elaine, Lisa, Richie).

**Mick:** With the brown you could go that extra few hours, you know. So I reckon it's (methadone 1mg/ml) not holding you. It might be stronger, but it doesn't hold you as long. It kicks in quicker than the brown Phy, right, but it doesn't hold as long, you know what I mean.

**Elaine:** I remember one guy telling me he would rather have a shorter lifespan on brown than a longer one on green, you know, that was his decision. He said he just could not manage - it was tiring him out trying to top up the green methadone with benzos and stuff ...

The reported "strength" of methadone 1mg/ml may have been related to the development of a tolerance for its intoxicating effects so that after a while patients no longer felt its euphoric effects (John, Mick, Jim, Tom).

**John:** See with the brown Phy that was always the case (got euphoric effects) if you took enough of it. But it's different with the green Phy. When you're first taking it you got that (euphoria) but then it dies off and you don't get that even if you take a load of it.

**Jim:** When you drink say 80mls of the brown Phy you'd be sitting there like that (intoxicated), like it makes you really drowsy quick. Whereas the green (methadone 1mg/ml), it's only in the beginning that it does that to you, but when you get used to it, you don't feel as drowsy then.

**Tom:** With this (methadone 1mg/ml) it's like nothing, it means nothing. I don't even know if it's got the same ingredients - it's just that you don't withdraw.

To summarise, it seemed that while participants identified a number of different physical and psychological adverse effects of methadone treatment, they were primarily concerned with its ability to prevent opiate withdrawal symptoms and its ability to produce opiate-related euphoria. The change from Physeptone® to methadone 1mg/ml and the availability of multiple versions of the 1mg/ml formulation were sources of anxiety and resentment for participants. Their dissatisfaction with the transition from Physeptone® to methadone 1mg/ml was associated with the reduced ability of the 1mg/ml formulation to produce this euphoria, and was related to a fundamental distrust in service providers.

# 9.3.5. Aspects of the Pharmacist/Patient relationship

Following the earlier study of patients' views (see Chapter 8), which reported that the majority of patients had good relationships with the pharmacists that dispensed their methadone, this study aimed to explore this issue to identify what constituted a "good" relationship and conversely, to ascertain what features of a dysfunctional relationship could result in conflict between pharmacists and their patients in methadone treatment. A number of themes emerged inductively in the course of the interviews.

Interviewees expressed mixed views on the pharmacists that dispensed methadone, with each relating the enquiry to specific individual pharmacists, rather than to the profession as a whole. Some participants said pharmacists were fair and caring (Richie, Derry, Mick, John).

**John:** These pharmacists are the nicest people you could meet! I think, like, if I got changed to another chemist now I'd kick up murder...

Richie: Pharmacists are ordinary people. I know one of the pharmacists that used to dispense for me lives on (name of street). He's very nice person, he'd stop and talk to you and whatever, you know. [Pharmacists] have an understanding, and I think they just see it (opiate addiction) as another illness. I think they're just there to treat you, you know, to look after you ... I mean that's the job they wanted, that's the profession they're in, so I wouldn't see them as being judgemental or anything like that.

**Mick:** They're very nice to me – well they wouldn't have got a Christmas present off me otherwise!

**Derry:** I've had no problems with me pharmacy. They're very nice now. Any dealing I have with them they have a smile on their face, and you know, that way.

Other participants had encountered pharmacists who were much less helpful and whose behaviour continued to make participants angry, even in hindsight:

**Jim:** She (DTC pharmacist) was a real snotty bitch. Sorry for using that language, but I don't like being disrespected like that ... They (DTC staff) have no mercy.

**John:** The bitch (community pharmacist), if she didn't like the look of you, she got you and ripped up your script.

While one participant explained that pharmacists in the DTC setting "would have an idea where the person (patient) is at" (Richie) as they were seen as integral members of the methadone treatment team, participants held two conflicting views on the role of community pharmacists who dispensed methadone. Two interviewees identified an extended role for community pharmacists in the provision of primary care for those in methadone treatment.

**Terry:** I think they should be a little more of a counselling role involved. Because people might only see the doctor once a week, so if problems come up during the week, who do they go to except the pharmacist - it's the only link they have. [And] I think people would like it - and this happens in clinics - if you have an abscess or and ailment of some sort and you mention it, they listen and they take it seriously and they might be able to refer you to somebody... that's something that would be nice to see.

Peter: A while ago I had a skin thing (condition) and I asked him (community pharmacist) about that, like you know. He had a look at it, gave me some ointment and that, you know. He's OK, he is, you know, he's alright. I didn't know him before I got my methadone there, but he's alright.

But another participant believed that community pharmacists had a straightforward supply function and should not interfere with other aspects of patients' methadone treatment.

Ray: ... the doctor had made the decision to write that (prescription for large volume of methadone), and he knew how I was doing and I didn't think it was down to her (community pharmacist) to change that. I thought it was their (community pharmacists) responsibility just to dispense ... That's another area altogether... that would rock the boat, that would, you know like, pharmacists turning around and saying "sorry, I can't give you your medication, I think you're stoned". Like in the clinics now if you're drunk or whatever, they have the right to breathalyse you and all before they give you your medication. But in the chemist I think they can do nothing but just go for the easy ride and just give it to the person.

The general legislative restrictions imposed on pharmacists dispensing methadone by the Misuse of Drugs Acts 1977 & 1984 and the subsequent 1998 regulation (Statutory Instrument No. 225) and the professional recommendations published by the Pharmaceutical Society of Ireland (McDermott 1999) are outlined in Chapter 1. This study explored how these externally imposed "rules" affected the pharmacist/patient relationship, as well as the effects of the local application of individualised pharmacy/patient contracts. Findings from this exploration can be studied in conjunction

with those from a concurrent survey of community pharmacies (see Chapter 5), which reported that over one-third of the community pharmacies participating in the MPS used pharmacy/patient contracts, 30% of which were devised in-house.

Feedback from these interviews indicated that the use of pharmacy/patient contracts produced a perception that community pharmacists had full control over the manner in which methadone was dispensed under the MPS. This locus of control was clear to participants and they were very aware that they had little option but to co-operate.

**Derry:** You're doing harm to yourself being aggressive or having a bad attitude to people, you know what I mean, because like you're getting your methadone off them, so you wouldn't want to throw a spanner in the works. You know the pharmacist could turn around and say, well I'm not prepared to accept that behaviour, and then the doctor would have to find another pharmacy for you. And in the mean time you're stuck, do you know that way...It's not worth it in the end.

**Mick:** If you suggested anything you'd be afraid that he'd turn the wrong way on you, like you know. You don't want to get on the wrong side of (pharmacist's name)!

**Peter:** There was one fella on the (satellite) clinic that I was on and the chemist refused to dispense to him because I think he robbed a packet of sweets or something from there. Your man (community pharmacist) told him he wasn't going to do it (dispense methadone) for him anymore, and then they had to get him on a different chemist. And there's not many chemists that will do it, you know...

However, this study found that, as reported elsewhere (Neale 1999), many participants accepted that some restrictions were reasonable and that dispensing pharmacists needed to have an element of control (Kate, Mick, Peter, Dave, Derry). In fact some welcomed the structure this provided (Kate, Mick, Peter, Dave).

**Kate:** It's OK if you say "This is what you have to do, right. We'll set it up, we'll give you treatment. But you have to adhere to these rules", that's fine. You know like, if you're teaching a person as you go along — "this is the way it has to be and you're going to gain from it", not just saying "this is the rule, right, you do what we tell you and you'll get your medicine — if you don't, you won't".

**Peter:** You have a contract that you sign, or else he won't dispense. ... It was reasonable enough. Like your man was saying "be fair with me and I'll be fair with you".

Dave: I think there is a thing that you sign to say you won't hang around

outside or anything but nothing intrusive or anything - nothing that I'd sit and look at or that I'd have a problem with like.

But three participants believed that the number of rules being imposed by community pharmacists participating in the MPS were excessive and expressed a desire for a more balanced approach (Kate, Elaine, Ray).

**Kate:** The chemists...are bringing out these contracts saying "I can refuse you, I can just snap you off...if you don't go through all these hoops and if I don't like this or that"... And it's vicious because you're dealing with a person's life and I know everyone has to adhere to rules, but just sometimes they're not practical rules for active drug users.

**Elaine:** Most of the pharmacists are saying you can't bring somebody in with you, so then you're exposed. And I would have a problem with pharmacists saying that, because I think, well my mother goes in to buy her blood pressure tablets and I can go in with her absolutely no problem, but the drug users are told not to bring anybody and not to buy anything, and it really isn't a service. I don't know what it is, but it isn't a service...

The primary problem participants expressed in relation to the pharmacists' rules did not appear to relate to the rules *per se* but to patients' inability to negotiate or have any say in how they were enforced. This led to an external locus of power, which further served to undermine patients' feelings of self-determination. As the pharmacists were seen to be totally in control, many participants lived in a state of anxiety and were afraid to express any views whatsoever in relation to their pharmaceutical services for fear of antagonising their pharmacists.

**Terry:** These contracts are all geared towards protecting the pharmacists. People are basically afraid to stand up to the chemist because the chemist has the power to cut you off for arguing or anything like that... And that has to affect you, you know, 'cos it's people who have only a little power anyway and now what they had is being taken away ... and nobody likes giving up their power.

Charlie: See that was another thing that was on this contract - you must not question, you know, you must just accept, whatever the chemist decides, you just have to accept it.

Participants recognised that they needed community pharmacists much more than community pharmacists needed them, and were concerned about the tenuous nature of their commitment to the MPS. Two participants described how easily pharmacists could reverse their decision to dispense methadone:

**Terry:** The thing is with pharmacies, they're all independent, I'm sure they're not making an awful lot of money out of it (dispensing methadone). It wouldn't be that big a deal to say "well I'm not dealing with methadone any more".

There was no advocacy system for patients in the MPS, which meant that there was little that they could do to change the nature of their pharmaceutical services, without risking incurring the wrath of their community pharmacist, thereby jeopardising their entire dispensing service. Two participants seemed to have genuine concerns about pharmaceutical services under the MPS, and both were without a way of addressing these concerns.

Charlie: There's one girl and the things in her contract, some of them were ridiculous... - whatever the chemist decided, she just had to accept it. And this girl suffered with her nerves...and it kept getting worse and worse every week ... and she ended up in hospital with a nervous breakdown.

Mick: I didn't say anything, because you can't give out to him, you know what I mean. 'Cos he's keeping you supplied with methadone, like you know what I mean ... it's a case of having to go in with a smile.

Two of those interviewed believed that it was important that patients were represented in conflict situations and that their views were taken into account in determining the outcome of any incidents (Terry, Charlie).

**Terry:** When we're looking for an ombudsman, it should work both ways (patient/pharmacist), like it shouldn't be all on behalf of the user. I think a lot of users cause their own problems. So I think it should be fair and work both ways. It'd be like an advocate between the two parties.

Participants described how pharmacists could improve their relationships with their patients on methadone by being clearer when outlining the rules they imposed and by learning to understand the behaviour of unstable patients.

Elaine: I think if they (pharmacists) demand something they should explain the reasons for it. I think sometimes the drug users don't know why ... and I find that drug users respond much better when they understand what's happening. And they (pharmacists) need to start being very clear and concise... you know, just because of all the various amounts of drug use and sometimes they (drug users) may be a bit stoned when they give them information. I think if they knew how

the pharmacists felt it might add to the quality of the relationship.

**Richie:** The ideal pharmacist could have an understanding of drug addicts, that they're not going to be the same every day, that they're going to have ups-and-downs and that that goes with the territory, do you know what I mean...

Despite their annoyance with the use of pharmacy/patient contracts and the implementation of many rules, participants described having good relationships with the pharmacists that dispensed their methadone. Three participants described how they had experienced pharmacists who had been diplomatic in averting confrontation or who were especially helpful or kind.

Richie: If someone came in and they were out of their face and they tried to rob something - a brush or a fucking make-up thing or whatever - they would tell them not to fucking take it, and that they won't be fucking served again here if they do it again... - there and then. Like they know what way they go on with... they know that he usually comes in and takes his Phy and goes out. He's out of his head today, so I'm going to have a word with him, say "don't do that, it's not acceptable", you know, that kind of thing.

**John:** If I ring ahead to say like I'm getting a lift in off the girlfriend - like I only get the lift once a week - Tuesday morning for to get me Phy - and I ring ahead, and they say, "oh no problem John...".

**Derry:** I've seen some occasions, right, where someone would be working, and the pharmacist would make an effort to work around HIS schedule. Like I know one pharmacy in particular, because he (patient) was working and he wasn't able to come in on time, the pharmacist told him there was no problem coming up on his (pharmacist's) lunch hour. This wasn't going to be a permanent thing, only a temporary measure, but the pharmacist opened up for him, just knock and he'd be there having his lunch.

One participant expressed sincere appreciation when describing how his community pharmacist had shown respect for him and his family:

**Mick:** My sister was written for fifteen year (in methadone treatment), like you know, and she died in November 1999. And when the driver of the hearse went by (named pharmacist) shut his shop and all, as a mark of respect, you know, and it's just little things like that...

One participant also recognised the intrinsic difficulties associated with managing drug misusers in the community setting and acknowledged the efforts that pharmacists made to treat them as best they could under less than ideal conditions.

**David:** I think you have to give it to the chemists as well, because there's an awful lot of people out there trying to help themselves (shop-lift). And I've often seen chemists, when I used to get me own stuff, they'd be dipping into the fucking *Impulses* and the perfumes and what have you.

When asked to describe conflict situations that they had experienced at their pharmacies, participants identified a number of different issues. The net effect in every instance, whether serious or relatively minor, was that the patient continued to harbour a degree of resentment against the pharmacist involved, even in instances where the situation was long resolved or they had since changed pharmacy or detoxified completely.

One participant expressed anger at the isolation of patients in community pharmacies compared to those in DTCs:

**Charlie:** Chemists seem to be a law onto themselves, you know. The fact that they know none of your history, they just couldn't care less about you. Basically, you're a nuisance to them, you know.

Even within the tertiary drug treatment setting, one participant felt misunderstood by his pharmacist:

Jim: I don't think she (DTC pharmacist) understands what it's like to be addicted. I think she read it out of a book and thought, "oh, yeah that's what it's about..." And I talked to her about it, and she just doesn't understand. And like, I don't think she wants to either.

Participants described a lack of respect and compassion among service providers. This specifically related to community pharmacists who provided an inferior service for their customers on methadone.

Christy: They treat you differently, you're not a customer... you're not the same as someone else going in and buying, you know. You're a kind of second class citizen.

**Mick**: She doesn't like giving the methadone out because she thinks you'll be like embarrassed. Yeah, she said to me, I don't want to give you your methadone because I don't know how you'll react. Now I'm glad she asked me, like you know what I mean, like. But I was still left waiting that half an hour, you know, before the question was asked.

Another participant described how he believed one community pharmacist was prejudiced against him due to his dealings with him prior to the introduction of the MPS.

**Richie:** I had a couple of bad experiences with him (community pharmacist), when I was on with (named GP) years ago and when I was chaotic I used to be always dabbling around with the prescriptions. And I used to go into him, and I did his head in, so he didn't like me from the start. So I didn't really want to go to him in the first place. See he knew of me, he knew I was a bogey ...

Instances where pharmacists refuse to dispense methadone to drug misusers due to problems with prescriptions are highly volatile and can be difficult to manage, even when pharmacists are experienced and patients are understanding. One interviewee described such an instance prior to the introduction of the MPS:

Ray: There's one (community pharmacy) around the corner I had a bad experience with. I had a doctor that was going away for two weeks and he gave me two prescriptions to be dispensed on the same day. They were for two 1,000ml bottles but your woman ...the chemist, made a decision on that, and I don't think it was in her - I didn't think it was in her power to make that decision. But she got on the phone to the doctor and made me come all the way back down to the surgery...

**John:** But the way she was looking at that you could've gone out an' sold that and then had nothing for yourself.

Ray: I understand that but the doctor had made the decision to write that, and he knew how I was doing and I didn't think it was down to her to change that. I thought it was their responsibility just to dispense. Maybe I was out of it or something - I'm not too sure - it was a long time ago and at that stage I was doing tablets and all so I probably was addicted to them. But it annoyed me the way she went on ... [she should have] dispensed one of the bottles and got in touch with the doctor about the other prescription... but she didn't want to deal with the prescription at all. She wanted me to go back to the doctor ... what ever it was, she said "I just cannot dispense that amount of Phy".

Another participant described how a lack of co-ordination between the GP and community pharmacist resulted in him being refused his methadone.

**Derry:** I went up to (named GP) for a prescription and he wasn't on that day and there was some other doctor on, and I was rushing, and I had to queue up for about 25 minutes. And the stand-in doctor says "as far as I know (named GP) left the prescriptions in the chemist". So I went back down to the chemist and your man (community pharmacist) looked and he says "no, there's no prescription here". And I just says "for fuck sake, I'm like a bloody years old-yo", and I walked out.

Participants reported a number of instances where they doubted that their dispensing pharmacists had given them proper methadone or they believed that their pharmacists had not given them the full amount of methadone prescribed. Instances such as these are very difficult to prove or refute, and they can result in rumours that make other patients question the accuracy of their methadone doses, thereby perpetuating the issue.

Charlie: This girl had this thing going with her chemist where she was always being left short of her Phy, just a bad attitude the chemist had towards her, you know. Now I've never been to a chemist, and it never happens in the clinics, but it seems that a lot of people in the chemists have these complaints. Now because she complained she's been having a hard time since.

Dave: There was one day that this bloke was in there (community pharmacy) and he had murder, right, and he says "you're after mixing that" and he's there (the pharmacist) saying "Shhhh, shhhh!". And your man actually took his script back off him and left the chemist. And there is that rumour that he mixes it. And some days you go in and it tastes different than other days. Like you can get a peppermint-y taste off it some days and more days there's none.

Methadone dispensing hours were another source of conflict specifically between patients and pharmacists who dispensed methadone in the DTC setting.

**Jim:** See on the weekdays it's (DTC pharmacy) open until 12, but at the weekends it's only open until half 11. And sometimes you do think you have until 12 o'clock. And then you realise Jesus, it's half 11 they'll be closing. And you'd think they'd give you 5 minutes bleedin' grace, but oh no...

Participants identified a difference in the relationships they developed with the pharmacists who worked in DTCs as compared with those in community pharmacies. One participant felt that there was a better rapport in the community pharmacy setting while two others preferred the more specialist support available in tertiary treatment services.

**Richie:** I think you build up more of a relationship with the pharmacist in the chemist that you do in the clinic. Because it's not as straightforward with the pharmacist in the chemist. Like the pharmacist in the clinic is just dealing with methadone, methadone, methadone and drug users, drug users, drug users. Whereas in a chemist it's different, and they'd see a different side of you. You wouldn't be only getting your methadone, you'd be buying other bits and pieces, sprays and things, and having the odd yap – how did your weekend go, and

things, and holidays, and that kind of thing.

**Terry:** When you'd be getting your Phy in (clinic) you'd sit there and you'd sip it. There was plenty of scope – you could sit there and talk and even though that wasn't counselling that was a way of getting help. And you don't have that with (community) pharmacists – they're not going to stand there and let you sit there in a chair and sip your methadone. And they're the kind of things that relationships are built on, so it makes it easier then when there is something you want to get out (i.e. discuss a problem).

Charlie: Say if you've a problem, say at home, and you're going though a bad time, in the clinics maybe you can talk to the doctor or there's always someone there you can talk to. Whereas in the chemist, they don't want to know your troubles.

Other participants described differences in the methadone dispensed at these sites, which appeared to be related to the extent of their trust in the dispensing pharmacists:

**John:** At the clinics now, but, it's a different story. I never trusted the Phy out of a clinic.

**Jim:** Now funnily enough in that clinic I've often thought the Phy was weaker. One day it'd hold you grand and the next day it wouldn't, you'd even be sick. And I said that to the chemist and she said "ah, it's all in your head". But I've heard of no other place that people see that. See on the weekdays it's real thick when you're drinking it, and on the weekends it's like water!

**Dave:** Like if you get it out of any of the clinics it's a completely different taste! It's real thick and all, whereas when you're getting it out of the chemist you don't know what way it's going to be.

To summarise, participants indicated that many of the pharmacists that dispensed methadone were helpful and considerate, and their efforts were appreciated. Participants suggested a number of ways in which their input could be ameliorated, by extending their role, by dispensing all prescribed methadone doses (thereby avoiding conflict caused by refusing doses), by explaining their "rules" more clearly and by being trained in the management of unstable opiate addicts. As well as those who provided adequate or good pharmaceutical services, participants also described pharmacists who were nasty or disrespectful. They explained how the pharmacists held all of the power in the pharmacist/patient relationship, which seemed to result in feelings of insecurity and anxiety among service users, who were obliged to submit themselves to the control of their pharmacists and had no real alternative ways of attaining methadone treatment. While recognising the necessity for some rules and limitations within the community pharmacy setting, the imposition of excessive restrictions implied that pharmacists did

not trust patients, and this made them feel afraid of their pharmacists, misunderstood, angry and resentful. Given this combination of emotions it is not surprising that participants were able to recount numerous instances where conflicts had arisen between pharmacists and patients, as they interacted with each other within the relative isolation of the community pharmacy setting.

#### 9.4. DISCUSSION

It is recognised that qualitative research techniques have distinct advantages over other research methods when complex, in-depth information is being sought from a relatively small sample (Caplehorn & Saunders 1993, Chernomas 1997, Maher et al 1999, Schwartz & Sprangers 1999, Strunin 2001). Despite its limitations (May & Foxcroft 1995, McKeganey 1995), self-report among drug misusers has been shown to produce accurate and consistent data (Adair et al 1995 & 1996, Høyer et al 1995, Darke 1998). While both the method and the sample used here did not allow for statistical analysis, nor can findings be externally generalised, this qualitative study provided a useful and detailed insight into pharmaceutical aspects of the MPS which had been initially investigated by a quantitative survey almost two years earlier in March 1999.

No comparisons can be made between the overall male/female ratio or the age groups seen here and those seen among patients in methadone treatment in general because the sample involved in this study was not exclusively made up of people who were on methadone. However, of the participants who were currently in methadone treatment, males were over-presented compared to the population as a whole (89% male here compared to 67% overall), but there was suitable balance in participants' dispensing sites, with five of the nine participants (56%) attending community pharmacies, which was equal to the proportion registered with the CDTL at that time (CDTL Statistics).

Findings from this study gave valuable insight into the earlier survey's reported high incidence of good pharmacist/patient relationships (see Chapter 8). While many participants here also reported good relationships, this study identified an underlying tension between pharmacists and patients in the MPS, which was largely due to unequal

power relations. One London study (Lovell et al 1999) described a similar element of suspicion underlying the pharmacist/patient relationship.

Participants in this study universally described how power relations between pharmacists and their patients in the MPS were fundamentally unbalanced, with pharmacists having total control. This was not always a problem and some participants reported great respect for individual pharmacists who dispensed methadone. But many displayed insecurity, resentment and fear of pharmacists who were not "nice", who could belittle or punish patients by imposing severe restrictions, by refusing to dispense their methadone or by ceasing to provide methadone dispensing services for them without warning or explanation.

The data suggested that reported "good relationships" may have been due more to participants' low expectations as opposed to the actual nature of their relationships with their dispensing pharmacists. From a community pharmacy perspective, the present study suggested that patients on methadone did not anticipate being treated as well as other customers and were therefore likely to report good relationships with their pharmacists even if they were only treated as well as others, a standard which may have been less than professionally appropriate given their clinical and psychological needs. In addition, many participants qualified their reports of positive relationships by saying that they had no choice but to get on with their pharmacists, on the pharmacists' terms, as they had no alternative ways of gaining access to methadone treatment.

This study illustrated how service users believed community pharmacists could discriminate against patients on methadone by manipulating the length of time they waited for their methadone to be dispensed or by reducing their privacy during on-site supervised dosing. It gave insight into findings from the earlier survey where most respondents reported very short waiting times and agreed that they would be embarrassed drinking methadone under supervision in a community pharmacy (see Chapter 8). Sheridan and Barber (1996) also reported respect for patients as a key issue and the provision of better privacy has been linked to a raised acceptance of on-site supervision among those in methadone treatment (Matheson 1998b, Neale 1999).

This study suggests that patients in methadone treatment strive for healthy and balanced relationships with their pharmacists, and accept that these relationships will be governed by rules imposed by pharmacists. Acceptance of pharmacy rules, as noted in this study, was also reported in Scotland, where patients showed an implicit understanding of what behaviour was appropriate in the community pharmacy. This finding resulted in the Scottish researcher suggesting that the application of overly strict rules was unnecessary and could antagonise patients (Neale 1999).

In light of these findings, Irish pharmacists could usefully examine their methadone dispensing procedures, paying particular attention to the differences between how it and other medicines are dispensed at their pharmacies, and looking at ways to standardise methods to ensure good quality, unbiased treatment for all. This study supports the idea of the provision of grants to Irish community pharmacists to allow modification of their premises to provide separate private areas (Jackson 2001) and suggests that MPS management should provide an independent mediator to monitor and address issues arising at the pharmacist/patient interface.

These findings also suggest that a relaxation of the rules enforced by Irish pharmacists could simultaneously enhance community pharmacists' professional image and reduce patient resistance, conflict and animosity towards community pharmacists. However, it would probably be difficult to persuade community pharmacists to reduce the level at which they impose control over their patients in the MPS, for fear of negative outcomes such as petty crime or abusive behaviour. A study comparing the behaviour of patients who signed strict pharmacy/patient contracts with that of patients under less harsh constraints could be useful in evaluating how externally imposed limitations affect patient behaviour in community pharmacies.

Feedback from participants in this study offered insight into the attitudes of service users to the application of obligatory supervised dosing to patients in treatment under the MPS. It identified a proportion of patients who accepted or welcomed such structures, while others struggled with the limitations and constraints they represent. These findings supported those of the earlier survey of patients' views where a sizeable minority of respondents preferred to drink at least some of their methadone under the supervision of a pharmacist (see Chapter 8). The behaviours and attitudes synonymous with patients

who accepted the restrictions imposed by the MPS suggested a degree of maturity or institutionalisation among patients in this category, and may have been indicative of a dependence, not just on methadone, but also on the support mechanisms that drug treatment services provide. Patients in this category appeared unwilling or afraid to take responsibility for their own treatment and this highly structured methadone treatment programme appealed to them. These patients were in contrast with those who actively sought control of their own programmes, and resented the MPS's application of constraints such as on-site supervised dosing. Patients in the latter category harboured resentment and anger against individual pharmacists and "the system", and these underlying emotions led to distrustful and volatile relationships with service providers, specifically methadone dispensing pharmacists.

These polarised patient identities pose a challenge for service providers, who need to encourage less confident patients to take a more active role in their own recovery and avoid undermining the confidence of self-motivated patients with undue constraints, while striving to achieve acceptable treatment outcomes for all. From a pharmacist's perspective this highlights the need for individualised interactions, where the differences between patients who need to be encouraged towards greater independence and those who instinctively prefer to manage their own treatment need to be recognised and acknowledged.

In addition, the absence of participant insight into pharmacists' motives and the legal limitations imposed on them highlights the need for greater transparency in this area. Research has already suggested that negative attitudes among pharmacy staff may evoke feelings of stigmatisation among patients (Sheridan & Barber 1996), with suggestions that the resulting stigmatisation leads to negative behaviour in community pharmacies (Matheson 1998c). While participants continue to misunderstand and misinterpret pharmacists' reactions, trust cannot develop and conflicts at the pharmacist/patient interface will continue to occur.

Research indicates that patients' views have value in determining the nature of their treatment, both in relation to their general healthcare (Krook et al 1995, Barry et al 2000) and regarding their treatment with methadone (Ball & Ross 1991, Powell et al 1993, Neale 1999). Therefore, they should be taken into consideration when planning

methadone treatment services, both nationally and on an individual basis. Recent national policy advocates the introduction of a patient charter for those in methadone treatment in Ireland (National Drugs Strategy 2001). This research supports the development of such a charter, which should be done in conjunction with patient representatives.

Participants described community pharmacy-based methadone dispensing services as convenient and user-friendly, and associated attending them with recognition of patient trustworthiness and accepting greater responsibility for one's own treatment. Some participants also outlined a number of ways in which community pharmacists could improve services for those in methadone treatment by extending their pharmaceutical role and by empathising more with their patients.

The data implied that patients valued community pharmacy-based methadone treatment services, and recognised the community pharmacist as a useful source of help and support. Collins and colleagues (1999) also reported that community pharmacists were perceived as healthcarers who were highly receptive to patients, with an image that combined professionalism with accessibility and approachability. But as well as describing methadone dispensing services that were functional and fair, this study described situations where patients were anxious and afraid and pharmacists were dogmatic and judgemental. MPS management should investigate ways of promoting healthy pharmacist/patient relationships. Perhaps the appointment of patient representatives or the introduction of mutually agreed pharmacy/patient contracts would be helpful in this regard. A "Four way Agreement" such as that used between patients, tertiary drug services, GPs and community pharmacists in Berkshire (Walker 2001) offers another practical alternative.

Community pharmacists need to look for ways to improve and extend service provision to better meet the needs of patients in methadone treatment. This study highlights the need to train pharmacists, both at undergraduate level, and on a continual basis in the course of their professional lives, to prepare them for working with patients in methadone treatment. Pharmacists need to learn to respect methadone patients as people and to acknowledge their right and ability to affect and determine their own recovery. Pharmacists themselves have identified their need for training in the management of

drug misusers (see Chapters 4 & 5), a skill which this study also suggests they should develop. In conjunction with this initiative, pharmacists should improve their ability to communicate their motives and limitations to patients on methadone, so that patients can understand the reasons for pharmacists' actions. Training in these areas could reduce the incidence of misunderstandings and misinterpretations between pharmacists and their patients on methadone, thereby reducing the number of conflicts experienced and improving pharmacist/patient relationships.

# **CHAPTER 10**

# **Discussion**

The role of the community pharmacist in the treatment of opiate misusers is broadly recognised internationally (Matheson et al 1999a) and this project aimed to explore the impact of the regulation of methadone dispensing services (via the introduction of the MPS) on the provision of methadone by Irish pharmacists, while also examining how these changes affected patients in methadone treatment at that time. The statutory changes that resulted in the introduction of the MPS took place in a professional environment that advocated the provision of methadone by community pharmacists, with the Pharmaceutical Society of Ireland taking a proactive stance in favour of methadone dispensing (*Policy on Drug Abuse*, 1996), and were largely a product of political pragmatism (Butler 2001).

This work provides quantitative and qualitative insight into a number of aspects of pharmaceutical services being provided under the MPS between 1998 and 2001, from the perspective of both service provider and service user.

However, while this study was successful in amassing information regarding aspects of pharmaceutical services for those in methadone treatment in Ireland from 1998 to 2001, its design was not without limitations. While high response rates were achieved, the use of structured questionnaires limited its ability to amass detailed or qualitative data pertaining to complex aspects of pharmacy involvement in the provision of methadone dispensing services. In addition, self-report may have affected participants' responses, particularly where the researcher's position, as liaison pharmacist, may have given rise to both subject and researcher bias. The longitudinal analysis undertaken among community pharmacists was confined to pharmacies in a restricted geographical area and could only be carried out on some of the data collected at each time point due to variation in the survey instruments used. In addition, the absence of feedback from non-service providers limited this study in its ability to identify barriers to service provision, and to investigate attitudinal differences between community pharmacists who dispensed methadone and those who did not.

Studies examining pharmaceutical services from the users' perspective also had limitations, with no non-treatment control group for the quantitative survey and no information regarding possible overlap between the samples involved in the quantitative

and qualitative studies. Future research initiatives should endeavour to address and overcome these limitations.

The implementation of the MPS using national legislation as well as medico-ethical considerations prohibited the establishment of control groups for comparison purposes, which could have been useful in proving causality.

Nevertheless, in view of its quantitative, qualitative and longitudinal aspects and given that this is the only research that has been carried out among community pharmacists and patients in methadone treatment nation-wide, it is of considerable value in providing insight and information regarding aspects of methadone treatment in Ireland prior to and following the introduction of the MPS.

This work hypothesised that the introduction of the MPS would have a positive impact on the provision of methadone treatment in Ireland, and investigated this impact by examining its effects on a number of aspects of service provision and service delivery. The effects seen in each of these areas are discussed below.

# 10.1. THE EXTENT OF METHADONE DISPENSING BY IRISH COMMUNITY PHARMACISTS

There was a substantial rise in the number of community pharmacists participating in the provision of treatment for patients on methadone 1mg/ml during the study period, a finding corroborated by other researchers (Keenan et al 1999, Farrell et al 2000). This increase was necessary, given that patients were being retained in methadone treatment and because Irish opiate misusers were presenting for treatment earlier in their drug misusing careers (Barry et al 1999).

Recent research reported methadone dispensing in almost half of the community pharmacies in the north sector of the E.H.B. region, which suggests that pharmacy recruitment is still underway, at least in that geographical area (Killen & Zayed 2001). However, in spite of the evidence of ongoing recruitment, many Irish community pharmacies still do not dispense methadone and this research can offer some insight into the barriers to their participation due to its limited investigations among non-service

providers. Although the later surveys of community pharmacists did not target non-service providers, a number of barriers to service provision were identified by Survey 1 carried out among community pharmacists in the southern sectors of the E.H.B. region. These included fears for personal safety, which were also reported among community pharmacists in the UK (Smith & Weidner 1996a, Sheridan et al 1997, Matheson et al 1999b). Other barriers included attitudinal objections from pharmacy staff and pharmacists' fear of being isolated as the sole methadone provider in a locality. Initiatives such as the limitation of MPS patient numbers in individual community pharmacies and the "all-or-none" approach (which avoided exposure of individual pharmacies as the only service providers in a given locality) were subsequently adopted by the liaison pharmacist in that region, in an effort to overcome these barriers.

The non-participation of some community pharmacists in the provision of methadone dispensing services may have implications for patients by prolonging their time in DTCs or on waiting lists for methadone treatment. Research has reported long waiting lists in the UK (Stewart et al 2000) and in Australia (Dore et al 1999) and identified their deterrent effect on service uptake (Fountain et al 2000). Australian research has associated poorer treatment outcomes with patients who spend longer on waiting lists for methadone treatment (Bell et al 1994), while one US study associated reduced waiting times with better service uptake (Dennis et al 1994). For these reasons, researchers have strongly advocated the reduction of waiting lists by expanding methadone treatment services (Wenger & Rosenbaum 1994, Dore et al 1999, Fountain et al 2000). Recent Irish policy recommends that opiate misusers have immediate access to counselling and assessment services, with appropriate treatment being provided within one month (National Drugs Strategy 2001). This recommendation cannot be achieved without adequate community-based methadone dispensing services, and all efforts should be made to promote primary carer involvement in the MPS.

There is a role for liaison pharmacists in promoting community pharmacist involvement in the MPS, and an external review of the E.H.B.'s Addiction Service reported that its liaison pharmacists had "achieved remarkable success" in developing community pharmacy-based methadone dispensing services between 1995 and 1999 (Farrell et al 2000). Recent national policy states that this trend towards increased community pharmacy participation in the MPS must be sustained to prevent undue pressure on

tertiary drug treatment services (National Drugs Strategy 2001), and all efforts to encourage community pharmacists to dispense methadone should be supported.

Research suggests that the provision of training may also encourage community pharmacists to participate in methadone dispensing initiatives (Sheridan et al 1997, Matheson et al 1999b), while offering adequate remuneration may also promote community pharmacist involvement (Matheson et al 1999b) and such initiatives should be undertaken in Ireland. Sheridan and colleagues (1997) also suggested that the provision of adequate support would encourage community pharmacist participation. Further research, which identified barriers to community pharmacy-based methadone dispensing services could help direct MPS management in planning future development and guide liaison pharmacists in their efforts to promote pharmacy participation. In the meantime, given the need for greater community pharmacist participation in the MPS, the success of the liaison pharmacists in recruiting community pharmacists suggests that they should continue to concentrate their efforts in this area.

The increase in community pharmacy dispensing of methadone 1mg/ml seen between August 1998 and March 1999 resulted in a statistically insignificant fall in the mean number of MPS patients per pharmacy and in the mean number of supervised patients in supervising pharmacies over that time and was a positive outcome following the introduction of the MPS. The accommodation of almost equivalent patient numbers under the new regime was an indicator of Irish community pharmacists' willingness to co-operate with the introduction of the MPS. This dispersal of patients over a greater number of pharmacies and the application of an upper limit to patient numbers per pharmacy, as recommended by the *Report of the Methadone Treatment Services Review Group* (DOHC 1997) should have facilitated the normalisation of patients' treatment (Farrell et al 2000), and can also be regarded as a positive outcome following the introduction of the MPS.

# 10.2. COMMUNITY PHARMACISTS' ROLE AND THEIR INTEGRATION INTO PRIMARY CARE-BASED DRUG TREATMENT TEAMS

Although Irish policy has advocated "shared care" for patients in community-based methadone treatment since 1991 (DOH 1991), this work found that Irish community

pharmacists had a simple supply function within the MPS. They were not formally involved in determining patients' methadone treatment programmes and did not have access to urinalysis data or patient files, and these constraints may have limited their ability to influence patient care.

Research suggests that community pharmacists spend only a small fraction of their time advising patients on general prescription medicines (Bell et al 1999), but links greater input at that level with improved patient satisfaction (Bernsten et al 2001) and better, cost-effective treatment outcomes in health promotion medical interventions such as smoking cessation programmes (Crealey et al 1998, Maguire et al 2001). Another study found public support for the role of the community pharmacist as a provider of health education and individual advice (Cordina et al 1998). A diverse range of specific services have been identified within the extended role of the community pharmacist, which could be of benefit to opiate users (Sheridan & Shorrock 2001) and should be explored within the context of the MPS.

Recommendations from Australia highlight the value of regular case discussions between methadone prescribers, dispensers and other members of the care team, especially during the initiation and stabilisation phases of methadone treatment (Pharmacy Guild of Australia 2000) and UK treatment guidelines also advocated closer liaison at this level (Department of Health UK 1999). If it is to maximise the potential of community pharmacists involved in the provision of community-based methadone dispensing services, MPS management needs to promote a shared-care approach to methadone treatment, which includes community pharmacists as key players in the treatment team.

The co-operation and support of Irish pharmacists in the provision of methadone treatment services have been acknowledged by external reviewers (Farrell et al 2000) and by recent Irish policy makers (National Drugs Strategy 2001), both of whom advocated greater pharmacist input at team level. This study indicated that Irish community pharmacists who participated in the MPS, despite working largely in isolation, had well-established communication links with local methadone prescribers and with the E.H.B. Addiction Service's liaison pharmacists (O'Connor et al 2001), a finding which was corroborated by a concurrent external review of the service (Farrell et al 2000). The

value of communication at this level has been noted in the literature (Sheridan et al 1997, Leal 1999, Department of Health UK 1999, Farrell et al 2000) and was particularly important during the period immediately prior to the introduction of the MPS.

Efforts should be made to encourage drug treatment teams to include community pharmacists as fully integrated members, with their valuable role being acknowledged and recognised by other team members. Community pharmacist remuneration for greater involvement in social and psychosocial aspects of patient care and for regular interaction with other members of the drug treatment team could be of benefit for patients in methadone treatment under the MPS.

Research has shown that the provision of a liaison pharmacy service has value in promoting communication between community pharmacists and other members of the drug treatment team (O'Connor et al 2001) and this should continue to be an important role for the E.H.B. Addiction service liaison pharmacists. The implementation of the "keyworker" system advocated by the National Drugs Strategy 2001 could also help to promote better interdisciplinary and primary/tertiary treatment service communication, and facilitate the integration of community pharmacists into the community-based drug treatment team.

# 10.3. PHARMACEUTICAL SERVICES UNDER THE METHADONE PROTOCOL SCHEME

The expansion in the provision of community pharmacy-based dispensing services for patients on methadone 1mg/ml between 1998 and 1999 can be regarded as a positive outcome following the introduction of the MPS. However, recent research has also highlighted the need for quality in drug treatment services, if desired treatment outcomes are to be achieved (Dore et al 1999, Stewart et al 2000), so that the nature of the pharmaceutical services provided under the MPS was also important. Dispensing site, attendance regimens, on-site supervised dosing and "take-home" methadone doses are among key aspects of pharmaceutical services for patients in methadone treatment and the impact of the introduction of the MPS on these elements of Irish pharmaceutical services is described below.

### 10.3.1. Methadone Dispensing Sites

During the initial stages of the MPS patients surveyed as part of this work reported a preference for community pharmacy-based methadone dispensing services. Other researchers have also identified a patient preference for community-based methadone treatment, although these studies related this preference to the prescribers involved (Bennett & Wright 1986, Hindler et al 1995). Research has suggested that the provision of community-based services may diminish some of the negative aspects of methadone treatment by reducing patients' contact with active drug misusers and the drug scene (O'Connor et al 1996), although the delivery of poor quality services due to time constraints on busy community pharmacists has also been identified as a potential disadvantage of community pharmacy-based methadone treatment programmes in Australia (Peterson 1999).

Other research suggests that patients do well in primary care if their carers have positive attitudes towards them (Gabbay et al 1996). Therefore the need to cultivate positive attitudes among community pharmacists participating in the MPS, possibly through the provision of on-going support and training cannot be overestimated (Sheridan et al 1997, Matheson et al 1999b). There is also a role for the liaison pharmacist in promoting positive attitudes among service providers.

The later qualitative study (see Chapter 9) of service users' views identified complementary roles for primary and tertiary methadone dispensing services. Although the research methodologies employed differed and the samples involved were not identical, these findings provided interesting insight into patient perceptions of two methadone dispensing sites at two different times. They highlighted a shift away from an almost universal preference for community pharmacies and suggest that, over time, service users began to recognise the value of both primary and tertiary level dispensing sites. Respondents to the later study acknowledged the limitations of community-based methadone treatment and appreciated the merits associated with specialist care. They described community pharmacy-based methadone dispensing services as less disruptive and more normalised, with DTC pharmacies providing opportunities for closer monitoring and greater support for patients in need, and indicated that patients' preferences for one or the other service depended on their own personal and medical needs. This finding mirrored that reported by one London study which suggested that

patients expressed a preference for one dispensing site above another based on personal convenience factors, but found that preferences for primary and tertiary sites were equally common (Lovell et al 1999).

If the MPS is to continue to attract opiate misusers into treatment, it needs to build on the positive attributes related to both community pharmacy-based and DTC-based methadone treatment services while working to minimise the problems associated with each. The popularity of the community pharmacy over the DTC setting appeared to be associated with its more extensive opening hours, suggested that service providers could improve the acceptability and accessibility of tertiary service based methadone treatment by re-examining DTC pharmacy opening hours. While there are cost implications for tertiary drug treatment services, this issue should be addressed as quickly as possible in order to maintain adequate standards of care for all patients and make MPS pharmaceutical services more user-friendly and accessible. Findings suggest that once transferred to primary care, patients were left largely to their own devices, with much reduced input and limited (and sometimes inadequate) support. This may highlight a need for community pharmacists to be able to extend their role and provide broader, more general services for patients in the MPS.

### 10.3.2. Attendance Regimens

Findings from this research suggest that high frequency attendance regimens were commonplace under the MPS. These regimens protected communities from the dangers associated with the diversion of dispensed methadone and provided structure and focus for patients on methadone whose lives were not complicated by work or social commitments. However, patients' attendance regimens had implications for other aspects of their lives because of the time involved and the travel obligations associated with them, and high frequency attendance regimens may have had a detrimental impact on patients who were already socially functional. It has been suggested that requiring patients to attend their methadone dispensing services very frequently can have a negative impact on them by reducing their ability to lead normal lives and reinforcing their perception of methadone and their addiction as central in their lives (Larkin 2002). High attendance regimens may also have familial implication for patients who have young children, and national policy highlights the need for adequate childcare facilities to be provided in drug treatment centres (National Drugs Strategy 2001).

In addition, attendance regimens can affect patients' working lives, with reports of patients' employment being interrupted or terminated due to an increase in the frequency of their attendance at their methadone dispensing services (see Chapters 8 & 9). Farrell et al (2000) recommended that a return to employment be regarded as a positive treatment outcome and used as a key performance parameter for methadone treatment services, given the 30% return to work rate they reported. In light of this recommendation, difficulties experienced by patients who work should be taken into consideration in the determination of their attendance regimens.

### 10.3.3. On-site Supervised Dosing

This study found that community pharmacy participation in on-site supervised dosing was low in Ireland compared to Scotland (Matheson et al 1999b, Pitcairn et al 2001), although the comparison is limited because these measurements were taken in two operationally and demographically distinct environments. This was symbolic of the overall ethos of the two treatment models, with the Scottish system emphasising the value of supervised dosing and linking monetary incentives to its provision by community pharmacists. The Irish system advocates on-site supervision by community pharmacists, but it aims to care for the majority of unstable patients within tertiary drug treatment centres and provides no additional payment to pharmacists supervising doses at their pharmacies. In practice, however, this is not always the case, with this work identifying a sizeable minority of patients who were drinking methadone under supervision in the community pharmacy setting.

Participants in the present study described the value of on-site supervision in some circumstances. They recognised its usefulness in the treatment of patients who were unstable, unable to control their own doses or at risk of selling (or being asked to sell) their methadone. Similar findings were also reported in Scotland (Neale 1999). By reducing the volume of methadone dispensed into the community the supervision of methadone consumption has been shown to reduce the incidence of accidental overdose (Swenson 1988), which should have improved the public acceptability of methadone treatment for Irish opiate users. Supervision in the community pharmacy setting has been associated with improved patient retention rates (Berbatis 2001) and recent treatment guidelines published in the UK also advocated the use of on-site

supervised dosing in community pharmacies as a way of improving patient compliance during the initial stages of methadone treatment (Department of Health UK 1999).

The provision of on-site supervised services under the MPS was indicative of the extent to which community pharmacists co-operated with best practice initiatives, because while the Pharmaceutical Society encouraged its provision (McDermott 1999) and a grant was available for premises modification (Jackson 2001), no contractual obligations or financial incentives were associated with its provision. This inconsistency between policy and practice needs to be addressed to ensure that community pharmacists continue to provide on-site supervision services for patients in the MPS. Scottish research has suggested that offering a financial incentive for pharmacists who supervise the on-site self-administration of methadone may help increase its overall provision (Matheson et al 1999b) and this should also be considered in Ireland.

Privacy was the primary emotive aspect of on-site supervision dosing from the patients' perspective. Participants in other studies of patients in methadone treatment also regarded their privacy during supervision as being of tantamount importance (Matheson 1998b, Neale 1999, Ezard et al 1999, Hewitt 2000, Luger et al 2000). Drinking methadone at their local community pharmacy poses a considerable threat to the confidentiality of patients in methadone treatment, although the provision of special private areas may go some way towards protecting them. The availability of Department of Health & Children grants for community pharmacists who modified their premises to build private areas where patients could drink their methadone should have encouraged community pharmacists to provide such areas (Jackson 2001), although a recent study from the northern sector of the E.H.B. region reported less than half of the 38% of pharmacies that had private areas for methadone consumption had availed of these grants (Killen & Zayed 2001). Irish community pharmacists should be encouraged to maximise the level of privacy afforded to their patients during the supervision process, to protect patient confidentiality and reduce resistance to the service.

#### 10.3.4. "Take-home" Methadone doses

When compared to the Pharmaceutical Society of Ireland's *Policy on Drug Abuse* (1996) and subsequent practice guidelines (McDermott 1999), this study reported substandard practices in the dispensing of "take-home" methadone doses in many cases, particularly

in the community pharmacy setting. Community pharmacists were not reliably dispensing methadone in child-resistant containers, which has implications for child-safety. There are no national data on the prevalence of parenthood among those in methadone treatment in Ireland, but most of the patients surveyed during this work (57%) had children under 14 years old. Although the survey sample was not randomised or representative by parental status, the high incidence reported suggests that many children are exposed to methadone in their homes.

"Take-home" doses have been implicated in child-overdose (Binchy et al 1994, Calman et al 1996, Harkin et al 1999), and all doses supplied by pharmacists in the MPS should be dispensed in a manner that protects children from this risk. Although the data indicated that child-resistant containers were more likely to be used when methadone was dispensed to parents, many "take-home" methadone supplies continued to be dispensed without child-resistant tops. The use of child-resistant containers, as recommended by the Pharmaceutical Society of Ireland (*Policy on Drug Abuse 1996*, McDermott 1999) should become standard procedure in all community pharmacies, with appropriate remuneration being provided, if necessary.

Infrequent supply of pharmaceutical measures with multi-dose methadone containers as reported by both community pharmacists and patients involved in this research is another issue of concern, particularly in light of one report that implicates the use of babies' bottles as methadone measures in child overdose in Dublin (Harkin et al 1999). Measures are currently provided free-of-charge to community pharmacists in the MPS, yet many refuse to supply them to patients. The Pharmaceutical Society of Ireland should actively encourage community pharmacists to provide measures with multi-dose "take-home" containers as, where community pharmacists fail to do so, their patients and their communities are being put at risk. Qualitative research into the reasons why community pharmacists refuse to supply measures is necessary to gain insight into the rationale behind this unsafe practice.

While the use of plastic bottles for "take-home" methadone doses is recommended by the Pharmaceutical Society of Ireland (McDermott 1999), there is no stability data on methadone that is stored in plastic. Until such evidence is available, it will continue to be difficult to enforce this professional recommendation. And until plastic bottles are used in

all instances, there will continue to be conflict between pharmacists and patients around alleged breakages of glass "take-home" methadone supplies. There is an urgent need for stability testing to be carried out on methadone in plastic containers, and for the results to be disseminated among both pharmacists and patients, so that this activity can be brought into line with scientifically approved best practice.

## 10.3.5. Provision of 1mg/ml formulation of methadone only

The MPS only allowed for the prescribing of methadone 1mg/ml in the treatment of opiate addiction and the resultant discontinuation of Physeptone® linctus caused much angst among patients in methadone treatment. Formulation changes have been shown to be important to patients in methadone treatment (Neale 1998, Lovell et al 1999) with changes of formulation being particularly problematic among patients in this group (Steels et al 1992, Silver & Shaffer 1996). For this reason changes should only be undertaken after due consideration of the inherent disruption for those involved. Given that Physeptone® was not licensed for the treatment of opiate addiction, and considering it contained several additives not used in the 1mg/ml formulation, it is likely that the change was justified on this occasion. However, the availability of a number of different varieties of the 1mg/ml formulation may merit reconsideration, given the widespread confusion that surrounds them. There is a need to establish patients' views on the relative merits of the various methadone 1mg/ml products, and to investigate their relative palatability and potency. The establishment of a forum where service providers and service users could discuss this issue in a practical and egalitarian manner could help to reduce the confusion and distrust that currently exists.

Given the diversity in patients' needs it might also be pro-active to consider introducing an alternative to methadone for the treatment of opiate addiction, and recent policy has recommended the investigation of alternative treatment modalities and alternatives to methadone in the treatment of opiate addiction (National Drugs Strategy 2001). To this end, a review and evaluation of buprenorphine in substitution therapy is currently being carried out for the National Advisory Committee on Drugs (Corrigan 2001).

### 10.4. COMMUNITY PHARMACISTS' ATTITUDES

Findings from this study suggested that pharmacists who participated in methadone dispensing services were motivated by a mixture of personal interest, social obligation and professional duty. Their confidence in their ability to manage drug misusers and in their professional knowledge was often combined with fears for their personal safety, business concerns and lack of trust in their patients on methadone. This amalgam of views and attitudes resulted in their desire to normalise patients' methadone treatment by providing it in the primary care setting being tempered by their need to control the situation to avoid potential conflict and reduce the perceived risks to themselves.

Attitudinal data from this research indicates that the provision of external support in times of need promotes confidence among community pharmacists who dispense methadone and all efforts should be made to ensure that external support continues to be available to community pharmacists participating in the MPS. Community pharmacists' fears in relation to the treatment of opiate users may be alleviated by recent research findings which showed that German pharmacists' concerns that patients would steal, use violence or harass them or their other customers were not realised (Kalke 1997) and that the risk of property crime was not significantly higher in Australian pharmacies where methadone was dispensed (Berbatis 2001). One study which established that community pharmacists who held negative attitudes provided treatment services for limited numbers of drug misusers also suggested that the provision of adequate remuneration and specialist training might improve pharmacists' attitudes and encourage more pharmacists to get involved (Matheson et al 1999b), and this option could be explored within the Irish context.

#### 10.5. SUPPORTING COMMUNITY PHARMACISTS WITH PRACTICAL PROBLEMS

From a community pharmacists' perspective, the MPS was limited in its ability to provide support and back-up in instances where problems occurred in the day-to-day management of patients. This work indicated that while the liaison pharmacy service was primarily used to organise community-based pharmacy services for patients in methadone treatment, it had a considerable secondary role in providing advice and support for those working in methadone treatment services, in particular for community pharmacists (O'Connor et al 2001).

The diversity in the nature of community pharmacists' enquiries meant that their management required a degree of expertise, specifically in relation to the properties of methadone itself, the workings of the MPS and Irish drug treatment services, and findings identified a clear need for a specialist worker (pharmacist or other discipline) to fulfil this role. Analysis of the enquiries handled by the liaison pharmacy service can also help service providers to identify the problems community pharmacists encounter when working within the MPS and can offer guidance in the future development of the scheme. In addition, it offers service providers insight into the training needs of community pharmacists operating within the MPS. This work reported that clinical and policy issues, regulation and drugs information were most likely to give rise to liaison queries, information which could be useful in determining the nature and content of future training initiatives for community pharmacists.

The analysis of the pharmacy-related enquiries that were received from non-pharmacists also provided useful insight into the information gaps these disciplines had regarding pharmacy matters. The single most common individual cause of enquiry was the problems methadone prescription, which highlighted at the prescriber/dispenser interface. Prescription problems were also reported by both pharmacists and patients as the primary reason why pharmacists withheld methadone doses (see Chapters 5 & 8). The liaison pharmacist should facilitate two-way communication both between prescribers and pharmacists, and between tertiary drug treatment centres and pharmacists, thereby helping to promote "shared care", improve interdisciplinary relations and reduce problems at the methadone prescriber/dispenser and the methadone patient/dispenser interfaces.

Research has also shown that community pharmacists who work closely with GPs either proactively, within the GP surgery setting, or reactively, in response to queries, derive greater job satisfaction than those who do not (Boardman et al 1999). Perhaps the need for training expressed by respondents to Survey 3 could be provided as a multi-disciplinary initiative, as research suggests that interdisciplinary liaison is essential in promoting collaboration and in raising the quality of patient care (Leal 1999, Walker 2001). This could be particularly useful in light of recent policy advocating greater

pharmacist involvement in the overall treatment of those on methadone (National Drugs Strategy 2001).

#### 10.6. PATIENTS' VIEWS

The views of patients have been shown to be of great value in determining the structure and content of their healthcare services (as described, for example, by Bensing 2000) and recent Irish drugs policy (National Drugs Strategy 2001) has recommended that service users have a voice, with their views being taking into consideration at all stages of their treatment. This work presents, for the first time, the views of service users on their pharmaceutical services under the MPS, and can give service providers and strategists useful insight into the patient's perspective on these services.

The data amassed in the course of this project suggested that patients in the MPS had many and diverse needs, with some patients preferring service providers to take a paternalistic role in their treatment while others sought mutual-participation in the decision making process. An exploration of patient characteristics early in their treatment could help to identify individuals' needs and preferences, and could be useful in determining the methadone treatment programmes most appropriate for them.

The identification of varying patient needs has cost and resource management implications for MPS managers. It also has implications for pharmacists who dispense methadone under the MPS as they need insight into patients' views and preferences to be able to support and encourage them in the course of their treatment. While DTC pharmacists can depend on the other disciplines present on-site to deliver any additional support services necessary, community pharmacists work in relative isolation and need to be trained to recognise and address patients' needs in the primary care setting.

Not withstanding its limitations, this work found that the majority of the patients affected by the introduction of the MPS had experienced a positive impact (as defined in Chapter 8) in terms of clinical care and treatment services. However, some people who participated in these studies were unhappy with the pharmaceutical services provided under the MPS. Similar views have been expressed in the UK, where some say that recent policy changes have pathologised drug misusers to the extent that their views are

no longer recognised as valid, and they are subjected to appropriate treatments as determined by external experts. They suggest that such treatments are typified by the application of rigorous on-site supervised dosing regimens to patients in methadone treatment despite the personal circumstances of these individuals. It is suggested that this approach has disempowered drug misusers and encouraged a dependence on drug treatment services, which has further eroded patients' feelings of self-determination and control (Hewitt 2000, Ford 2001).

It is possible that the Methadone Protocol Scheme's paternalistic approach to service provision has undermined Irish patients' ability to "get better", with high frequency attendance regimens undermining patients' ability to work or lead "normal" lives (see Chapters 8 & 9). Traditionally, Irish drug treatment services have found it difficult to strike a balance between care and control, and moral judgements have affected the nature of some treatment modalities employed (Butler 1991 & 1993). It can be argued that the implementation of Statutory Instrument No. 225, which resulted in the introduction of the MPS, took control and self-determination away from individual patients by eliminating private prescribing, thereby forcing them to accept a more passive role in their own treatment. In such paternalistic treatment modalities, healthcare professionals disregard patients' views as intrinsically flawed and do not take them into account during decision-making processes (Parsons 1991). This process can create a level of dependence among service users and can result in feelings of resentment and disempowerment, such as were in evidence among some of those who participated in this research project (see Chapter 9).

MPS management should consider the structures enforced by the scheme, and evaluate them in terms of positive versus negative treatment outcomes. For example, this work showed that the primary role of one E.H.B. liaison pharmacist was to organise community pharmacy-based methadone dispensing services for patients (O'Connor et al 2001). But the liaison pharmacist organised these services without consultation with patients, and patients were allocated to individual pharmacies on the basis of availability and geographical location. The lengthy travel times reported by a minority of patients surveyed in the course of this project (see Chapter 8) suggested that their dispensing sites could have caused undue disruption to their lives, especially for patients who were attending very frequently and for those who were working. Although all community

pharmacies do not participate in the MPS, it is still possible that this situation could have been ameliorated by consulting with patients prior to their allocation to a particular methadone dispensing service. In addition, while the application of stringent attendance regimens and on-site supervision are useful in encouraging compliance, particularly during the stabilisation of patients (Department of Health UK 1999) and in reducing the volumes of methadone available for diversion, thereby reducing the risk of overdose to the community at large (Binchy et al 1994, Calman et al 1996, Cairns et al 1996, McCarthy 1997, Neale 2000), these treatment criteria may undermine patients' motivation (Larkin 2002) and study findings suggest that they may also cause difficulties for patients who work.

Irish policy makers and practitioners are challenged to balance the need to control the supply of methadone into the community as a whole with patients' right to autonomy and self-determination. Researchers have suggested that service providers should consider reviewing the key performance indicators applied to patients in treatment under the MPS, possibly including return to work as a positive treatment outcome (Farrell et al 2000). In those circumstances, it is possible that patients who work could have more flexible treatment programmes. Other aspects of patients lives could also merit due consideration, and service providers, including liaison pharmacists, need to listen to patients' views to gain more insight and understanding of their perspective. The appointment of patient representatives and the introduction of a patient charter as recommended by recent Irish policy (National Drugs Strategy 2001) should help to encourage such initiatives among those involved with the MPS.

It should be recognised that without feedback from opiate users who were not in the MPS it was impossible to determine whether the terms and conditions applied to those availing of its services may have represented a barrier to treatment participation. Further research is necessary to investigate this possibility as it is vital that the MPS, as the only methadone treatment programme available in Ireland, be accessible to all those who need it.

### 10.7. MANAGING CONFLICT IN THE COMMUNITY PHARMACY

Most community pharmacists involved in this study reported that their patients were easy to manage under the MPS (see Chapter 5) and most patients reported good relationships with their pharmacists (see Chapter 8). However, the embarrassment patients associated with the process of on-site supervised dosing and the widespread use of pharmacy/patient contracts suggests that many patients felt uncomfortable in their community pharmacies and that community pharmacists were applying conditions to the provision of methadone under the MPS. This work suggests that the juxtapositioned positive and negative attitudes reported by community pharmacists who dispensed methadone produced tension in the pharmacist/patient relationship. Patients believed that community pharmacists could easily refuse to dispense their methadone, and had concerns about the tenuous nature of their positions in community pharmacies, particularly should conflict arise. These unequal power relations resulted in fear and resentment among patients, which could ultimately give rise to anger and dispute.

Research has reported that the provision of methadone treatment services does not result in more acquisitive crime in community pharmacies (Berbatis 2001). But the nature of their business means that community pharmacists are subjected to more frequent disruptive incidents than other high street retailers, incidents which many pharmacists (either correctly or incorrectly) associate with drug misusers (Smith & Weidner 1996a & b), and perhaps the use of pharmacy/patient contracts developed in response to such incidents in the Irish context. The use of pharmacy/patient contracts is in accordance with good practice guidelines (Pharmaceutical Society of Ireland 1996, McDermott 1999). However, the use of individualised contracts by a number of community pharmacists may be indicative of an increase in the level of the control they exerted, and suggests that standard conditions were not being applied to all patients.

Although service providers and users must recognise the needs of society as a whole, so that methadone treatment programmes do not pose a danger to the communities that they serve, service providers should also acknowledge patients' rights and respect them in the determination and delivery of their care. Although practical considerations dictate that pharmacists continue to determine most aspects of the services they provide for opiate misusers, findings from this study suggest that there are many ways that they could improve the delivery of those services. These include maximising the privacy

afforded to patients during on-site supervision, not discriminating against patients with regard to their waiting times in the pharmacy and ensuring that pharmacy/patient contracts are fair and easy to understand. As research indicates that quality of service delivery is important in the ultimate achievement of treatment outcomes (Dore et al 1999, Stewart et al 2000), addressing these practical issues could make the MPS a more successful treatment service for Irish opiate misusers.

This issue needs further exploration and clarification, particularly in light of negative feedback from participants in the qualitative study undertaken as part of this research. Feedback from this study suggested that some community pharmacists make unreasonable demands on patients and that patients were antagonised by the use of pharmacy/patient contracts which they perceived as excessively strict (see Chapter 9). One Scottish study has also associated patient resentment with the application of excessive "rules" in the community pharmacy (Neale 1999). The incidence of the discontinuation of patients' treatment by community pharmacists in Scotland, where patients could take their methadone prescriptions to a community pharmacy of their choice and no data were available on the use of pharmacy/patient contracts was comparable with findings from a recent study in the northern sector of the E.H.B. region (42% reported by Matheson et al 1999b compared to 53%, Killen & Zayed 2001). These data suggest that limiting patients to one community pharmacy and using a pharmacy/patient contract may not reduce the number of instances of unacceptable behaviour in community pharmacies and further research is necessary to investigate the role of pharmacy/patient contracts in the management of patients in community pharmacy-based methadone dispensing services. The data suggest that a mutual agreement between community pharmacists and their patients, where patients agree to abide by a set of rules in return for appropriate pharmaceutical services, would be more acceptable and useful in addressing this situation, and the implementation of such an agreement should be explored and piloted to assess its value.

It is imperative that MPS organisers find ways of providing suitable and readily accessible support mechanisms for community pharmacists operating within the MPS. The present study indicates that provision of a liaison pharmacy service is a useful support mechanism, providing advice and expertise for community pharmacists and facilitating aspects of the pharmacist/patient relationship. In addition, MPS management

training initiatives and providing professional guidance and support to pharmacists participating in the MPS in Ireland, and these services should continue to be provided by them.

Australian recommendations advocate remuneration for community pharmacists who attend training in the field of drug use and methadone treatment, to improve quality of service and reduce pharmacist culpability by raising their knowledge base (Pharmacy Guild of Australia 2000), and such remuneration should also be considered in Ireland.

This work included the only national studies of pharmaceutical aspects of the MPS from the perspective of the community pharmacist and the patient. It provides original information and insight into practical aspects of methadone treatment service delivery, as well as exploring many important attitudinal issues. Findings from this work will be useful in planning future community-based treatment initiatives for Irish opiate addicts. In the following chapter the original aims of this work will be revisited and on the basis of the conclusions drawn from that analysis, recommendations will be made in Chapter 12.

## **CHAPTER 11**

# Conclusions

This study aimed to explore the impact of the regulation of methadone dispensing services (via the introduction of the MPS) on the provision of methadone by Irish pharmacists and to examine how these changes affected patients in methadone treatment at this time.

This work suggested that, as originally hypothesised, the introduction of the MPS had a largely positive impact on the provision of methadone treatment via Irish community pharmacies. This was reflected in terms of community pharmacy participation levels, standards of service provided and in the views of patients who were affected by the introduction of the scheme.

The study reported an increased level of community pharmacist participation in the dispensing of methadone 1mg/ml following the introduction of the MPS. This increase was a positive outcome of the introduction of the MPS, and further efforts to increase the provision of community pharmacy-based methadone dispensing services should be supported and encouraged if waiting lists for methadone treatment are to be controlled.

This research showed that liaison pharmacists had a role to play in the recruitment of community pharmacists to the MPS, and suggests that they will continue to play an important part in supporting community pharmacists who dispense methadone and encouraging others to get involved.

The introduction of the MPS also resulted in more normalised community pharmacy-based methadone treatment by reducing the mean number of patients per pharmacy, which should have improved the acceptability of such treatment programmes to the communities in which they were provided. Continued recruitment of community pharmacies can ensure that individual patient loads remain low.

Good communications existed between community pharmacists and the E.H.B. Addiction Service's liaison pharmacists. The liaison pharmacists facilitated further communication with local methadone prescribers and members of other disciplines. However, the concept of "shared care" was still in its infancy, with community pharmacists only having an auxiliary role in the community drugs team and their skills being largely under-exploited. Greater pharmacist involvement could have potential

benefits both for other team members and for patients in methadone treatment, and could be facilitated by a liaison pharmacist.

In relation to aspects of the pharmaceutical services provided for patients in methadone treatment in Ireland, this work initially recorded patient preferences for community-based methadone dispensing services, but a later qualitative study showed more balanced views, with patients recognising the value and limitations of both community and tertiary dispensing services. Service users view the community pharmacy as a less disruptive, more normalised dispensing site, while attending a DTC pharmacy meant that patients were more closely monitored and could benefit from a higher level of support. If methadone treatment is to remain user-friendly and accessible, MPS managers need to work to maximise the positive characteristics attributed to both dispensing sites while minimising their negative aspects. In particular, DTC pharmacies need to review their opening hours and the extent to which their patients are exposed to the drug scene.

A considerable proportion of community pharmacies were providing on-site supervision services for patients in the MPS when this work was carried out, although there was no direct remuneration associated with this activity. This was indicative of the extent to which community pharmacists co-operated with the introduction of the MPS, and their efforts should be acknowledged and commended. The anomaly between policy and practice which means that community pharmacists are not paid for providing on-site supervision services should be addressed, and could result in an increase in the extent to which it these services are provided.

Patients involved in this work recognised the advantages of on-site supervision in some instances, although the provision of adequate privacy remained a contentious issue. Community pharmacists who supervise the self-administration of methadone at their premises should do their utmost to protect the confidentiality of their patients by providing as much privacy as is physically possible.

MPS managers need to balance their obligation to protect individual patients and the community at large from the risks associated with dispensing methadone with their responsibility to allow (and actively encourage) people on methadone to function socially and lead "normal" lives. A review of the MPS's positive treatment outcome measures

could enable the system to be more flexible, particularly in determining the attendance obligations of patients who work.

While the introduction of the MPS was associated with some changes in pharmacy practice, substandard practices continued to be commonplace in the dispensing of "takehome" methadone doses, particularly at community pharmacies. They related to the provision of child-resistant tops, individual dose containers and the supply of pharmaceutical measures with multi-dose methadone dispensings. The supply of methadone in large volumes in containers that were not child-resistant has obvious associated risks, particularly considering the high incidence of parenthood reported. This issue should be addressed as a matter of urgency by the Pharmaceutical Society of Ireland. The Society's recommendation that "take-home" methadone is supplied in plastic bottles needs to be reviewed in light of future stability data.

The introduction of the MPS resulted in the discontinuation of the linctus formulation of methadone, which caused considerable difficulties for many patients. The availability of a number of different 1mg/ml products continues to be a source of confusion for patients in the MPS, although it would be difficult to change the situation now without causing further anxiety and antagonism. In light of the views of patients in the MPS, there is a need for policy makers to investigate alternatives to methadone for the treatment of opiate addiction.

When their attitudes were explored, many of the pharmacists who participated in the MPS appeared to hold mixed views about their involvement, with evidence of conflict between professional obligations and personal fears. This affected patients as some pharmacists attempted to control patients' behaviour using excessively strict pharmacy/patient contracts. MPS management needs to identify the legitimate fears of pharmacists who dispense methadone, and address them in ways that do not compromise patient care. Training in the management of drug misusers and adequate remuneration could help to promote more positive attitudes among community pharmacists.

Pharmacists need a variety of skills and external support mechanisms in managing patients in methadone treatment. Apart from the provision of training, MPS management

needs to identify and address the supports necessary for community pharmacists managing patients on methadone, and do its utmost to provide them. The liaison pharmacists represent one source of support for community pharmacists, and they should continue to prioritise this supporting role as it is vital for the continuation and expansion of community pharmacy-based methadone dispensing services.

This study found that the MPS was introduced without undue disruption to treatment services for many patients already participating in the MPP and the majority of those whose treatment was affected by its introduction reported that it had had a positive impact. But the introduction of the MPS took away patients' ability to self-select aspects of their methadone treatment by eliminating the option of attending private methadone prescribers. Patients reported experiencing more difficulty in accessing methadone treatment and more problems with their attendance regimens under the MPS. When it examined service users' views, findings from this research study suggested that their needs varied considerably. A mechanism should be put into place, which allows their views to be taken into account, in as much as it is practically possible to do so, in the determination of their methadone treatment programmes.

This research found tension in the pharmacist/patient relationship due to conflicting pharmacist attitudes and unequal power relations. This tension resulted in feelings of vulnerability and resentment among service users, particularly in the community pharmacy setting, which could ultimately result in anger and conflict. The use of pharmacy/patient contracts needs to be reviewed, and if they are to continue to be used, a standard format needs to be introduced. Perhaps the introduction of a "Four way Agreement" (as describer earlier) offers a practical alternative. The liaison pharmacists can also be helpful in dissipating tension in individual pharmacist/patient relationships at local level and recent national policy that recommends the introduction of a patient charter should also help in addressing this issue (National Drugs Strategy 2001).

The queries addressed to the liaison pharmacy service led to the identification of a number of information gaps for community pharmacists and members of other disciplines working with the MPS. Pharmacists participating in this study also expressed a desire for specialist training in the use of methadone, in the management of drug misusers and in the supervision of methadone self-administration. Such training should

be provided to make pharmacists' attitudes more positive, improve standards of care and extend the role of the pharmacists in the MPS. Training initiatives need to be planned and organised in direct consultation with pharmacist representatives, as the training previously provided did not appear to have met pharmacists' needs. This work also suggested that multidisciplinary training could have value in promoting mutual understanding and better communication between members of the community drugs team.

### **CHAPTER 12**

## **Summary Recommendations**

In the course of the analysis of the information collated from the quantitative surveys of both community pharmacists and service users; the queries addressed to the liaison pharmacy service and the qualitative exploration of service users' views on pharmaceutical aspects of the MPS, the following recommendations emerged:

#### 12.1. Community pharmacist participation

Community pharmacist participation is vital to the provision of methadone treatment under the MPS and on-going efforts should be made to recruit additional community pharmacies to the scheme.

#### 12.2. Community pharmacist communication

- 12.2.1. Members of community-based drug treatment teams should be encouraged to involve community pharmacists more fully and more formally in the overall care of patients in the MPS, moving towards a "shared care" treatment model.
- 12.2.2. Community pharmacists should be encouraged to participate more fully in their patients' treatment programmes, communicating on a regular basis with other members of the community drugs team.
- 12.2.3. Liaison pharmacists should continue to be a source of expert advice and information for community pharmacists working with the MPS, and should also facilitate communication links, particularly with methadone prescribers, vital in resolving day-to-day problems.

#### 12.3. Pharmaceutical Services under the MPS

#### 12.3.1. Dispensing Sites

- 12.3.1.1. Community and DTC-based methadone dispensing services have complementary roles in the provision of methadone treatment for patients in the MPS and should be developed in tandem to ensure adequate resources are available at both levels.
- 12.3.1.2. MPS management should promote the normalising effects associated with attendance at community pharmacy-based methadone dispensing services, while attempting to increase the levels of support provided to patients at these dispensing sites.
- 12.3.1.3. MPS management should maximise the support services available to patients attending DTC based methadone dispensing services, while endeavouring to

reduce the negative connotations of attending tertiary drug treatment services i.e. limited pharmacy opening hours and high exposure to the drug scene.

#### 12.3.2. Attendance Regimens

A review of the treatment outcomes that are taken into account in the determination of patients' attendance regimens may be merited in light of recent social and economic changes in Ireland, particularly in relation to high levels of employment among patients in methadone treatment.

#### 12.3.3. On-site supervision

Community pharmacists should endeavour to provide patients with adequate privacy during the supervision process.

#### 12.3.4. "Take-home" methadone doses

- 12.3.4.1. The Pharmaceutical Society of Ireland should move to enforce best practice guidelines regarding the use of child-resistant closures and individual dose containers and the supply of measures with multi-dose methadone dispensings.
- 12.3.4.2. There is an urgent need for stability testing to be carried out on methadone in plastic containers, and for the results to be disseminated among both pharmacists and patients.

#### 12.3.5. Exclusive use of methadone mixture 1mg/ml

- 12.3.5.1. There is a need to establish patients' views on the relative merits of the various methadone 1mg/ml products marketed in Ireland, and to investigate their relative palatability and potency.
- 12.3.5.2. The establishment of a forum where service providers and service users could discuss the issue of the formulation of methadone 1mg/ml in a practical and egalitarian manner could help to reduce the confusion and distrust that currently exists.
- 12.3.5.3. There is a need to look beyond methadone 1mg/ml in the provision of substitution therapy for opiate addiction.

#### 12.4. Community Pharmacists' Attitudes

- 12.4.1. Community pharmacists should be encouraged towards more positive and empathic attitudes towards the provision of methadone treatment under the MPS, and in particular towards the provision of on-site supervised dosing for participating patients.
- 12.4.2. Community pharmacists should be supported in overcoming their personal fears and concerns regarding patients in methadone treatment.
- 12.4.3. In as far as is practically possible, community pharmacists should acknowledge and respect the views of the patients for whom they dispense methadone.
- 12.4.4. Specialist training should be provided for undergraduate pharmacy students and for post-qualification pharmacists, to promote positive attitudinal changes towards the provision of methadone under the MPS and towards patients on methadone.

#### 12.5. Support for community pharmacists who dispense methadone

- 12.5.1. Community pharmacists need training in the clinical use of methadone, practical and policy aspects of the MPS, the on-site supervision of methadone consumption and in the management of patients on methadone. Such training should be provided as a matter of urgency.
- 12.5.2. The liaison pharmacists represent one source of support for community pharmacists, and they should continue to prioritise this supportive role.
- 12.5.3. Other external support mechanisms for community pharmacists need to be identified and implemented in order to promote community pharmacist involvement in the MPS.
- 12.5.4. The potential of a "Four way Agreement" such as that used in Berkshire (Walker 2001) should be investigated as a possible way of providing structured support for community pharmacists who dispense methadone.

#### 12.6. Patients' Views

12.6.1. MPS service providers need to recognise that different patients have different needs, and be more flexible and innovative in the design and delivery of their methadone treatment programmes.

- 12.6.2. A patient charter should be implemented and/or patient representatives should be appointed to present the views of service users in the development of methadone treatment policy.
- 12.6.3. Service providers should take individual patient's views into account as much as possible in the determination of their methadone treatment programmes.

#### 12.7. Pharmacist/patient conflict in the community pharmacy

- 12.7.1. There is a need to review current practice regarding the use of pharmacy/patient contracts.
- 12.7.2. MPS management, in conjunction with community pharmacist and patient representatives, needs to develop a mutually acceptable service level agreement to regularise the delivery of community-based methadone dispensing services.
- 12.7.3. MPS management should investigate the potential value of an independent mediator in resolving conflict between community pharmacists and patients in the MPS.

#### 12.8. Community pharmacists' training needs

- 12.8.1. MPS management needs to provide specialist training for community pharmacists who dispense methadone, including training in the management of drug misusers and those in methadone treatment, clinical information on methadone and its use and information on drugs of abuse and legal aspects of the MPS.
- 12.8.2. Multi-disciplinary training initiatives where community pharmacists trained with other members of the community drugs team could help to encourage teambuilding, interdisciplinary communication and mutual understanding.

### **CHAPTER 13**

### **Suggested Further Research**

This work highlighted several other areas with research potential and identified a number of potentially useful interventions. Future studies could include the following:

- 13.1. A qualitative investigation among community pharmacists to explore their views on their professional role in the provision of methadone treatment for opiate users. Such research should include community pharmacists not involved in the MPS to identify barriers to participation and attitudinal differences between these pharmacists and those who do dispense methadone. Findings from such work could help plan future developments in the MPS and guide liaison pharmacists in their efforts to recruit community pharmacists to the scheme.
- 13.2. An investigative study could explore community pharmacists' perspective on their place in the drug treatment team. It could examine the nature of their relationships with liaison pharmacists and methadone prescribers. In addition, it could examine qualitative aspects of pharmacist-initiated contacts with methadone prescribers, particularly in relation to problems with methadone prescriptions and dosage issues. A pilot research project could investigate the potential for a "shared care" approach to methadone treatment under the MPS with the community pharmacist being a fully integrated member of the community drugs team.
- 13.3. Qualitative research should be undertaken among community pharmacists to identify their fears and concerns in relation to methadone dispensing and the provision of treatment for opiate misusers. Such research could help to identify support mechanisms that could be provided to encourage community pharmacist involvement in the MPS.
- 13.4. Research should be carried out among community pharmacists to identify user-friendly and easily accessible ways of providing specialist training initiatives for them. A pilot multi-disciplinary training initiative should be carried out to assess its potential value in promoting shared care and encouraging interdisciplinary communication, support and co-operation.
- 13.5. Research should be carried out among a non-treatment sample of opiate misusers to investigate barriers to participation in the MPS.

- 13.6. A randomised control trial could investigate treatment outcomes among patients who were allowed to determine their own dispensing sites, attendance regimens and frequency of on-site supervised dosing (with due consideration to safety concerns) compared to a group of patients whose dispensing conditions were externally determined. A third group where these conditions were predetermined on initiating treatment (i.e. using a fixed methadone dosage schedule for a fixed treatment period) could also be examined.
- 13.7. Researchers should consult community pharmacists and patients regarding ways of maximising privacy during on-site supervision in the community pharmacy.
- 13.8. An independent audit of community pharmacies participating in the MPS could be useful in investigating the extent to which pharmacists adhered to the good practice guidelines published by the Pharmaceutical Society of Ireland (McDermott 1999) as pharmacists' self-reports from elsewhere have been shown to differ from those of service users (Assa & Sheppard 2000).
- 13.9. Qualitative research into the reasons why community pharmacists refuse to supply measures is necessary to gain insight into the rationale behind this unsafe practice.
- 13.10. Stability testing should be carried out on methadone stored in plastic containers so that pharmacists dispensing methadone can conform with scientifically approved best practice.
- 13.11. The pharmacological properties and relative potency of the various formulations of methadone 1mg/ml should be investigated.
- 13.12. The value of pharmacological alternatives to methadone in the treatment of Irish opiate misusers (e.g. buprenorphine) should be evaluated.
- 13.13. Research should be undertaken to examine the nature of the pharmacy/patient contracts employed by community pharmacists operating within the MPS and to look at the value of these contracts in assuring that community pharmacists deliver professional

pharmaceutical services and that patients behave appropriately in Irish community pharmacies.

- 13.14. An investigation into the incidence of violent or acquisitive crime against Irish community pharmacists could help to establish whether participation in the MPS is a factor affecting the incidence of crime in this country. While community pharmacists associate disruptive and violent incidences with drug misusers and patients on methadone (Smith & Weidner 1996b), one Australian study (Berbatis 2001) has reported that the incidence of violent crime against community pharmacists is not linked to their dispensing methadone. And community pharmacists in Hamburg found dispensing methadone considerably less disruptive than they had anticipated (Kalke 1997). A comparative study could look at the impact of the use of pharmacy/patient contracts on the nature of the pharmacist/patient relationship and the incidence of disruptive incidents or conflict in the pharmacy.
- 13.15. A pilot initiative using a "Four-way Agreement" could be useful in examining the potential role of such a system in facilitating co-operation and mutual respect among service providers and service users in the MPS.
- 13.16. A qualitative study could be undertaken to investigate the views of tertiary drug services management on how the pharmaceutical services offered to patients in methadone treatment were affected by the introduction of the MPS. Such a study could investigate management's views on the efficiency of pharmaceutical aspects of the MPS and the impact of its introduction on waiting lists, on the cost of methadone treatment and on the accountability of service providers.

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