

PHARMACY IRELAND 2020  
WORKING GROUP

**Interim Report**  
**April 2008**

Advancing Clinical Pharmacy Practice to Deliver  
Better Patient Care and Added Value Services



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# INTRODUCTION

As per part 2, section 7 para 7(2)(v) of the Pharmacy Act 2007: "it is the duty of the Society (Pharmaceutical Society of Ireland) to give the Minister such information and advice about such matters relating to its functions as the Minister may call for".

The President and Registrar of the PSI met with the Minister for Health and Children on the 14th of February 2008 and agreed to furnish a report within a three month timeframe agreed with the Minister, on how the pharmacy profession can contribute to the development of a more integrated approach to healthcare in Ireland in order to enhance services to patients. This followed on from the Registrar and the Council of the PSI, in the PSI Service Plan for 2008, commissioning a review of pharmacy services entitled Pharmacy Ireland 2020.

The PSI, in the publication of this Interim Report, is taking due regard of the fact that input would be desirable ahead of the deadline for consultations on a new generation contract for community pharmacy services. This Interim Report is intended to assist in those deliberations.

The Council of the PSI is of the opinion that pharmacy can make a further significant contribution to patient value, through accessible and cost effective services. It also acknowledges that the environment in which pharmacy is practised will have to continue to provide for patient safety and confidentiality and a high level of commitment to patient care.

This Interim Report is based on a discussion paper prepared by the Clinical Pharmacy Practice Research Group based in the School of Pharmacy in University College Cork, including Prof. Julia Kennedy, Prof. Peter Weedle, Dr. Mark Ledwidge, Dr. Stephen Byrne and Dr. Laura Sahm. The input of Dr. Paul Gallagher from the School of Pharmacy in the Royal College of Surgeons in Ireland is also gratefully acknowledged. Public and stakeholder submissions were invited during March, and any submissions which may be received after the publication of this Interim Report will be fully explored in the context of a final report.

The options detailed in this interim document look at the potential there is to deliver cost effective care to patients, both public and private, through pharmacies. The PSI would envisage that whatever services are implemented could be funded by the re-allocation of resources from within the health service.

Ireland has much to learn and gain from experiences in other jurisdictions, not least our nearest neighbours, whose health services bear many similarities to our own.

Pharmacy services in other countries, for example Scotland and New Zealand, are adding significant patient value.

Most jurisdictions, including the United Kingdom, are utilising evidence based approaches in the reform of their health services. Pharmacy services are deemed to be frontline services with an increasing potential to support home care, self care and effective care at the lowest levels of cost and complexity.

The Irish healthcare system is already undergoing significant reform and this document is intended to assist the deliberative processes ongoing throughout the health service on how best patient value can be delivered.

The PSI remains of the view that it is a necessity that the Department of Health and Children appoint a new Chief Pharmacist. The post has not been filled on a full-time basis for some time.

Pharmacy stakeholders, across all sections of the profession, as well as patient advocate groups, are invited by the PSI to participate in the ongoing debate, to chart a course for pharmacy services in Ireland to release more patient value.

This Interim Report was subsequently reviewed by the sub-committee of the PSI Council involving Ms. Ita Kelleher, Ms. Cathriona Hallahan and Mr Brendan Hayes (Chairman). The sub-committee was assisted by the Registrar of the PSI, Dr. Ambrose McLoughlin and the Policy Development Officer for the PSI, Dr. Cheryl Stokes.

The PSI hopes that this Interim Report will contribute to the ongoing discussions about the future of pharmacy service in Ireland, and intends to publish a final report later in the year.

# PRINCIPAL AUTHOR BIOGRAPHIES

## **Clinical Pharmacy Practice Research Group at the School of Pharmacy, University College Cork**

### **Professor Peter Weedle**

Professor Peter Weedle is a community pharmacist and adjunct Professor of Clinical Pharmacy at the School of Pharmacy, University College Cork. He is also a member of the Council of the Pharmaceutical Society of Ireland. Professor Weedle has a particular interest in the use of medicines by older patients, which has been the main focus of his research. He is the author of *Medicines and Pharmacy Law in Ireland* and a co-author of *Medicines: a guide for everybody* (9<sup>th</sup> edition).

### **Dr Mark Ledwidge**

Dr Mark Ledwidge is a pharmacist and holds a PhD in pharmaceuticals from Trinity College Dublin. A Clinical Lecturer in the School of Pharmacy, University College Cork, Dr Ledwidge is also the Director of Heart Failure Research at St Vincent's University Hospital, Dublin. A founding member and director of the registered charity Heartbeat Trust, he previously served for five years on the Irish Heart Foundation's Council on Heart Failure. He is also currently a member of the Advisory Group on Human Medicines of the Irish Medicines Board.

### **Professor Julia Kennedy**

Professor Julia Kennedy leads the Clinical Practice department at the School of Pharmacy, University College Cork, which covers both undergraduate and postgraduate education. A native of New Zealand, she holds a PhD from Otago University. Prior to joining the academic staff at that institution in 1989, she worked as a clinical pharmacist in hospitals in New Zealand and England. Professor Kennedy's research interests include perioperative drug use and pain management, drug metabolism in AIDS patients and medication safety.

## EXECUTIVE SUMMARY

1. The Council of the Pharmaceutical Society of Ireland (PSI) at its meeting on the 26th of February 2008, approved the establishment of a sub-committee entitled Pharmacy Ireland 2020 to perform a review of pharmacy services in Ireland and prepare an Interim Report which would be presented to the Minister for Health and Children.
2. The sub-committee placed an advertisement on the website of the PSI and also in The Irish Times newspaper on the 7th March 2008, inviting stakeholders and patient advocacy groups to make submissions to the sub-committee with a deadline for submissions by the 28th of March 2008 at 5:00pm.
3. The purpose of the Interim Report is to review pharmacy services currently provided in Ireland and compare them with best practice in other countries. Because of limited time and resources, the sub-committee's Interim Report can be regarded only as preliminary work.
4. The Interim Report will enable key decision and policy makers to engage in the development process in a structured and systematic way.
5. International and national evidence demonstrates the significant impact pharmacists can have in health gain for patients. The Interim Report outlines services that could be provided by pharmacists in Ireland, that are currently carried out in other jurisdictions around the world with great success, enhancing services to patients and providing cost effective solutions to problems currently encountered by our health system.
6. Submissions to the sub-committee included a number which made specific recommendations:
  - i. The need for broadband access within pharmacies to enhance pharmacists' access to up to date information.
  - ii. The establishment of a minor ailments scheme.
  - iii. The need for greater funding for pharmacy practice research to enhance the services provided by pharmacists and expand their role was identified.
  - iv. The role pharmacists could play in medication use reviews.
  - v. The need for a national needle exchange programme.
  - vi. Re-classification of certain medicinal products.
  - vii. The role the pharmacist can play in chronic disease management was highlighted.
  - viii. The need for sharing of patient medication records to enhance the services provided to the patient and increase patient safety.
  - ix. The role the pharmacist can play in routine immunisation.
  - x. That health screening could be provided in community pharmacies.
  - xi. Pharmacists involved in clinical pharmacy activities in hospitals can contribute significantly to patient care.
  - xii. Any modifications to practice should give incentives to community pharmacists to optimise their involvement in patient care.
  - xiii. Pharmacists can contribute to an improvement in adverse drug reaction reporting.
  - xiv. Pharmacists have a critical role to play in ensuring that the benefits of self-medication are fully realised.
  - xv. Pharmacists are particularly well placed to help their patients get the best from their medicines and ensure these are used appropriately, providing greater patient safety, improved disease and drug therapy management, effective healthcare spending, improved adherence and improved quality of life.
  - xvi. There is a need for internationally recognised, effective training and intervention models to be given to pharmacists to ensure that they can give appropriate advice and intervene if necessary to prevent misuse or abuse of medicines.
  - xvii. Pharmacists should be allowed to prescribe under specified protocols to enable greater access to treatment and promote early intervention.
7. Chronic diseases e.g. diabetes mellitus, general cardiovascular disease and chronic obstructive pulmonary disease, are major causes of death and disability in developed and developing countries, and represent a significant burden on healthcare spending. This burden on the healthcare system will continue to grow unless there is earlier intervention in the management of chronic diseases.
8. The clinical benefits of pharmacy involvement in chronic disease management are compelling, with a large evidence base detailing that pharmacists have the most frequent contact with chronic disease patients due to their accessibility, and that pharmacists could provide clinical and cost benefits through the existing community pharmacy network.
9. Avoidable medication errors occur every day and the role of the pharmacist in minimising drug errors has been shown to be both clinically and cost effective.
10. As the evidence-based drive to greater polypharmacy results in greater drug-drug and drug-disease interactions, the pharmacist's role in pharmaceutical care of patients should be recognised and developed. The pharmacist could also play a more central role in adverse drug reaction (ADR) reporting, which currently in Ireland is significantly under reported.

11. Medication management and medicine use reviews (MURs) have significant benefit for patients, in ensuring they receive the best therapy possible in compliance with internationally accepted guidelines, that all patients receive optimal therapy and that the process is quality assured and validated. The Joint Committee on Health and Children's Eighth Report on The Adverse Side Effects of Pharmaceuticals' recommended that the role for the pharmacist in community health should be expanded and provision made for regular medication reviews for all patients.
12. Clinical services provided by pharmacists in hospitals have become an established part of hospital healthcare. The emphasis for pharmacists has now shifted to assuming responsibility for pharmaco-therapeutic outcomes. Pharmacists are also increasingly taking lead roles in patient care across all the medical and surgical specialties, from neonatal intensive care, through to ambulatory care of the older person and palliative care.
13. The frontline role of the community pharmacist in the management and treatment of minor ailments and in the provision of professional advice on self-care, is an important part of the primary health care process. The implementation of a National Minor Ailments Scheme would benefit the patient by providing greater access to healthcare advice, would benefit the health service by targeting resources and making savings which can be redistributed, and would benefit the general practitioner (GP) by freeing up their time to treat more patients with serious or chronic illness.
14. The switching of medicines so that they are more readily accessible to patients could be facilitated by the introduction of a new legal category "pharmacist prescribed", which would require the pharmacist to carry out a number of clinical checks and record details of the consultation. An example of this would be codeine, which could be switched from over-the-counter to this new category, and therefore allow greater pharmacist supervision and benefit patients' health and welfare. It would also provide patients with a wider range of medicines to treat their own ailments without referral to a GP, thereby freeing up the GP's time.
15. With the introduction of nurse prescribing, and following the commencement of the Pharmacy Act 2007, pharmacists, due to their training and knowledge in pharmaceutical chemistry, pharmaceuticals, pharmacology, clinical pharmacy and therapeutics, are in a position to have prescribing rights assigned to them through supplementary and/or independent prescribing. A national policy on pharmacist prescribing should be developed by the Department of Health and Children and the Health Service Executive (HSE).
16. The initiative of pharmacist prescribing would need to be supported by a system enabling healthcare professionals' access to patient medication records (PMRs). The establishment of an integrated patient record system, to ensure that prescribers have ready access to all relevant information on patients, was also recommended in the Joint Committee on Health and Children's Eighth Report on The Adverse Side Effects of Pharmaceuticals.<sup>1</sup>
17. Health screening is guided by principles set down by the World Health Organisation (WHO) and requires careful targeting to maximise its impact. It is currently limited by lack of accessibility and/or availability of facilities and appropriate testing. With the average community pharmacy in Ireland open 50% longer than GP clinics, and with the continuous availability of health professional advice without appointment in those pharmacies, it is possible that pharmacy-based health screening may have advantages in terms of reach, accessibility and cost effectiveness.
18. Health screening could prove effective in the diagnosis of numerous diseases, including chronic diseases. Evidence suggests that conditions such as diabetes mellitus, infectious diseases, cardiovascular disease, depression, some cancers, osteoporosis and chronic obstructive pulmonary disease could be identified through health screening. A national policy is necessary with respect to health screening and a co-ordinated approach with the HSE and the Department of Health and Children.
19. Prevention of illness, rather than treatment of the patient once illness has occurred, is the primary focus of all forms of vaccination whether it occurs at a local, national or global level. It is widely accepted that annual vaccination remains the best protection against influenza, especially in people who are at high risk of complications from influenza. The provision and delivery of vaccination services has occurred through the network of community pharmacies in other jurisdictions.
20. In order for pharmacies to provide vaccination services, a national policy should be developed and a strategy for maximising the use of vaccines which takes account of the huge potential of the community pharmacy network.
21. There are four levels of care: self care, primary care, secondary care and tertiary care. This report highlights that significant advances could be made in self care, by moving people from primary care to self care under the expert supervision of a pharmacist. This could free up primary care services so that they could deal with chronic disease more effectively, thereby

freeing up resources in secondary care. The contribution that clinical pharmacists can make, to both primary and secondary care, is also emphasised in this report.

22. The Interim Report proposes that a Strategic Policy Advisory Group (SPAG), representative of all stakeholders, be appointed by the Minister for Health and Children. The Report also proposes the appointment of a Resource Implementation Group (RIG) by the Minister for Health and Children on the nomination of key service providers and regulators, to oversee the implementation of any initiatives over the next two to three years, having due regard to the constraints on resources available to the health system. In appointing the SPAG, the Minister for Health and Children should consider appointing experts from other jurisdictions to support the SPAG and the RIG in their work.

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# **1. Chronic Disease Management in Pharmacy Patient Centred Care**



# 1. Chronic Disease Management in Pharmacy

Chronic diseases are the major cause of death and disability in developed and developing countries.<sup>1</sup> In Ireland, chronic diseases such as diabetes, cardiovascular disease (including heart failure and coronary artery disease) and chronic obstructive pulmonary disease (COPD) account for just over 60% of deaths and the major national morbidity burden.<sup>1,3</sup>

Chronic disease is estimated to absorb three quarters of all health care spending in Ireland and accounts for 80% of all consultations with general practitioners (GPs).<sup>1,2</sup> Currently, two out of every three patients admitted to hospitals as medical emergencies have exacerbations of chronic disease. As chronic diseases tend to cluster, a small number of people with multiple chronic illnesses are extremely high users of acute services: HIPE (Hospital In-Patient Enquiry) data has shown that this 5% of the general population accounts for 35% of the bed-day occupancy on an annual basis.<sup>1</sup>

There is a growing realisation that the internationally acknowledged failure of western countries to satisfactorily manage chronic diseases will in time overload healthcare resources. This arises because chronic diseases cannot be cured and must be managed by patients and healthcare providers on an on-going basis. Ireland is unusual amongst western countries in having a relatively young population profile.<sup>3</sup> Accordingly, as the population over 65 in Ireland is set to triple over the next 30 years, and services are already under strain, the HSE has already acknowledged in relation to chronic diseases that “our existing model of care for these diseases is now inadequate to the challenge.”<sup>2</sup>

Poor screening structures for major chronic diseases result in under-diagnosis and delayed treatment being offered to patients. Elsewhere in this report (see Section 8), is an outline of the role and evidence base supporting the need for a national policy on chronic disease screening in community pharmacy. It is worth noting here that almost all pharmacies in Ireland employ computerised databases which can facilitate the screening of populations at risk of chronic diseases using medication identifiers.

Moreover, all the major chronic diseases of particular concern to the HSE are characterised in national and international studies by under-treatment and failure to achieve guideline management goals in routine care structures.<sup>4</sup> This represents a complex systems failure involving the patient, physician, allied healthcare professional bodies and health services provider, involving failure to adhere to guideline treatment standards by the healthcare providers and an endemic problem of adherence and compliance to treatment advice by patients. It results in unnecessary morbidity, mortality and healthcare cost.<sup>4</sup>

Pharmacists as frontline healthcare professionals are frequently in contact with chronic disease patients. This arises because the vast

majority of patients are managed with medication and community pharmacists have at least monthly contact with these patients or their representatives. Therefore, the rationale for the development of the professional role of the pharmacist in chronic disease management is compelling and is supported by a substantial national and international evidence base, a selection of which is described in this report.

Scotland, arguably, has a similar profile of chronic disease as Ireland, and a formal initiative involving Scottish pharmacists in the management of chronic diseases will commence later in 2008. Entitled the Chronic Medication Service (CMS), it will enable community pharmacists to contribute to the management of long-term conditions. Over a 12-month period, pharmacists will provide monitoring, medication review and, if they are supplementary prescribers, adjustment of the doses of patients' medicines. This will require a shared care agreement between the pharmacist, GP and the patient. The CMS will require patients to register with a pharmacy and payment will be on a capitation basis. This service requires underpinning by IT support to facilitate the integrated service.

It is the CMS that will present community pharmacy in Scotland with the greatest opportunities in providing preventative, anticipatory care by managing long-term conditions. It will also allow pharmacists to use their supplementary prescribing skills and, ultimately, independent prescribing skills.

However, whilst the HSE's National Service Plan 2008<sup>2</sup> repeatedly highlights important goals relating to prevention and management of chronic disease, there is no mention of the professional role which pharmacy might play. This overlooks the growing evidence base for the beneficial effects of pharmacy interventions in the management of chronic disease and is a major deficiency in that plan.

## EVIDENCE BASE IN CLINICAL PHARMACY PRACTICE

The following is a selection of the evidence base for clinical benefits of pharmacy involvement in chronic disease management, with emphasis on the key chronic diseases as set out in the HSE National Service Plan 2008.<sup>2</sup>

### Diabetes Mellitus (DM)

In Ireland in 2005, the estimated prevalence of Type 2 DM in adults was 4.3%.<sup>5</sup> When population change is taken into account (and assuming that obesity rates continue to rise in a linear fashion), the PHO-Brent-SchARR (PBS) diabetes population prevalence model estimates that this figure will rise to 4.6% by 2010 and to 5.2% by 2015.<sup>6</sup> Nolan *et al.* expect that an ageing population, obesity and sedentary lifestyles will be the reasons for this expected rapid growth in the number of people affected by Type 2 DM.<sup>7</sup>

Correction of hyperglycaemia is a vital objective in the treatment of Type 2 DM. However, therapy should also include measures to combat obesity, dyslipidaemia and hypertension. In Ireland, the CODEIRE study (based upon a prevalence of 3.9% for Type 2 DM) estimated that the annual cost of managing diabetes was €377.2 million, which corresponded to 4.1% of total healthcare expenditure.<sup>7</sup> Importantly, this high cost of managing Type 2 DM was mainly attributable to tackling the long term microvascular and macrovascular complications.

Krass *et al.*<sup>8</sup> has demonstrated that a pharmacy care programme for patients with DM, over a relatively short six month period, improved indices of glycaemic control, medication adherence and significantly reduced HbA<sub>1c</sub> by 0.97% compared to controls. This level of improvement in long-term glucose control approximates in the UK Prospective Diabetes Study (PDS) to a one third reduction in the development of microvascular and macrovascular complications. Similarly, Rothman *et al.* looked at the impact of pharmacy-based professional support for diabetes and demonstrated significant reductions in blood pressure and glycaemic control (HbA<sub>1c</sub>) compared to controls.<sup>9</sup> Furthermore, in this study, intervention patients had significantly greater improvements in diabetes knowledge and satisfaction than controls. In the longer term, structured pharmacy care has been shown to significantly reduce end-stage renal disease and death by 60% in vulnerable patients with diabetes and nephropathy.<sup>10</sup>

#### General Cardiovascular Disease

Pharmacy-based screening studies have shown that only 37% of high risk coronary artery disease patients achieve guideline goals.<sup>11</sup> Pharmacist management of high cholesterol has been shown to more than double the proportion of patients achieving guideline levels.<sup>11</sup> Amongst a more selected cohort of peripheral artery disease patients, pharmacy clinical care resulted in a goal achievement rate of 79%, compared to 54.8% in the usual care group.<sup>12</sup> Accordingly, patients and pharmacists are positively disposed to the role of pharmacists in the active management of cholesterol problems and the provision of statins.<sup>13</sup>

Similarly, pharmacist-based management of hypertension in diabetics and non-diabetics has been shown to significantly improve blood pressure control.<sup>10,14</sup>

#### Chronic Obstructive Pulmonary Disease

A range of studies have demonstrated clinical benefits and cost-effectiveness of professional pharmacy interventions. McLean *et al.* demonstrated that community pharmacy-based intensive care of asthma improved disease prognosis, reduced medication dependency and resulted in a reduction of days off work and

school, per patient treated, of 0.6 per month.<sup>15</sup> Armour *et al.* recently reported a randomised pharmacy-based care programme which resulted in improved asthma control, with patients receiving the intervention 2.7 times more likely to improve from “severe” to “not severe” than control patients.<sup>16</sup> The intervention also resulted in improved adherence to “preventer” medication and decreased mean daily dose of “reliever” medication. Similarly, with a pharmaceutical care programme, Mangiapane *et al.* demonstrated improvements in asthma-specific quality of life, self-efficacy, knowledge, medication adherence, asthma severity, self-reported symptoms and peak expiratory flow.<sup>17</sup>

#### Heart Failure

Heart failure accounts for about five per cent of all medical admissions, has high readmission rates, is dramatically increasing in prevalence and has a prognosis rivalling that of major cancers.

Following the publication in 2007 of ‘Ireland: Take Heart’ (The audit of progress on the implementation of the 1999 cardiovascular strategy ‘Building Healthier Hearts’),<sup>18</sup> a major gap in the provision of heart failure care across primary and hospital services was identified by the HSE. Heart failure is predominantly managed medically and adherence to medical therapy is critical in heart failure as with all chronic diseases.<sup>19</sup> Despite the life-threatening potential of heart failure, non-compliance with effective therapy is well described.<sup>19,20</sup> This observation, that failure to adhere to therapy remains a significant problem in a well-educated heart failure population managed by disease management programmes, points to potential gaps in an optimal service.

A major gap in the current approach to community care of heart failure is the lack of systematic use of the pharmacist in disease management programmes. Given the frequency of contact between community pharmacists and patients, this existing network of health professionals in the community should be more closely linked to general practice and hospital services.

Irish work has shown that one third of stable, community-managed heart failure patients have severe adherence problems and that, independent of disease severity, this is associated with a 2.4 fold increase in hospitalisation and a 72% increase in annual direct costs of care.<sup>20</sup> Intensive pharmacy care has been shown to significantly reduce adherence problems to 39% of control levels.<sup>21</sup> Because of under-treatment, it is not surprising that evidence-based disease management of heart failure results in increased polypharmacy and increased drug interactions,<sup>22</sup> which results in increased complication of therapy and increased potential for patient confusion. Therefore, the arguments in favour of a more systematic role of the pharmacist in addressing compliance problems is compelling.<sup>22</sup>

The improvement in outcome with pharmacist care of heart failure can be directly linked to medication adherence and dosing, which can be improved with pharmacist/physician care compared to physician care alone.<sup>21,23</sup> Furthermore, the improvement in medical care delivered by pharmacist involvement was associated with reduced hospitalisation and reduced costs of care over a six-month period of between US\$4,200 and US\$6,000 per patient.<sup>23</sup> The improvement in medication adherence and dosing is also associated with improved self-care, reduced smoking, reduced alcohol consumption and a 42% reduction in the proportion of patients with severe (New York Heart Association (NYHA) Class III and IV) symptoms.<sup>24</sup> Tsuyuki *et al.*<sup>25</sup> have also demonstrated that structured pharmacist care of heart failure results in a 2.4 fold reduction in re-hospitalisation and a reduction in total costs of care by \$2,531 over six months.

In summary, chronic diseases present the greatest actual and future challenges to the healthcare system. The HSE describes current care models as “inadequate” in the face of these challenges. Effective medical therapy is a key factor in good chronic disease management programmes. Furthermore, there is a large and growing evidence base which points to cost-effective, clinical benefits of structured pharmacist involvement in these programmes. There is an urgent need to develop the role of Irish pharmacists in the provision of a high quality chronic disease management service to patients and the key benefits are as follows:

### BENEFITS TO PATIENT AND HEALTHCARE PROVIDER

1. Pharmacy is the primary care service with greatest accessibility for the general population and the pharmacist has the most frequent contact with chronic disease patients of any healthcare professional in Ireland.
2. There is continuous availability of highly trained health professionals in pharmacy.
3. There are proven clinical benefits and cost-effectiveness arguments for patients’ management supported by pharmacists in a range of chronic diseases such as osteoporosis, diabetes, cardiovascular disease, heart failure and COPD. Each of these has been identified by the HSE as priority areas.
4. There would be minimal capital expenditure in rolling out chronic disease management programmes in the existing pharmacy network and it therefore represents a cost effective solution to a significant problem.

5. There is easy access to medication identifier data for patients at-risk of chronic diseases using patient medication record databases which are employed in almost all pharmacies.
6. Pharmacists can play a greater role in disease management and also increase compliance in taking medicines correctly.

### CONCLUSIONS

The current review of chronic disease management by the National Steering Committee of the HSE has not identified an evidence-based role for the involvement of community pharmacy in chronic disease management. The evidence base supporting the clinical benefits and cost-effectiveness of pharmacy chronic disease management programmes to address adherence, self-care and guideline goal achievement by patients are clearly outlined in this Interim Report and should be given significant consideration.

The utilisation and development of the existing community pharmacy network could deliver cost-effective clinical benefits in the care of chronic disease.

In order to achieve consistently high levels of service delivery, there is a need to provide conversion training and ongoing accreditation for pharmacists in each of these chronic disease areas. This accreditation should be through the PSI and provided within the three Schools of Pharmacy.

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## **2. Pharmacy and Drug Safety**

### **Protecting Patients**



## 2. Pharmacy and Drug Safety

Prescribers are human and will make mistakes. Errors made during drug prescription writing and dispensing are the most common type of avoidable medication error and are important intervention targets as part of safe systems of medical care.<sup>1</sup> Other types of avoidable medication errors include untreated indications, drug use without an indication (inappropriate), improper drug selection, sub-therapeutic dosage, over-dosage, medication non-adherence, drug interactions, adverse drug reactions (ADRs), adverse drug withdrawal events (ADWEs), and therapeutic failure.<sup>2</sup>

Furthermore, an important element of safe drug systems involves feedback on ADRs which may or may not have been foreseen by the prescriber. Drug regulatory authorities in various jurisdictions have developed this role since the 1960s<sup>3</sup>, although it is now widely acknowledged that the current systems are limited.<sup>3,4</sup>

ADRs in particular have recently been estimated to result in more than 250,000 hospitalisations per annum in the UK, at a cost of almost half a billion pounds in 2004.<sup>5</sup> Despite the intervention of pharmacists in prescribing errors, there is a widespread and serious problem with the feedback systems to statutory drug regulatory authorities with regard to ADRs.<sup>4</sup>

Pharmacists in Ireland have an important role to play in both elements of a safe medication management system. As in the UK and other countries, the pharmacist can play a greater role in the management of drug safety monitoring, and in ADR reporting/feedback.<sup>2</sup>

It may be appropriate to have an intensive monitoring system for certain selected medicines with novel chemistry or pharmacology, in addition to an improved general post-marketing drug safety surveillance system. In early 1977, following the withdrawal of the drug prazosin from the worldwide market, such an Intensive Medicines Monitoring Programme (IMMP) was instigated in New Zealand. The IMMP is designed as an early warning system whereby isolated incidents are reported without having to attribute them to the actual drug, e.g. a patient admitted to an orthopaedic ward from a fall and who was on one of the medicines on the scheme would have that admission reported. This event may be an isolated report, but also it may be that several other patients were suffering from falls and the drug was causing hypotension, a side effect which may not have been able to be predicted from the pharmacology of the drug. A group of six to eight selected new medicines in the early post-marketing period are chosen each year and put onto the intensive monitoring list. Specific duplicate prescriptions are used for those drugs, with one copy being retained by the pharmacist and the other sent to the IMMP centre. Patients are monitored for any events that may have occurred whilst taking those drugs and doctors, pharmacists, nurses and other health care professionals may independently report adverse events.

The purpose of this programme is to identify signals of previously unrecognised ADRs and establish risk profiles for each drug. This programme has a considerable international reputation. This scheme differs from usual ADR reporting schemes in that causality does not have to be linked by the reporter to the suspected drug. The “event” is reported to the IMMP centre in Otago University and each event is then reviewed by a physician, and a relationship is established between each event and the drug, using the same process as for reviewing ADR reports. The events are then sorted into reactions and incidents. The latter are used to assist signal detection and control for bias. Rates for reports, reactions and incidents are used to assess the adequacy of reporting, signal detection and identification of confounders. Most signals are identified by clinical evaluation of the reports at a stage when statistical analyses are unlikely to have the power to detect them with confidence.

However, as recent experience with cardiovascular risk associated with non-steroidal anti-inflammatory drugs (NSAIDs) and COX-II inhibitors (including the withdrawal of Vioxx) has indicated, important ADRs are also associated with medications that have been marketed for considerable periods of time and used in vast populations. The IMMP system has merits in itself and the principle of reducing the “reporting threshold” should be applied across the spectrum of drug therapy. In addition to the IMMP system, there is an urgent need for a wider and more consistent safety net for ADR and drug safety reporting.

### EVIDENCE BASE IN CLINICAL PHARMACY PRACTICE

Errors made during drug prescribing are the most common type of avoidable medication error and are hence an important target for improvement.<sup>2,5,6,7,8</sup> As well as fulfilling a supply role, pharmacists monitor prescriptions to detect errors that may occur, and this active pharmacist/physician collaboration has been shown in a randomised study to reduce inappropriate medications in pregnancy by 53% compared to usual care.<sup>9</sup>

Pharmacist participation in the management of patients' medication has been shown to contribute to more appropriate prescribing,<sup>10,11</sup> reduced use of inappropriate medications and a reduced rate of ADRs.<sup>14</sup> Furthermore, the important role provided by pharmacists can have an impact on the cost of care, as well as the cost of medication, partly by reducing ADR-related hospital admissions.<sup>14</sup> Although much of this work is undocumented in the community and its current impact in Ireland is not determined, it is known that the less time a pharmacist has to spend checking prescriptions, the less time they can spend checking for errors<sup>15,16</sup>. Indeed recent research from the US has determined that the higher the workload of the pharmacist, the lower the number of pharmacists per hour of opening and the greater the degree

of automation, the more likely pharmacists are to dispense medications with drug-drug interactions.<sup>16</sup> This also highlights the need for an appropriate level of pharmacist cover in each community pharmacy depending on the throughput of the pharmacy.

This is particularly important in the context of the evidence-based drive to greater levels of polypharmacy as a medical means of managing chronic disease.<sup>17</sup> Studies have consistently shown that this trend toward increased evidence-based polypharmacy in chronic disease results in increased prevalence of clinically significant drug interactions.<sup>17,18</sup> For example, Nguyen *et al.* have demonstrated that polypharmacy is almost twice as likely to cause ADRs in older patients,<sup>19</sup> and published Irish data in relation to heart failure have demonstrated that there is a 62% increase in potential drug interactions, with a one third increase in the number of prescribed drugs.<sup>17</sup> Therefore, polypharmacy is becoming more prevalent and more complex to manage.

Interestingly, a recent US study has also shown that in up to 58% of older patients, there is prescribing of at least one inappropriate medication<sup>20</sup>. In other studies the prevalence of inappropriate medication use and dangerous drug interactions was 31% and 10% of all patients. The corresponding figures rose to 37% and 20% respectively in those with polypharmacy (>8 medications).<sup>21</sup>

Several studies have demonstrated that pharmacist recommendations significantly improved the appropriateness of medication use among patients receiving home health care.<sup>22,23,24</sup> Boockvar *et al.* demonstrated that pharmacy intervention within a 168 bed nursing home facility identified a total of 696 prescribing discrepancies over a three-year period.<sup>24</sup> Furthermore, following the implementation of a clinical pharmacy service which focused on the post-discharge prescribing, discrepancy-related adverse events were significantly reduced from 14.5% to 2.3% and 89% of the identified discrepancies were acted upon by medical staff.<sup>24</sup> In care institutions, based on audit data in the National Health Service (NHS) UK, it is estimated that between 50 and 165 preventable adverse drug events occur annually per 100-bed care institution and that pharmacy involvement is critical in reducing such preventable ADRs.<sup>23</sup>

Because the majority of patients change physician on discharge from hospital to community services, pharmacy intervention in medication planning and evaluation of appropriateness of medication results in fewer inappropriate medicines and a 62% reduction in hospital usage and repeat emergency department visits.<sup>25</sup> Accordingly, pharmaceutical care programmes across a range of chronic diseases of the older person also improve health-related quality of life.<sup>26</sup> These programmes can help with routines for taking medication, improving compliance, reducing therapeutic

duplication, reducing confusion associated with polypharmacy and improving liaison between multiple prescribers and medicines management.<sup>25,26,27</sup>

Pharmacist interventions have been shown to reduce errors in children<sup>28</sup>, in acutely ill populations<sup>29</sup>, in geriatric populations<sup>30</sup> and in the general community population.<sup>31</sup> However, this role is frequently neither recognised, reported nor resourced.<sup>31</sup>

Furthermore, although it has been shown that pharmacist interventions increase the rate of medication error reporting,<sup>32</sup> voluntary systems of drug error reporting remain limited by reporting bias and under-reporting levels as low as 4%.<sup>33,34,35</sup> Since 1998, for the Food and Drug Administration (FDA), the frequency of ADR reporting has increased at a faster rate than the increase in out-patient prescriptions. Furthermore, 20% of marketed drugs accounted for 87% of the serious ADRs.<sup>35,36</sup> In order to overcome the widely described variability in ADR report quality, biased reporting and under-reporting, improved systems of serious ADR reporting are required.<sup>3,35</sup>

Accordingly, focused data collection and a compulsory, “no-blame” reporting system is required to capture information on drug errors and to modify this large source of morbidity and mortality in our healthcare system.<sup>3</sup> Pharmacists have an important role to play in this system because as medicines experts with the most frequent contact with medicine takers, they may be able to identify ADRs more quickly and across the entire population. While the ADR reporting by pharmacists has been shown to have improved in the UK since pharmacists were introduced to the scheme in 1999, a greater role for community pharmacists in providing feedback to regulatory agencies on the community ADR level is required.<sup>36</sup> In one study, half of pharmacists believe that ADR reporting by pharmacists should be compulsory.<sup>37</sup> Almost three quarters agreed that it was a professional duty.<sup>37</sup>

A further requirement of safer systems of medication licensing is improved dialogue between regulatory agencies to provide consistency between the clinical and safety information about drugs worldwide.<sup>38,39</sup> Improved feedback about drug safety, increased responsiveness of agencies to the identification of new ADRs and the provision of uniform corrective advice to the medical community will result in significantly safer systems of medication control for patients.<sup>3,39</sup>

Finally, in an unprecedented editorial in which a senior FDA scientist evaluated the performance of the FDA in relation to the Vioxx withdrawal and the delay in response to emerging ADR data, the limitations of the current ADR reporting systems were outlined.<sup>3</sup> Furthermore, the possibility that “part of the problem lies with FDA policies, practices, and procedures that lead it to ignore

potential safety problems” has led to concern that the FDA, as licensing authority may not be the appropriate agency to process post-marketing ADR data. Accordingly, it may be appropriate for pharmacy based ADR monitoring to report not only to the Irish Medicines Board (IMB), but also to statutory agencies such as the Health Information Quality Authority (HIQA), whose central remit is the safety of patients and users of healthcare services in Ireland.

In summary, drugs have the potential to cause significant harm to health in routine clinical practice. This harm arises from high levels of medication errors in healthcare systems and from the unanticipated adverse effects of medications themselves in individuals. In both instances, there is a need for safer systems of medicines prescription, administration, monitoring and adverse event reporting in the HSE. Pharmacists, as medicines specialists, are ideally placed to support this work. They provide an important safeguard role in reducing medication errors and this role can be expanded in the Irish healthcare setting. Furthermore, they are ideally placed to address the significant gap that exists in feedback systems with regard to drug adverse events.

## BENEFITS TO PATIENT AND HEALTHCARE PROVIDER

Pharmacist involvement in drug safety systems, such as medication error reduction and ADR reporting systems, can:

1. Reduce relatively high levels of inappropriate prescribing of medications.
2. Reduce emergency admissions and associated healthcare costs related to ADRs.
3. Improve rates of medication under-prescribing.
4. Improve patient adverse events associated with polypharmacy.
5. Improve discharge planning in the community.
6. Improve patient quality of life associated with better medicines management.
7. Provide more accurate information on ADR rates to statutory drug regulatory authorities and develop better patient centred safety systems.

## CONCLUSIONS

The pharmacist’s role in minimising drug errors has been shown to be clinically effective and cost effective. As the evidence-based

drive to greater polypharmacy results in greater drug-drug and drug-disease interactions, the pharmacist’s role in pharmaceutical care of patients should be recognised and developed.

A collaborative pharmacist/physician model is most effective in this regard and an open, “no-blame” culture of medication error reporting involving pharmacists should be developed in order to address chronic under-reporting of adverse events.

Furthermore, a more central role in ADR reporting for the pharmacist should be found as a potential remedy for the current under-reporting of drug reactions to regulatory authorities. This should be a compulsory element of the contractual work of the pharmacist within the HSE. These data should be provided not only to the IMB, but also should be co-ordinated by HIQA as part of its remit in improving patient safety systems.

Finally, as part of the proposed drug safety surveillance system, pharmacists should have a “low threshold” for event reporting and a system like the New Zealand IMMP system should be implemented for novel drugs.

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### **3. Pharmaceutical Care, Medicines Management and Medicine Use Review**

**Maximising Benefits to Patients  
and the Health Service**



### 3. Pharmaceutical Care, Medicines Management and Medicine Use Review

Pharmaceutical care and medicines management are often used synonymously and in practice they describe a process of helping patients to get the most from their medicines.<sup>1</sup> This process has three steps<sup>2</sup>:

- *Assessment* - to ensure that all drug therapy for a patient is indicated, effective, safe and convenient and to identify drug therapy problems.
- *Development of a care plan* - to resolve and prevent drug therapy problems and to achieve therapeutic goals.
- *Evaluation* - to record patient outcomes, to evaluate progress in meeting therapeutic goals and to reassess for new problems.

Unlike the UK, US, Australia, New Zealand and most western European countries<sup>3</sup>, pharmaceutical care and medicines management are under-developed in Ireland. Ideally, pharmaceutical care and medicines management require access to the clinical notes. However, medicine use review (MUR), which is a component of the medicines management process, does not require access to the medical history.

Medicines are the direct cause of 4%-6.5% of emergency admissions in the UK<sup>4,5</sup> and it is a priority for the NHS to reduce these avoidable hospital admissions. According to HIQA, international research demonstrates that up to 13% of patients admitted to hospital experience adverse events due to errors and this has led to the participation of HIQA, with support from the Department of Health and Children, in the WHO Collaborative Project on Patient Safety.<sup>6</sup> In the wider healthcare system, medicine-related factors leading to poor outcomes from treatment include prescribing errors, under-prescribing, inappropriate prescribing, drugs prescribed to patients at higher risk of adverse event and poor adherence. The international research demonstrates that medication errors are common, costly, are caused by systems and can be prevented.<sup>7</sup>

Recent research from UCC has demonstrated that a majority of patients in residential care institutions in Ireland receive at least one inappropriate medicine. Clinical medication review is the best method for assessing prescribing risk, under-prescribing and high-risk drug use, as it includes access to the clinical record<sup>8</sup>. A pharmacist conducting a clinical review can detect prescribing errors, under-prescribing, inappropriate prescribing, drugs prescribed to patients at higher risk of adverse event and poor adherence.

Medicine use review (MUR) is likely to be most appropriate for assessing compliance and improving medicines-taking through concordance. However, it is clear that careful patient questioning can also identify some aspects of the risk associated with prescribing. MUR involves the pharmacist and patient talking

about the patient's medicines on a one-to-one basis. This includes all prescription medicines and all medicines purchased over-the-counter. All older people and those taking medication for long-term conditions should have a regular MUR, at a minimum annually. Domiciliary visits were highlighted in submissions as an area where pharmacists can make a significant impact.

#### EVIDENCE BASE FOR CLINICAL PHARMACY PRACTICE

One third of medicines-related hospital admissions are due to prescribing errors.<sup>4</sup> These types of errors include incorrect dosage prescribed, wrong medicine prescribed, prescription of a medicine to which the patient is allergic, or failure to stop a medicine after a fixed course of treatment. In a recent Irish study conducted in a community pharmacy in a suburban location, the pharmacist made clinically relevant interventions 57 times in a 5000 prescription item sample (1.14%).<sup>9</sup> Interventions included a penicillin antibiotic prescribed for a patient with a known penicillin allergy, potential drug interactions and potential ADRs.

The most common long-term conditions associated with emergency hospital admissions are exacerbations of COPD and heart failure.<sup>10</sup> There is clear evidence that these exacerbations can be reduced by the correct use of medicines. For example, the best treatment of heart failure due to systolic dysfunction is a triple regimen of a loop diuretic, an angiotensin-converting enzyme (ACE) inhibitor and a beta-blocker,<sup>11</sup> yet only 30% of people with heart failure are prescribed a beta blocker.<sup>12</sup> It has been stated that for every 100 people treated with a beta blocker, four hospital admissions and three deaths could be avoided in the first year of treatment.<sup>13,14,15,16</sup> Accordingly, it is important that as part of the pharmaceutical care of heart failure patients, systems are put in place to ensure that as well as minimising inappropriate medicines, patients receive the evidence-based life saving medicines they need.

Each winter, hospitals throughout Ireland have capacity difficulties due to respiratory diseases. Inhaled steroids, prescribed to COPD patients with a forced expiratory volume (FEV<sub>1</sub>) of less than 50% and two exacerbations in the last year, are beneficial in preventing further exacerbations.<sup>17</sup> Long-acting beta-agonists and anticholinergics can also prevent exacerbations.<sup>18</sup> Pharmacy care of COPD using treatment algorithms can improve patient outcomes<sup>19</sup> and because medicine related costs are dwarfed by the hospitalisation costs associated with poor medicine usage,<sup>20</sup> pharmaceutical care of COPD is likely to be a clinically and cost effective approach.

Non-steroidal anti-inflammatory drugs (NSAIDs), aspirin, diuretics and warfarin account for well over half of emergency admissions associated with medicines.<sup>4,21</sup> Pharmacists can reduce the risk

from these medicines by ensuring they are only prescribed when necessary and are reviewed regularly, by making sure that patients understand how to maximise the benefit of these medicines and how to recognise adverse events when they occur. As an example, several Irish studies have reported that pharmaceutical care of patients taking warfarin can promote better outcomes. In the first instance, common indications for warfarin are deep vein thrombosis (DVT) 9.5% and Pulmonary Embolism (PE) 7.7%.<sup>22</sup> This is significant as a recent study published in the Lancet found that 59% of Irish patients admitted for surgery, and 43% of those admitted to a medical ward, are at risk of developing a clot. Yet only 47% of medical patients and 64% of surgical patients received the appropriate treatment.<sup>23</sup> Pharmaceutical care of such patients would ensure that the appropriate therapy was used and DVT/PE risk would be reduced.

Furthermore, the main indication for warfarin therapy in Irish patients is the management of clot risk associated with atrial fibrillation (AF).<sup>24,25</sup> Typically the method used to evaluate the performance of any anticoagulant clinic is an audit of the point prevalence of INRs within 0.5 INR units of the target range. The 2005 BCSH guidelines state that 60% of INR should be within 0.5 and 80% should be within 0.75 INR of their target.<sup>26,27</sup> Irish research in pharmaceutical care of warfarin patients has shown significantly better performance over a six month period, compared with the same patients monitored by a physician in a specialised anticoagulant clinic i.e. the median time in therapeutic range increased from 22.5% ( $\pm$  24.8%) in the anticoagulation clinic (control period) to 73.6% ( $\pm$  8.48%) during the study period. Furthermore, this improvement in anti-coagulation performance was not associated with hemorrhagic or thromboembolic complications in the study period.<sup>22</sup> Therefore, pharmaceutical care or medicines management in targeted, high risk groups can improve patient safety, improve medicine effectiveness and reduce medicine related adverse events, thereby keeping patients out of hospital.

Another important element of pharmaceutical care and medicines management is patient non-adherence and non-compliance. Adherence has been defined as “the extent to which the patient’s behaviour matches agreed recommendations from the prescriber.”<sup>28</sup> The reasons for poor adherence are multi-factorial and include inability to obtain a supply of medicines, patient forgetfulness, patient confusion, patient adverse effect, patient’s lack of confidence in the medication.<sup>29</sup> Adherence problems are increased in the setting of chronic disease and the consequences of poor adherence are considerable. Between 20% and 50% of patients with chronic diseases are non-adherent and this is associated with poorer outcomes and increased healthcare costs.<sup>29</sup>

Several pharmacy-led strategies for improving adherence have been recognised and advocated.<sup>30</sup> Improvement in medication

adherence, based upon pharmacist involvement in primary care, has been well documented.<sup>31,32</sup> In 2006, Lindenmeyer *et al.* highlighted the potential benefit of pharmacist interventions to improve medication adherence, especially in the provision of patient education.<sup>33</sup> Pharmacists are the most easily accessed members of the healthcare profession,<sup>34</sup> and they are the health professionals with the training, knowledge and responsibility for pharmaceutical care of their patients. Although much of a pharmacist’s time is spent dispensing medicines, pharmacists are frequently consulted by patients, parents and care-givers for advice about medications.<sup>35</sup> However, at present in Ireland, the provision of pharmaceutical care in the management of chronic disease is ad-hoc, unstructured, poorly resourced and undocumented. This is of concern because increasing numbers of older people are dependent on multiple drug regimens<sup>36</sup> and are at high risk of problems associated with poor adherence, administration errors and treatment failure because they may have poor understanding of their medicines.<sup>37</sup> Medicines management supports such as pharmacy supported monitored-dosing-systems dramatically improve patient adherence, improve safety by reducing dosing errors and improve patient outcomes.<sup>38</sup>

These pharmacist supported monitored-dosing-systems may be a factor in preserving patients’ independence in their own homes and in certain instances, domiciliary visits by pharmacists have also been advocated as the best means to identify and address medication-related risk factors associated with poor health outcomes.<sup>39</sup> These risks include:

1. Lack of routine for taking medicines.
2. Multiple storage locations.
3. Therapeutic duplications.
4. Hoarding of medicines.
5. Confusion with medicines’ names.
6. Multiple prescribers.
7. Still using non-repeatable medicines.
8. Poor compliance.
9. Older age.
10. Increasing number of medicines found in the home.

For a small group of vulnerable patients, these risks can only be identified completely by a domiciliary visit by the pharmacist to the patient. This means the pharmacist can see how the patient manages their medicines and how much medicine is stored in the home, including unused or discontinued medicines.

Other areas in which pharmaceutical care of patients has been shown to improve outcomes include chronic cardiovascular disease and diabetes, in which the positive influence of pharmacist interventions is assessed by using the HbA<sub>1c</sub>.<sup>40,41,42</sup> In all of these

studies, each patient acted as their own control, and change in HbA<sub>1c</sub> from baseline was the dependent variable. In these instances, the pharmaceutical care goals are closely linked to the goals of chronic disease management, which is discussed in more detail in section 1 of this document.

With the rising incidence of Type 2 DM, many of these patients will need injectable insulin as therapy. However, currently there is no coherent scheme where diabetic patients can dispose of their old needles and syringes in Ireland. Many store them up and return them to their GPs or local health centre, some return them to community or hospital pharmacies, who in turn have difficulty in disposing of them. Furthermore as the rate of speciality pharmaceuticals requiring home injection (including many medications dispensed on the High Tech scheme) increases dramatically, the need for a pharmacy based national needle exchange scheme for diabetics, High Tech patients and injecting drug users (IDUs) increases. In the submissions received to the working group, a national needle exchange programme was highlighted as being of huge importance in the prevention of the spread of infectious diseases among IDUs.

Pharmaceutical care of patients extends to addiction services. Drugs which require injection into the body leave misusers at particular risk. Poor injecting technique can lead to abscesses, cellulitis, thrombophlebitis, arterial puncture or DVT. Needle sharing exposes addicts to infection from Hepatitis B and C or Human Immunodeficiency Virus (HIV). Where the contents of tablets or capsules are used intravenously or addicts make their own injections, contaminants can lead to abscess, overdose, gangrene and thrombosis.

With the advent of HIV, and later the realisation of Hepatitis B and Hepatitis C risk to patients through needle sharing, needle exchange schemes have been implemented in many countries. The first such scheme was introduced in Amsterdam in 1984. In Ireland, needle exchange is currently provided by the HSE Addiction Service and Merchant's Quay Ireland. The aim of these schemes has been harm reduction to both the individual and the group that individual comes into contact with. For instance, these schemes stop dirty needles being discarded in public places where children may be at risk from them.

The New Zealand Needle Exchange Programme (NEP) was the first national NEP in the world and was originally conceived as a pharmacy and GP based scheme, and initially more than 200 pharmacies were recruited as outlets. In order to provide peer based educational support to the NEP, a number of drug user groups were formed and contracted to provide complementary educational programmes. The groups decided that they would

also provide after-hours needle exchange services at evenings and weekends to complement pharmacy outlets. The proportion of used needles and syringes returned for destruction improved from a national average of 26 percent of sales in 1994, to 52.9% of sales in 2000. Since the advent of free needle distribution the return rate has risen considerably to around 90%. The NEP has to date been extremely successful at preventing the spread of HIV amongst IDUs. New Zealand currently enjoys one of the lowest rate of HIV infection amongst drug users according to statistics published by the OECD, at 0.5% of injecting drug users infected.<sup>43</sup> In terms of cost-efficacy, every \$1 spent on New Zealand's NEP saved an estimated \$3.35 in healthcare costs which would otherwise have accrued over the period of investment.

Another example of a healthcare problem which urgently needs a pharmaceutical care and medicines management solution is tuberculosis (TB), which continues to be a leading killer disease worldwide causing three million deaths annually. It is also an occupational disease in the health care system which has begun to increase in incidence this decade after more than four decades of steady decline.<sup>44</sup> In multi-drug resistance tuberculosis (MDR-TB), oral therapy frequently fails despite the use of multiple second-line anti-tubercular drugs. One of the main problems in TB therapy is compliance and adherence over the six to nine month treatment periods. It is widely believed that this adherence problem has contributed significantly to MDR-TB. Treatment given as directly observed therapy (DOT), where a healthcare professional observes or supervises the consumption of medication, has been shown to be effective in certain patient cohorts. DOT is a WHO approved initiative, and normally is delivered in other countries by home-care based nursing teams. This has proved very expensive, and pharmacy based DOTs are currently being piloted in Ireland. The success of this initiative will be measured by a reduced incidence of MDR-TB and should be implemented according to guidelines which might be developed with appropriate stakeholder organisations such as the National TB Centre at St. James's Hospital.

## **BENEFITS TO PATIENT AND HEALTHCARE PROVIDER**

Pharmaceutical care, medicines management and medicine use reviews, if implemented in Ireland, would provide the following benefits:

1. For patients, in ensuring that they receive the best therapy possible in compliance with internationally accepted guidelines.
2. For patients, by quality assuring and quality controlling the prescribing of their medicines and improving compliance.

3. For the health service, by ensuring that all patients receive optimal therapy and that the process is quality assured and validated.
4. For the GP, by giving them assurance that they are operating at best international standards.
5. For the pharmacist, in playing a greater role in managing patients' therapy.
6. Reducing medicine related hospital emergency admissions.

## CONCLUSIONS

A national policy for pharmaceutical care, medicines management and medicine use review should be developed.

Medicines management supports especially benefit targeted groups of vulnerable patients: examples include appropriate community and residential care compliance/adherence aids for patients with chronic disease; safe needle exchange schemes for increasing proportions of patients using home-injection therapy and for injecting drug users; a directly observed therapy scheme for TB to ensure compliance and reduce treatment failure.

A research group might be an appropriate approach to monitor and report on the introduction of medicines management and MUR, and to monitor the scheme on an on-going basis, including a cost/benefit pharmacoeconomic assessment on an annual basis.

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## **4. The Role of the Clinical Pharmacist in Hospital Practice**

### **An Under Resourced Service**

# 4

## 4. The Role of the Clinical Pharmacist in Hospital Practice

Following the Noel Hall report<sup>1</sup> on pharmacy services in 1970, the nature of hospital pharmacy in the UK changed markedly, from a purely manufacture and supply function, to one where pharmacists became the leaders and providers in drug information services (early 1970s). Pharmacists became key members of Drug and Therapeutics Committees in 97% of British hospitals by 1990, and from the 1980s became proactive on the wards in providing not only information and advice on drug therapy, but also prescribing and administration advice, to clinicians, nurses and patients.

This model has evolved considerably over the last thirty years and whilst still retaining the core functions of procurement, distribution and safe and secure handling of medicines, clinical services provided by pharmacists have become an established part of hospital healthcare. Evidence is accumulating to show that clinical pharmacy activities lead to improved patient care, with better use of medicines, that in many cases is more cost-effective.<sup>2</sup> Analysis of US hospital data examining four health outcome measures – mortality, length of stay, drug costs and total cost of care – revealed the ratio of clinical pharmacists to occupied beds as the only pharmacy variable associated with positive outcomes for all four measures and similar data are becoming available for the UK.<sup>2</sup>

The emphasis for pharmacists has now shifted to assuming responsibility for pharmacotherapeutic outcomes. Advanced pharmaceutical services in specialty practices, for instance ambulatory care, diabetes, cardiology, nephrology, paediatrics, nutrition, transplantation and critical care continue to grow to meet patients' needs. Modern-day clinical pharmacists in UK hospitals spend a substantial proportion of their time on wards, reviewing drug therapy and tailoring optimal treatment regimens for individual patients, often as members of collaborative multi-disciplinary healthcare teams. Pharmacists are increasingly available on ward rounds to provide advice at the point of prescribing, or alternatively they will be in a position to intervene and influence prescribing before therapy commences by triaging requests for new medications.<sup>2</sup>

### EVIDENCE BASE FOR CLINICAL PHARMACY PRACTICE

In addition to the roles mentioned above, pharmacists are increasingly taking lead roles in patient care across all the medical and surgical specialties, from neonatal intensive care, through to ambulatory care of the elderly and palliative care. Detailed documentation of all of these areas of clinical pharmacist contribution is unrealistic within this document but global examples of areas of clinical pharmacy involvement are outlined. Clinical pharmacy services are available to varying degrees in many Irish hospitals. Since the establishment of the School of Pharmacy

at UCC in 2003, two taught M.Sc. programmes in Clinical Pharmacy have been available in Ireland. Each student is required to undertake a thesis; this requirement is instrumental in increasing research into medicines usage in Irish hospitals. Examples of research at the School of Pharmacy, UCC, are provided in this section, to highlight the contribution pharmacists are making to patient care in Ireland.

### Antibiotic pharmacists

There is increasing concern about antibiotic resistance in Ireland, the UK and elsewhere. About 90% of all antibiotics are consumed in the community, the remainder being used in hospitals. Whilst relatively small in amount overall, hospital consumption is considered more important by some because of the proliferation of multiresistant organisms seen in hospitals, when compared with the community. Costs to hospitals are also considerable, in some cases, representing approximately a fifth of their pharmacy budget.<sup>4</sup>

Specialist antibiotic pharmacist posts were established in a small number of UK hospitals in the early 1990s. The value of pharmacists was highlighted by the UK Department of Health's Standing Medical Advisory Committee who contended that pharmacists, particularly in hospitals, have an important role in controlling prescribing and identifying inappropriate prescribing. Clinical pharmacists have played important roles in significantly reducing the 30-day mortality for hospitalised patients treated by physicians who participated in a guideline programme, for achieving significant and sustained reductions in *Clostridium difficile* associated diarrhoea and resistant *Enterobacteriaceae*, and in generating cost savings, with annual savings of £10 per patient reviewed on multi-disciplinary ward rounds per day and some hospitals having reported annual cost savings associated with antibiotic management activities of between £23,000 and £500,000.<sup>2</sup>

There is no doubt that *C. difficile* infections are increasing in frequency and severity. From 2000–2001, the Centre for Disease Control and Prevention (CDC) reported that the rate of a hospital discharge diagnosis of *C. difficile*-associated disease (CDAD) increased by 26%. This increasing rate of CDAD is now a major problem worldwide. A conservative estimate of the cost of CDAD in the US exceeded \$1.1 billion in 2001. In 2005, with a reported annual three million US cases of CDAD and an increasing mortality rate of 1.0%–2.5% (occasionally even with aggressive treatment of CDAD), the national cost was probably much higher.<sup>5</sup>

The inappropriate use (at longer duration and higher doses than appropriate) of proton pump inhibitors (PPIs) is postulated to be associated with a higher risk of developing CDAD.

The results of a study in a Cork teaching hospital indicate that the trend of increased PPI usage over the last decade has not diminished and that the utilisation of PPIs in this hospital was

greater than that reported in other published figures (41.88% of inpatients).<sup>6</sup> Nearly 40% of PPI prescriptions reviewed were for unspecified or unlicensed indications. Whilst the overuse or inappropriate use of these drugs is worrying in itself, there is a greater concern with respect to the links and possible causality in the increasing trend in cases of *C. difficile* infections.<sup>6</sup> Cunningham *et al.* found that PPI use within the preceding eight weeks was associated with an increased risk of *C. difficile* diarrhoea.<sup>7</sup> Reduction of unnecessary PPI use may be an additional strategy to reduce the incidence of this infection.

### Intensive care pharmacists

Pharmacist involvement in improving the clinical outcomes of critically ill patients is associated with optimal fluid management and substantial reductions in the rates of ADRs, medication administration errors and ventilator-associated pneumonia, and is well documented<sup>8</sup>. Furthermore, economic evaluations of clinical pharmacy services in the intensive care unit (ICU) consistently reveal both real and potential scope for considerable cost savings.<sup>9</sup> An example of one such initiative was the use of sedation protocols, which have been shown to decrease the incidence of ventilator-associated pneumonia. Pharmacists have taken a lead role in encouraging adherence to these protocols and in one study this led to a decrease in the mean duration of mechanical ventilation of nearly seven days, which translated into a substantial decrease in both ICU and hospital length of stay of a (conservatively) approximate value of \$7,500 per patient.<sup>10</sup>

### Pharmacist-led diabetes clinics

Between 1990 and 2000, the number of obese people aged 16 - 24 has more than tripled, rising from 3% to 10% - in Ireland, 18% of adults are obese and 39% are overweight. Obesity now affects 16% of women and 20% of men in Ireland, according to the North South Food Consumption Survey<sup>11</sup>. A further 33% of women and 46% of men are overweight. The indirect cost of obesity in Ireland is estimated at €0.4 billion per annum and around €30 million has been estimated for in-patient costs alone in 2003, for a number of Irish hospitals.

Overweight or obesity contribute to the following illnesses: hypertension; Type 2 DM; excess cholesterol; stroke; cardiovascular disease. Type 2 DM now accounts for 6% of Ireland's total healthcare budget, with almost half of this money being spent on hospitalisation costs.

### Complications of diabetes

It has been demonstrated unequivocally, in controlled trials, that the microvascular complications of diabetes mellitus, such as the development and progression of neuropathy, nephropathy

and retinopathy, can be prevented by the maintenance of HbA<sub>1c</sub> below 7.0%. These microvascular complications are a major problem for patients with Type 1 DM.

In contrast, macrovascular complications (e.g. ischaemic heart disease, cerebrovascular disease and peripheral vascular disease) are the major cause of morbidity in patients with Type 2 DM, who have a 2- to 4-fold increased risk of dying from a myocardial infarction or a stroke, and a 10- to 15-fold increased risk of a lower extremity amputation when compared with a non-diabetic individual. These complications can be reduced with careful attention to the patient's lipid profile and control of blood pressure.

Supplementary prescribing is intended to encourage a team approach to the care and management of patients and to make the best use of the skills of trained healthcare professionals. In the US in particular, and more latterly in the UK, pharmacists have been involved directly in this type of patient care. An example of this is within diabetes clinics. The clinical pharmacist works in unison with the physician(s) and within particular guidelines for assessing endpoints and medication review and prescribing. Their duties include blood glucose, HbA<sub>1c</sub>, lipid and blood pressure monitoring, and the results of these measurements are used to adjust medications to achieve specific targets in defined endpoints. They have been shown to be successful in significantly reducing HbA<sub>1c</sub> levels to <7% when compared with control and blood pressure measurements overall have been reduced by more than 10mm Hg. In one clinic in Harrogate, England the cost effectiveness of this clinic was calculated. There was a statistically significant reduction in the CHD risk over ten years with a cost avoidance per event of €54,231. The cerebral vascular accident (CVA) risk reduction was also statistically significant at €98,938 cost avoidance per event (2002 costings).<sup>12</sup>

In January 2008, nine wards in one teaching hospital in Cork city were surveyed by fourth year pharmacy students. These included medical, surgical, geriatric, coronary care and intensive care patients. Patient notes were scrutinised for diagnoses, both pre-existing and those made during that admission, biochemistry results and medications charted. One hundred and sixty three patients' records were examined in the five day period i.e. a snapshot of the in-patients was gained during that period. Nineteen (12%) of these patients were known diabetics on admission and two patients were diagnosed as having diabetes during their hospital stay. The American Diabetic Association (ADA) has guidelines on a range of clinical parameters for patients with diabetes, with specific goals for HbA<sub>1c</sub> blood pressure, lipid profile, and recommendations regarding pharmacological interventions.

In summary, in this survey, almost 40% of patients had fasting blood glucose levels above the recommended 6 mmol/L, and all patients who had HbA<sub>1c</sub> measurements performed failed to meet the ADA guidelines. There were seven non-diabetic patients who had abnormal lipid profiles. Many of the patients had concomitant cardiovascular disease.<sup>13</sup>

Whilst this survey can be criticised from many aspects, it is clear that at any one time there is a significant burden of diabetic and pre-diabetic patients within this hospital, which incidentally does not employ a full-time endocrinologist who can dedicate specific time to these patients. There is sufficient evidence from overseas<sup>12,14,15</sup> that a pharmacist-led diabetes clinic in this institution would greatly assist in getting patients to achieve the goals set by the ADA guidelines and reduce the future burden on the health system.

### Pain management

Treatment of postoperative pain is important for humanitarian and ethical reasons, but it also has economic implications, as pain may contribute to prolonged convalescence. Acute postoperative pain is followed by persistent pain in 10%–50% of individuals after common operations, such as groin hernia repair, breast and thoracic surgery, leg amputation and coronary artery bypass surgery. Since chronic pain can be severe in about 2%–10% of these patients, persistent post-surgical pain represents a major, largely unrecognised, clinical problem. The intensity of acute postoperative pain correlates with the risk of developing a persistent pain state. Early postoperative pain is the only factor that significantly predicts long-term pain after thoracotomy. Similarly, chronic pain after open inguinal hernia repair can be predicted by the intensity of early postoperative pain.<sup>16,17</sup> Inadequate pain management remains a problem. Studies have been carried out in the US to evaluate the role of pharmacists in improving pain management in post-operative patients, and results have confirmed that pharmacists have been instrumental in achieving better patient outcomes both in patient and pharmacoeconomic terms.

Postoperative analgesia is prescribed by medical staff to be given either regularly or on an “as required (prn)” basis. However, it is being accepted increasingly that to avoid chronic surgical pain syndromes, and also to maintain patient comfort postoperatively, analgesia should be given regularly. The advent of intravenous paracetamol has circumvented the problems of reduced oral absorption in the postoperative period,<sup>19</sup> and this parenteral preparation has greatly aided in the regular administration of paracetamol, which has been shown to be opiate sparing, thus reducing perioperative morbidity, especially in the older person. Research from postgraduate students at UCC has reported, in one institution, that 59% of patients experienced moderate pain postoperatively. Although 63% of patients were prescribed regular paracetamol in the first 48 hours postoperatively, none received all the prescribed doses. As a result of this, further surveys in three more hospitals are underway and as part of these research projects, analgesic protocols and algorithms are being introduced and tested for improvement in patients’ pain scores postoperatively and the development of chronic postoperative surgical pain syndrome.

Enthusiasm for giving parenteral doses of paracetamol higher than would normally be given has been reported anecdotally amongst anaesthetic staff. The upper dose limit for parenteral paracetamol perioperatively has been debated at the local hospital Drugs and Therapeutics Committees. Research is underway at the School of Pharmacy, UCC to establish the safety of this drug in the perioperative period. The first stage of this protocol is completed and a dose limit is being recommended as a result of this work, thus ensuring improved patient safety. The second and third phases are currently being undertaken.

Palliative care services are generally provided by a multidisciplinary team that works with the person who is dying and their family. Pharmacists in Auckland, New Zealand, have been an integral part of this service since 1989. A group of community pharmacists throughout the wider Auckland area are involved in providing the medicines for patients. They are responsible for dose changes and escalation of doses and have a thorough knowledge of drug incompatibilities which are important in this type of patient care.<sup>18</sup> Through this scheme, over 10,000 patients have been supplied with medicines in a timely manner, allowing patients to remain with their families in their own homes during their last days.

### Neurological services

Epilepsy is the most common serious neurological condition. The lifetime prevalence of seizures (the risk of having a non-febrile epileptic seizure at some point in an average lifetime) is between 2% and 5%. Pharmacist-managed antiepileptic drug therapy was evaluated in nearly 10,000 patients with diagnosed epilepsy or seizure disorders treated in 794 US hospitals. Clinical outcomes (death rates, hospital length of stay, and aspiration pneumonia rate) and economic outcomes (Medicare and laboratory charges) were improved among hospitalised Medicare patients whose antiepileptic drug therapy was managed by pharmacists.<sup>20</sup> Seizures may occur post-trauma, and phenytoin is the most commonly administered antiepileptic agent for the prevention of early (< or = 7 days) seizures. Use of this agent, however, requires strict monitoring due to its narrow target range and nonlinear pharmacokinetics. In a study by Brophy *et al.*, inclusion of a clinical pharmacist in managing these patients resulted in a decrease in the number of days a patient received the drug, the number of blood samples drawn and analysed and most importantly, the number of seizures experienced by patients. The savings made on that particular unit were \$28,000.<sup>21</sup> Antiepileptic drugs are difficult to use as they require close monitoring, are not “switchable” across brands and have significant side effects if not monitored closely. Pharmacists who assume a primary-care role in seizure clinics have significantly improved the care of epileptic patients with improved detection of ADRs and tighter monitoring of seizure control, thus improving quality of life.<sup>22</sup>

More than six million people worldwide live with Parkinson’s

disease (PD) - a chronic, degenerative neurological disorder that is characterised by symptoms that typically progress from mild tremors to complete physical incapacitation. Despite modest advances in pharmaceutical and surgical therapies, there is no known cure for Parkinson's disease. Levodopa is the most efficacious therapeutic agent in PD; however, the response of patients to levodopa changes over time. Eventually, the duration of response becomes shorter and more unpredictable and complications emerge. With early identification and optimisation of treatment, wearing-off can be managed effectively, resulting in improved quality of life for patients with PD, and pharmacists are playing an increasingly important role in the management of these patients.<sup>23</sup>

#### Cost containment/avoidance

Clinical pharmacists play a major role in cost containment or cost reduction. Several examples have been given in the global situation. Closer to home, three studies in the Cork area have quantified this role.<sup>24</sup>

A Disposal of Unwanted Medicines Campaign (DUMP) was carried out in the HSE Midlands Area (Counties Laois, Offaly, Longford and Westmeath). Seventy four pharmacies in the region took part in this campaign and there were three collection periods from September 2005 to May 2006. A total of 7308 returns were made to the 74 pharmacies during the study period (September 2005 to May 2006). Interestingly, unused amoxicillin/beta-lactamase inhibitor combinations contributed 5% of the returns and 10% of returned medicines were analgesics. As prices were not available for all returned medicines, the cost prices of 6791 medicines were calculated and totalled €230,631. This was extrapolated to a cost of over €4 million for the Republic of Ireland as a whole.<sup>24</sup>

#### Proton pump inhibitors (PPIs) over-prescribing

Proton pump inhibitors (PPIs) control gastric acid secretion and have been a tremendous therapeutic advance. Especially in the long term, they have transformed the lives of patients with previously intractable symptoms of gastro-oesophageal reflux with its associated complications, and they have also proved valuable for patients who are at risk of iatrogenic upper gastrointestinal pathology. A short term trial of a PPI is also a good option for treating a wide range of acid-peptic conditions. But the drugs are clearly being overused.

PPIs are one of the most frequently prescribed classes of drug in the world, because they combine a high level of efficacy with low toxicity. In 2006, expenditure on these drugs was £425m (€595m) in England and £7bn globally. Yet studies consistently show that PPIs are being over-prescribed worldwide in both primary and

secondary care. Between 25% and 70% of patients taking these drugs have no appropriate indication<sup>24</sup>. This means that, at the very least, £100m from the NHS budget and almost £2bn worldwide is being spent unnecessarily on PPIs each year. PPIs are the most expensive class of drug reimbursed under the General Medical Services (GMS) scheme in Ireland, with costs of €64 million in 2002, which represented an eight-fold increase since 1995.

Studies have suggested that PPI prescribing is not always in line with the manufacturers' licensed indications. A drug usage evaluation audit was carried out in a teaching hospital by the School of Pharmacy, UCC to assess the extent and appropriateness of PPI prescribing within the in-patient setting.

Of the 382 patients reviewed, 160 had been prescribed a PPI, indicating that 41.88% of patients within this hospital had been prescribed this medication. Similar Irish studies carried out in 2001 and 2003 indicated that 30.6% (n=157) and 32% (n= 272) respectively of patients in the in-patient setting were prescribed PPIs. This shows that the positive prescribing trends for PPIs have continued. Nearly 40% of PPI prescriptions reviewed were for unspecified or unlicensed indications.

Of the 160 patients prescribed a PPI in the hospital during the study period, the medicine was prescribed generically for 48.1% (n=77).<sup>24</sup> The cost implication of medicines not being prescribed generically within a hospital setting is negligible as most hospitals substitute the most cost effective PPI for the prescribed brand.

Upon discharge from hospital, the community pharmacist does not have the authority to substitute at their discretion but is bound to dispense as per the prescription. Therefore, the cost of branded medicine is borne by the Primary Care Reimbursement Service. This is in contrast with the situation in the UK. The first generic PPI (omeprazole) was introduced in 2002 and now comprises more than four fifths of all prescriptions for PPIs in the UK. In the five years since the introduction of generic omeprazole, prescriptions for PPIs have doubled, although the reasons for this rise are not obvious. Despite this substantial increase in drug usage, the decrease in price means that overall expenditure on PPIs has been falling in recent years.

Based on the study in the Cork teaching hospital, if each patient prescribed a branded PPI in this study had a bioequivalent generic product dispensed, a cost saving equal to €514.13 per patient would have resulted i.e. a total cost saving of €20,565.20 for the 160 patients could have been made through the generic prescribing of PPIs.

#### Recycling of drugs

Recycling of ward drugs in hospitals is a source of savings if manpower were available to hospitals. One hospital in the Cork region has estimated that if areas such as ICU or Accident and Emergency department were able to be visited daily by pharmacy staff, considerable savings could be made by ensuring that

medicines which are seldom used are returned to the pharmacy department for redeployment to other wards. Approximately €25,000 worth of drugs was returned to the pharmacy in that hospital in the first two months of 2008. With proper recycling, these drugs could be utilised on other wards, resulting in accrued savings of approximately €150,000 per year. The quality control of drugs, i.e. checking of batch numbers and expiry dates, would also provide a valuable service to the wards and is recommended as part of best practice in patient safety. Without proper surveillance by pharmacy staff, stock stays on wards and tends to go out of date. Additionally, nursing staff have difficulty in finding stock if the drug cupboard is overfilled, due to the space constraints. The same hospital has saved approximately €6,000 on High Tech medicines within the first two months of the year, but could increase this by at least 25% if the necessary manpower was in place, which would result in further savings of approximately €8,000 per quarter or €32,000 per annum.

#### Manpower issues

Clinical pharmacy services can only be undertaken if there is a critical mass of suitably qualified staff able to perform these roles. Undergraduate education at the three Schools of Pharmacy in Ireland are preparing students for such roles, and the provision of the two M.Sc. Clinical Pharmacy programmes from UCC and Trinity College Dublin (TCD) further enhances the ability of staff to fulfil these roles. Under current international manpower recommendations, for a 350 bed hospital it would be recommended that a hospital would have an establishment of five pharmacists and four to five pharmaceutical technicians.<sup>25</sup> Many Irish hospitals are currently unable to comply with these recommendations and thus the advantages to patients through clinical pharmacy services are being lost.

In summary, clinical pharmacists working in multidisciplinary teams provide significantly improved patient care and cost savings.

#### BENEFITS TO THE PATIENT AND HEALTHCARE PROVIDER

1. Pharmacists can make a significant impact in critical areas of patient care.
2. There are proven clinical benefits and cost-effectiveness arguments for patient management supported by clinical pharmacists in a range of clinical specialities in hospital e.g. intensive care and diabetes clinics.
3. Pharmacists can contribute to decreasing levels of mortality, length of stay, drug costs and contribute to pain management in post-operative surgery and reduce the burden on the health system.

4. Pharmacists can provide advice at the point of prescribing and intervene and influence prescribing before therapy commences.

#### CONCLUSIONS

A national policy should be developed to further advance clinical pharmacy services and also to further utilise clinical pharmacy services in hospitals. Hospital pharmacy pilot sites should be identified to develop, evaluate and refine the service provided by clinical pharmacists.

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## **5. Minor Ailments Scheme**

**A National Acute Episodic Illness Scheme  
Which is Patient-Focused, More Accessible  
and Better Value for the Health Service**

# 5

## 5. Minor Ailments Scheme

The concept of self-management in healthcare includes disease prevention, self-diagnosis, self-treatment and appropriate consultation with a health care practitioner.

Community pharmacists deal routinely with minor ailments as part of their normal practice, giving advice to patients on how to treat self-limiting conditions and distinguishing between minor illness and major disease.<sup>1,2,3,4</sup> By giving appropriate advice and recommending effective treatments, community pharmacists play a major role in keeping minor ailments out of the GP surgery and furthermore act as a filter for referral where a GP consultation is needed.<sup>1</sup>

### EVIDENCE BASE FOR CLINICAL PHARMACY PRACTICE

This frontline role of the community pharmacist in the management and treatment of minor ailments, and in the provision of professional advice on self-care, is an important part of the primary health care process.<sup>2,3,4</sup> It has been a fundamental role of pharmacists for generations and it is a service which works well and has widespread acceptance by patients and other professionals,<sup>5,6</sup> although certain studies have indicated that more awareness of the potential role and benefits of pharmacist advice in self-medication is needed.<sup>7,8</sup>

However, there are times when patients go to their GP with minor, self-limiting ailments which could easily have been appropriately dealt with by their local community pharmacist. This is a waste of resources, patients' time and the GPs' time.<sup>3,4</sup>

The major reason patients who hold medical cards go to their GP for minor ailments is financial.<sup>9,10</sup> A routine question asked of pharmacists when they are counselling patients on minor ailments and recommending a product is *"Is it available on the medical card?"*

The following scenario helps to illustrate the point: A woman comes in to the pharmacy with her young son and asks the pharmacist for something to treat head-lice. The pharmacist confirms that the child does have head-lice and recommends an insecticidal product to kill the head-lice. The woman asks if the product is available on the medical card, the pharmacist tells her it is, so the woman leaves saying she will go to the surgery to get the doctor to write a GMS prescription to avoid paying for the treatment. She then waits in the GP surgery with her son, who plays with other children and passes on head-lice to them while they are waiting. Eventually, they get to see the GP, who confirms the pharmacist's diagnosis, dutifully writes out a GMS prescription, which is then brought back to the pharmacy for dispensing.

This type of scenario is a regular occurrence, on a daily basis, in

every pharmacy and GP surgery in the country. The rational use of health service resources could be improved dramatically by the introduction of a protocol driven Minor Ailments Scheme, where medical card holders could be prescribed certain medicines for self-limiting conditions from their local pharmacy, without charge. A pharmacist prescription would be completed and submitted to the HSE, and a copy sent to the GP thus keeping the GP informed of the patient's consultation with the pharmacist. Valuable GP time and resources would be freed up to deal with patients with more serious conditions where medical intervention is required.

The following is a list of suggested minor ailments which could be included in the scheme, which could be augmented over time:

Acne, Allergic rhinitis, Athlete's foot, Back pain, Chickenpox, Colds and flu, Cold sores, Conjunctivitis, Constipation, Corns and callouses, Cough, Cradle cap, Cystitis, Dandruff, Dermatitic and mild eczema, Diarrhoea, Dry skin, Dysmenorrhoea, Ear wax and earache, Foot care problems, Fungal infections, Haemorrhoids, Hayfever, Headache, Head lice, Heartburn, Indigestion, Insect bites and stings, Irritable bowel syndrome, Male pattern baldness, Migraine, Motion sickness, Mouth ulcers, Nappy rash, Nasal congestion, Nausea and vomiting, Oral thrush, Pain, Pre-menstrual syndrome, Psoriasis, Scabies, Smoking cessation, Sore throat, Sprains and strains, Temporary sleep disturbance, Vaginal candidiasis, Verrucas and Warts.

It would be necessary for certain conditions, for example diarrhoea, dysmenorrhoea and others, that the protocols involved in determining the ailment also provide for appropriate referral, as certain symptoms could be masking other more serious conditions. Strict protocols of this nature would add to the safety of the scheme compared to existing arrangements.

In a recently published report<sup>12</sup> data were analysed from 210 general practices in the UK. The data covered over four million patient records and 190 million prescriptions. In 2006, 7.5 million patients consulted their GP about a minor ailment, which suggests that 51.4 million GP consultations a year nationwide were solely for minor ailments. The authors estimate that this represents 18% of a GP's workload, or the equivalent of at least an hour a day. Furthermore, the report estimates that the total cost to the NHS of these consultations is £1.8 billion (€2.5 billion) and 80% of this cost (£1.5 billion, €2.15 billion) is due to the cost of the GPs' time. Ten minor ailments: back pain, indigestion, dermatitis, nasal congestion, constipation, migraine, acne, cough, sprains and strains, and headache, were responsible for 75% of the cost of minor ailment consultations and 85% of the cost of prescriptions for minor ailments.

It has been proposed in England that a national minor ailments scheme be established where pharmacy is the first port of call for all

cases of minor ailments.<sup>11</sup> Where they operate, they can eliminate one third of GP consultations.<sup>4</sup> Other research has shown that the number of GP consultations in an area does not decline, but that the proportion of GP consultations associated with minor ailments is significantly reduced and accordingly there is more appropriate management of illness and more effective use of health services resources.<sup>3</sup> Furthermore, the minor ailments scheme results in screening and referral to GPs of more serious illnesses and can, accordingly, provide an early warning mechanism.<sup>11</sup>

In such a scheme, responsible self-care and self-medication would be supported and encouraged and there would be supply of treatments on the GMS for people who are exempt from paying for their prescription. It is of note that it would not only include over-the-counter (OTC) medicines but there would also be a mechanism to allow prescription-only medicines to be supplied when necessary (see Section 6).

Scotland's minor ailments scheme started in 2006 and recently the Head of Corporate Affairs at Community Pharmacy Scotland stated: "*Patients like it and pharmacists like it and it has really started to make a difference in the pharmaceutical care of patients who are exempt from NHS prescription charges. What I am most pleased about is that it is improving access to consultations, advice and medicines for common illnesses and allowing community pharmacists to prescribe where appropriate.*" There are now 70,000 consultations a month in Scottish pharmacies that previously would have taken place in GP surgeries and the average cost of medicines prescribed by pharmacists under the scheme is lower than those prescribed by GPs under the same circumstances.<sup>13</sup>

## BENEFITS TO PATIENT AND HEALTHCARE PROVIDER

A Minor Ailments Scheme, if implemented in Ireland, would have significant benefits:

1. Benefits for patients in becoming empowered to treat their own ailments.
2. Benefits for patients in extended access times to healthcare advice.
3. Benefits for the health service in better targeting of resources and making savings which can be redistributed.
4. Benefits for the GP by freeing up their resources to treat more patients with serious or chronic diseases.
5. Benefits for the pharmacist by ensuring the maximum use of their professional expertise and developing a greater role in managing minor ailments.

## CONCLUSIONS

The immediate introduction of a national Minor Ailments Scheme would provide a cost effective, easily accessible service for patients with minor conditions, thus reducing the time and resources GP services have to spend on more minor ailments.

Standards would need to be established for the scheme including the type and range of ailments that can be treated, the protocols to aid diagnosis, the development of a minor ailments formulary, private consultation areas, audit procedures and inspection validation procedures. Pharmacy pilot sites could be used to develop, evaluate and refine the scheme.

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## **6. Re-Categorisation of Medicines**

**From Prescription Only Medicines  
to Pharmacist Supervised and the  
Development of a New Pharmacy Legal  
Category (Pharmacist Prescribed)**



## 6. Re-Categorisation of Medicines

All medicines fall into one of three legal classifications which control the circumstances under which they may be supplied and by whom. The three classifications are prescription-only medicine (POM), pharmacy medicine (P) and medicines available for general sale (GSL). The classification is specified in legislation and in each product's marketing authorisation.<sup>1,2,3</sup>

All new medicines are normally POM for their first five years on the market and may only be sold or supplied by authorised practitioners to their own patients or from pharmacies on receipt of a prescription from an authorised practitioner. Manufacturers can apply to the IMB for medicines to be reclassified for sale and supply from pharmacies (P or PS {pharmacist supervised – supplied by, or under the direct personal supervision of, a pharmacist}) or from any shop (GSL) depending on evidence of their safety in use.

The reclassification of certain medicines from prescription only to pharmacy status is usually referred to as POM-to-P switching.<sup>4</sup> Based on patient need, in conjunction with available skills, pharmacists can add significant patient value to the medicines use process. Wider access to medicines with a proven safety profile, and greater patient choice, allows patients to take more control of their own health care, thereby reducing the burden of healthcare costs on the State.

In Ireland, there does not appear to be a co-ordinated approach to POM-to-P switching, as it is being done by and when the pharmaceutical industry decides, usually following on from what is decided by the parent company in the UK. There is a need for the Department of Health and Children to take control of this process, in the best interest of the healthcare needs of patients.

### EVIDENCE BASE FOR CLINICAL PHARMACY PRACTICE

A drive to increase the number of POM-to-P switches started in the UK in 2002 when a number of changes in the regulatory process took place.<sup>5</sup> The process was streamlined so the statutory approval of legal classification change was not required, but rather changes are allowed through assessments by the Medicines and Healthcare Products Regulatory Agency (MHRA). Under the old regulatory process once a company had applied to the MHRA to change a drug's classification the application went out for consultation. This meant that other manufacturers were then aware of the application so were able to apply quickly for similar changes once the first company's licence had been granted, leading to fast access to the OTC market. This was deemed to be unfair. The new strategy reduced by over half the time to get a product reclassified. The change was consistent with the NHS plan which puts an emphasis on ensuring wider access to medicines. Over the previous ten years, 50 treatments had been switched from POM to P status. It was envisaged that a further 50 would be switched

in the following five years. In addition, pharmaceutical companies applying for reclassification under the new process were given three months of marketing exclusivity as an incentive.

The Royal Pharmaceutical Society of Great Britain (RPSGB) prepared a list of specific therapeutic categories where there was a potential for POM-to-P switches based on British National Formulary (BNF) categories.<sup>6</sup> Examples of medicines suggested included beta-blockers, diuretics, statins, oral contraceptives, hormone replacement therapy and PPIs.

Stakeholders of this list, led by the RPSGB, included the Proprietary Association of Great Britain, the Association of the British Pharmaceutical Industry, the Royal College of General Practitioners (RCGP), patient groups and the MHRA. Any switches that took place were carefully managed with training of pharmacists and staff to allow a smooth transfer to that market. The new reclassification process allowed a wider use of pharmacists' skills than had been the case in the past.

### Need for a new legal category

Concern has been expressed about the availability of certain medicines over-the-counter<sup>7</sup> and restrictions in pack sizes have made an impact to overcome certain concerns with analgesics.<sup>8</sup> The switching of medicines so that they are more readily accessible to patients could be facilitated and safeguarded, given the concerns expressed,<sup>7,8</sup> by the introduction of a new legal category "pharmacist prescribed". While the medicine would be available for purchase, the pharmacist would be required to carry out a number of clinical checks and to record details of the consultation. A number of medicines that are currently available "over-the-counter" could be moved to such a category with considerable benefit to public health e.g. codeine,<sup>7</sup> pseudoephedrine.<sup>9</sup> This new category could also include drugs which can be prescribed by pharmacists on a repeat basis following initiation by a medical practitioner, with the repeat prescriptions issued under an agreed protocol. This would also make the pharmacist responsible for monitoring patients. The "pharmacist prescribed" category should overcome the problem of patients buying medicines for themselves without receiving regular counselling and monitoring.<sup>7,8,9</sup>

If drugs for chronic diseases are to be made more widely available, access to patient records and registration of patients in pharmacies would be needed. It is clear that patients should be registered with one community pharmacy to ensure that chronic conditions are properly managed.

It would also be vital to establish robust and secure electronic links with community pharmacies and to agree appropriate levels of access to patient-sensitive information. This should ensure that any drug issued to a patient would be recorded on their medical record to ensure that a complete account of their medication history is available.

### Specific Medicines

Analgesics for migraine, treatments for motion sickness, malaria prophylaxis, antifungal treatments for topical and oral use, and inhaled bronchodilators have all been suggested as potential POM-to-P switches.

A number of reclassifications of prescription-only medicines to pharmacy medicines have been proposed or completed in the UK in the past few years,<sup>6</sup> including:

*Amorolfine* - for the treatment of fungal nail infections.

*Azithromycin* - for the treatment of the sexually transmitted infection chlamydia.

*Chloramphenicol* - for the treatment of conjunctivitis.

*Naproxen* - for the treatment of joint pain and dysmenorrhoea.

*Nitrofurantoin* - for uncomplicated urinary tract infections.

*Omeprazole* - for the treatment of reflux-like symptoms in adults.

*Simvastatin* - for the prevention of a first major coronary event in people at moderate risk of coronary heart disease.

*Sumatriptan* - for the acute relief of migraine attacks.

*Tranexamic acid* - for the treatment of dysmenorrhoea.

*Triamcinolone* - for mouth ulcers.

*Trimethoprim* - for uncomplicated urinary tract infections.

In addition to the medicines listed above, serious consideration should be given to emergency contraception and also to oral contraception.

**Emergency Contraception** – the ready availability of emergency contraception from pharmacies in the UK has been a significant development. Early fears that availability of emergency contraception would result in failure of young women to initiate regular contraception were unfounded, according to a UK study.<sup>10</sup> Routinely the majority of emergency contraception prescriptions are supplied during the weekends when the patient's GP is not available. The prescriptions are issued by locums working for after-hours doctor services. This is time-consuming, expensive and an unnecessary obstacle to women seeking access to emergency contraception. It would be far more appropriate that the patient could go directly to

her local pharmacy and within the terms of a defined protocol, her pharmacist could supply the emergency contraception.

**Oral Contraceptives** – the potential benefits of reclassifying oral contraceptives from prescription-only to pharmacy medicines are being discussed in the UK. The MHRA in 2007 organised a seminar,<sup>11</sup> which suggested that the contraceptive pill should be available without prescription from pharmacies. There was a predictable negative response from certain groups within the medical profession to such a switch, voicing the concerns that pharmacists would not be aware of those women at risk of complications, either because of existing medical conditions or other medicines they are taking. However, access to medical records could address those issues.

Although making the oral contraceptive pill a pharmacy medicine would be a complicated process, it could have several benefits. The patient would attend a pharmacy and complete a checklist. Her blood pressure would be checked and she would discuss the situation with the pharmacist. Pharmacists would be able to provide help and advice and could easily reassure women about some common concerns and side-effects.

### BENEFITS TO PATIENT AND HEALTHCARE PROVIDER

A “pharmacist prescribed” scheme, if implemented in Ireland, would have significant benefits:

1. Benefits for the patients in providing a wider range of medicines to treat their own ailments.
2. Benefits for the health service, in that more ailments could be treated without referral to a GP, which would allow for better targeting of resources and hence making savings which could be redistributed.
3. Benefits for the GP, by freeing up their resources to treat more patients with serious or chronic diseases.
4. Benefits for the pharmacist, in playing a greater role in managing a wider range of minor ailments.

### CONCLUSIONS

A national policy should be developed with regard to POM-to-P switching, and the introduction of a “pharmacist prescribed” category given serious consideration.

This may require the development of an efficient system to allow access to patient medication records throughout the healthcare system.

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## **7. Pharmacist Prescribing Enhancing Pharmacy Services**



## 7. Pharmacist Prescribing

Previously, only doctors and dentists have been able to prescribe prescription-only medicines to patients. However, the Minister for Health and Children extended prescriptive authority to nurses and midwives in 2006,<sup>1</sup> by including in primary legislation a provision for the prescriptive authority of nurses. This was implemented by way of Regulations in May 2007.<sup>2</sup>

Pharmacists were not included in this initiative, which was surprising to many, including pharmacists, given pharmacists' training and knowledge in pharmaceutical chemistry, pharmaceuticals, pharmacology, clinical pharmacy and therapeutics, which is, arguably, the most intensive training in prescribing and drug usage of any of the healthcare professionals.

However, up until last year pharmacists were operating under antiquated legislation which obstructed the development of the profession. It is clear that since the enactment of the Pharmacy Act, 2007<sup>3</sup> the position has improved dramatically. Pharmacists are now subject to the most rigorous regulatory regimen in Ireland. The Minister for Health and Children, through the introduction of the Pharmacy Act, 2007<sup>3</sup>, has now facilitated pharmacist prescribing.

### Supplementary prescribing

Supplementary prescribing allows additional health care professionals, including pharmacists, to prescribe medicines. It can be described as: a voluntary partnership between an independent prescriber (e.g. a doctor or dentist) and supplementary prescriber (e.g. a pharmacist), to implement an agreed patient-specific clinical management plan (CMP), with the patient's agreement.

Extending prescribing rights to other healthcare professionals was first proposed in the UK in 1999.<sup>4</sup> A new category of prescribers, known as 'supplementary prescribers', who would continue the care of patients who have already been assessed by an 'independent prescriber', was created. Supplementary prescribers are professionals who are 'authorised to prescribe certain medicines for patients whose condition has been diagnosed or assessed by an independent prescriber, within an agreed assessment and treatment plan'. Recommendations for the new prescribing framework included details of restrictions for dependent prescribing, the importance of clinical reviews by the assessing clinician, and how to allow both prescribers access to the necessary patient records.

Supplementary prescribing follows assessment by an independent prescriber and requires an agreed CMP; good communication between healthcare professionals caring for the patient is therefore essential. Once the patient has consented, supplementary prescribers can then prescribe within the CMP guidelines.

Independent prescribers are responsible for reviewing the patient at predetermined intervals, advising and supporting the supplementary prescriber, sharing a common patient record with the supplementary prescriber and reporting adverse incidents within national and local risk management or clinical governance schemes.

Supplementary prescribers are responsible for accepting professional accountability and clinical responsibility for their prescribing practice, passing prescribing responsibility back to the independent prescriber should the agreed clinical reviews not be met by that party, recording prescribing and monitoring activity in the shared patient record and reporting adverse incidents within national and local risk management or clinical governance schemes. It should be noted that supplementary prescribers cannot prescribe controlled drugs or unlicensed drugs.

Supplementary prescribing is mainly used for patients with long-term medical conditions, such as diabetes and coronary heart disease (CHD), or with long-term health needs, such as anticoagulation.

Each CMP must be patient-specific and included in the patient's records. It should refer to any relevant National Institute for Health and Clinical Excellence (NICE) guidelines (these should be available to the supplementary prescriber) and fulfil certain requirements, such as including the patient's name and the illnesses and conditions that the supplementary prescriber may manage.

Supplementary prescribing is intended to encourage a team approach to the care and management of patients and to make the best use of the skills of trained healthcare professionals. To become supplementary prescribers, pharmacists must go through a full clinical skills assessment and undergo appropriate training.

### The limitations of supplementary prescribing

Whilst supplementary prescribing has been found to be a useful mechanism for some patients, there have been concerns expressed about the complicated nature of the process and the associated administrative burden. CMPs are developed between the primary prescriber (doctor/dentist) and the pharmacists – however, it is time consuming for both.<sup>7</sup> Accordingly, it appears to limit the willingness of primary prescribers to participate. Co-morbid conditions are often not covered, even though managing them may form important elements of good patient care.<sup>7</sup> Furthermore, the MHRA has further shown that restriction of prescribing to formularies in the UK was resource intensive as it involves statutory public consultation, consideration by the Committee on Safety of Medicines and changes to legislation. This entire process takes more than a year to finalise and makes it impossible to keep the formulary up to date with innovations in care.<sup>8</sup>

### Independent prescribing

In 2005, acting on concerns that supplementary prescribing was not having the desired impact, due to a number of constraints, the MHRA decided to consult on proposals to introduce independent prescribing by pharmacists.<sup>7</sup> The consultation process presented a number of options for consideration:

1. No change (that is, no independent prescribing by pharmacists).
2. Prescribing for certain conditions from a limited formulary.
3. Prescribing for any condition from a limited formulary.
4. Prescribing for specific conditions from a full formulary.
5. Prescribing for any condition from a full formulary.
6. Different approaches for the different clinical settings.
7. A hybrid approach – prescribing from a full formulary where there is a diagnosis from a doctor, and from an agreed formulary where there is no access to a diagnosis by a doctor.

Of the 250 responses received in England, there was little support for option 1 (2.8%) which came mainly from the medical profession. The RCGP favoured option 1 or 2 and the British Medical Association reported that doctors in secondary care preferred option 1, and GPs option 2. The majority view from the pharmacy profession, NHS and other health professions was that this option would not benefit patients or the NHS, and would fail to take full advantage of pharmacists' training and skills.

Option 2 received slightly more support (3.2%) as it was viewed by some as a prudent starting point in preparation for wider prescribing responsibilities for pharmacists, but overall, a majority of respondents viewed this option as too restrictive and that it would be too complex and demanding.

Options 3 and 4 received little support (0.8% and 2% respectively) for roughly the same reasons as given for option 2.

Option 5 was preferred by the greatest number of respondents (48.4%). The RPSGB favoured this option and said that appropriately trained pharmacists should be able to prescribe any appropriate medicine for any condition that they were competent to treat. They felt that this option gave the greatest flexibility and was least likely to create constraints for patients and other NHS professionals. The decision on clinical areas for which pharmacists could prescribe should be left to local need and the pharmacist's competence. The NHS bodies, including the National Patient Safety Agency (NPSA), were also in favour of this option (58%).

Option 6 was preferred by 16.6% of respondents but a number commented that a legislative approach that distinguished between work settings would not be feasible, acceptable or suitable. Finally, option 7 was preferred by 22.8% of respondents but was viewed by some as too complicated.

What is clear from this consultative process is the vast majority were in favour of pharmacist independent prescribing, as options 5,6,7 accounted for more than 90% of responses. Following this consultative process, in 2006<sup>8</sup>, pharmacists in the UK can now obtain additional qualifications to allow them to prescribe as an independent prescriber. Pharmacist independent prescribers are able to prescribe any licensed medicine within their level of competence and experience, except for controlled drugs.

Independent prescribing pharmacists in the UK can now prescribe in the following areas, ensuring patient gain:

1. Admission to hospital.
2. Discharge from hospital.
3. Administrative changes in hospital prescriptions.
4. Specialist pharmaceutical services:
  - a. Therapeutic monitoring.
  - b. Parenteral nutrition.
  - c. Long term care clinics.
  - d. Minor ailments.
  - e. Medication review.
  - f. Public Health.
5. Other areas:
  - a. Repeat prescribing.
  - b. Prophylaxis (e.g. travel vaccines, antimalarials, influenza vaccines).
  - c. Preparations used prior to certain surgical and diagnostic procedures.
  - d. Products used for therapeutic monitoring.
  - e. Administration devices.

Evidence from the UK and other jurisdictions is heavily in favour of independent prescribing for pharmacists over models of supplementary prescribing.

In summary, independent prescribing qualifications in specific areas of competence are available to pharmacists in Northern Ireland but not in the Republic. Prescribing qualifications are also available to nurses in the Northern Ireland and in the Republic of Ireland. There is a need to bring the role of suitable pharmacists in the Republic in line with that in the UK. Supplementary prescribing is suitable and practical for certain patients, but has significant practical limitations which have resulted in increased administrative burden for pharmacists and primary prescribers. Independent prescribing in areas of proven competence has been widely advocated as part of a modern healthcare system and is further supported by the recent White Paper on Pharmacy in England presented to the UK parliament in April 2008. Introduction of similar arrangements for suitably qualified pharmacists in Ireland would provide many benefits.

## BENEFITS TO PATIENTS AND HEALTHCARE PROVIDER

Pharmacist prescribing has the following benefits for patients<sup>9</sup> and the HSE:

1. For patients in the community with conditions characterised by a pattern of relapses and remissions, fast access to an independent pharmacist prescriber will enable patients to obtain treatment earlier which should reduce exacerbations of long term conditions.
2. Discharge from hospital could be more efficient with medicines available when the patient is ready to be discharged and the patient having received appropriate counselling.
3. Improved access to a healthcare professional with the ability to assess their symptoms and treat a wide range of conditions.
4. Improved access "out of hours" without the need to use the out-of-hours centres. It would mean some people would receive treatment earlier and reduce the incidence of relapses, hospital admissions and demands on GPs. This is particularly relevant at weekends and in the evenings, when many GP practices are closed but most pharmacies remain open.
5. Increased patient choice - patients would have another option for obtaining health care and treatment with medicines.
6. They are less likely to miss doses of essential medicines in hospital.
7. Minor changes to patients' repeat prescriptions could be implemented without the need to see a doctor.
8. Outbreaks of certain infections e.g. meningitis could be managed more effectively.
9. Patients could receive immediate treatment following results of certain tests, such as chlamydia screening.
10. Improved access to a healthcare prescriber may be especially important in remote rural areas.
11. More effective use of doctors' time as they will not need to authorise prescriptions for administrative changes, e.g. when patients move from intravenous to oral formulations, change of product due to patients being admitted on non-formulary medication that has already been agreed.
12. Not having to take responsibility for prescriptions written by another health professional, although a second check system should be in place whereby another pharmacist would assess the prescription.
13. Pharmacists would be able to provide a service where the demand is greater than can be met by existing healthcare prescribers.
14. Improved multidisciplinary working, leading to more effective use of resources and improved patient outcomes.
15. Pharmacist independent prescribers involved in the repeat prescribing process could help to reduce costs by only prescribing products that patients are likely to take/use. They could also be used to prescribe in quantities that relate to original packs and so reduce waste, which will lead to further efficiency and improved overall effectiveness and quality of the repeat medication process.
16. More effective use of resources, manpower, finance and decreased wastage of medicines.

## CONCLUSIONS

A national policy on pharmacist prescribing, in particular independent prescribing, needs to be developed which has due regard to the experience of other jurisdictions.

A system for allowing all healthcare professionals access to patients' medication records would require to be developed, to facilitate safe and effective prescribing. Pharmacists would be required to undergo a full clinical skills assessment and appropriate training, in association with the Schools of Pharmacy, to achieve the required standards and levels of competence for pharmacist prescribing.

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## **8. Community Pharmacy and Health Screening**

### **A Missed Opportunity**



## 8. Community Pharmacy and Health Screening

Health screening has been defined by the UK National Screening Committee<sup>1</sup> as a public health service in which members of a defined population are questioned or offered a test, in order to identify people who will benefit from further tests or treatment, thereby reducing the risk of a disease or its complications.

While it can help individuals to make informed choices about the improvement of their health, there a number of important practical considerations:

1. Health screening is guided by widely acknowledged principles set down by the WHO.<sup>2</sup>
2. It requires careful targeting to maximise its impact, should be evidence based and should be delivered in a continuous manner.
3. It may be limited by lack of accessibility and/or availability of facilities and appropriate testing.
4. While health screening has the potential to save lives, improve quality of life and reduce healthcare provider cost, it is rarely absolute and is more akin to a risk reduction process. Therefore, it usually requires professional support and intervention.
5. Because of disease clustering (e.g. within diabetes and cardiovascular diseases), screening existing service users for disease progression or new onset illness is a key feature of health screening.

There are more visits to the current network of approximately 1,600 community pharmacies in Ireland on a monthly basis than to any other element of the primary healthcare service, with more than 10 million visits/consultations per annum. A recent survey reported three quarters of the adult Irish population use community pharmacies at least once per month.<sup>3</sup> Therefore, health screening and promotion activities in Irish community pharmacies have the potential for relatively high penetration into the population.

However, there is no current HSE policy on health screening in community pharmacy. The services provided are therefore uncoordinated, ad-hoc, unsupported and not audited. There continues to be debate about the cost effectiveness, location and availability of screening programmes. With the average community pharmacy in Ireland open more than 50% longer than GP clinics, and with the continuous availability of health professional advice without appointment, pharmacy-based health screening may have advantages in terms of reach, accessibility and cost effectiveness.

### EVIDENCE BASE IN COMMUNITY PHARMACY PRACTICE

The HSE National Service Plan 2008<sup>4</sup> identifies the following chronic diseases as presenting particular challenges to the service: “diabetes, heart failure, some cancers, chronic obstructive

pulmonary disease, dementia and arthritis”. There is community-wide acknowledgement that each of these chronic illnesses is under-diagnosed and therefore under-treated. It is estimated that approximately half the patients of diabetes in the community are not aware of their condition.<sup>5</sup> More people have undiagnosed rather than diagnosed hypertension in the community.<sup>6</sup> Up to 80% of prevalent COPD in the community remains undiagnosed.<sup>7</sup>

Existing pharmacy-based screening programmes play an important part in disease prevention, disease management and public health improvement. They are a key feature of the public health response to, but not limited to, infectious disease,<sup>8</sup> endocrine disease,<sup>9,10,11</sup> cardiovascular disease,<sup>11</sup> depression,<sup>13,14,15</sup> cancer,<sup>16</sup> osteoporosis,<sup>17,18,19</sup> COPD<sup>20,21</sup> and men’s health.<sup>22</sup> These disease areas account for the majority of annual deaths in Ireland.<sup>23</sup>

### Example: Diabetes

Undiagnosed diabetes may affect approximately 150,000 Irish people.<sup>5</sup> Undetected diabetes predisposes patients to greater disease progression, more severe disease, worse outcome and increased healthcare costs compared to timely detection of disease. Furthermore, there is increasing awareness that impaired glucose tolerance and impaired fasting glucose, known precursors of diabetes, put people at higher risk of adverse outcome. Research suggests that 11% of adults, or more than a quarter of a million people in Ireland, have impaired glucose tolerance and are at high risk of developing diabetes.<sup>24</sup> The vast majority of these people are unaware of their condition.<sup>24</sup>

Krass<sup>10</sup> looked at the efficacy and cost-effectiveness of two methods of screening for undiagnosed Type 2 DM in community pharmacy, using a random sample of 30 pharmacies allocated into two groups. In both groups a questionnaire, which focused on risk factors for diabetes, was administered to people in the community pharmacy, and those with one or more risk factors were advised to contact their GP. In the active screening group, as well as risk factor assessment, people were offered a finger-prick blood test before referral on to the GP. Three quarters of people had risk factors. In the control group, two thirds of these refused to participate in further screening, whereas in the active pharmacy screening group, only 15% refused to participate further.

There was an eight-fold higher rate of newly diagnosed diabetes in the active pharmacy screening group. Moreover, there were more GP referrals in the questionnaire only group. For every patient diagnosed in the questionnaire group, there were more than six GP consultations required and the total cost of the programme was AU\$6248, whereas for every patient diagnosed in the active pharmacy screening group there was less than one GP visit required, at a total cost of AU\$788. This study illustrates that active pharmacy screening:

1. Is more effective than simply informing people about their risk.
2. Results in more successful identification of undiagnosed diabetes.
3. Results in reduced workload for GPs and lower overall healthcare provider cost.

**Example: Cardiovascular Disease**

Since several chronic diseases aggregate in individuals, Snella *et al.*<sup>12</sup> demonstrated that by limiting the screening to high risk people (first-degree relative with diabetes, age 55 years or older, obesity, previous diagnosis of hypertension, or a previous diagnosis of dyslipidaemia), pharmacy-based screening is particularly worthwhile, with 81% of people screened being referred for follow-up for at least one abnormality (15% glucose, 68% blood pressure, 66% total cholesterol and 26% HDL-C). Of those with follow-up data available, 16% received one or more new diagnoses (diabetes, hypertension, dyslipidaemia) and therapy was directly changed amongst 42% of participants. Pharmacists identified individuals with elevated glucose, cholesterol, and blood pressure values through community-based screenings. Pharmacists also identified individuals who could benefit from further control of previously diagnosed hypertension and hyperlipidaemia.

**Example: Osteoporosis**

In another important area, osteoporosis affects up to one in five Irish adult men, and one in three Irish adult women, and the vast majority is undiagnosed.<sup>25</sup> Naunton *et al.*<sup>17</sup> demonstrated that pharmacy-based ultrasound screening for osteoporosis was an effective means of identifying osteoporosis in the community, with approximately six out of 10 people screened requiring referral and three out of 10 requiring therapy. Twenty percent of people screened were at high risk of the development of osteoporosis. Furthermore, it has been demonstrated that 43% of the participants reported increasing their dietary intake of calcium, 29% began or increased calcium supplements and 55% positively modified smoking status, exercise level, alcohol consumption or caffeine intake. Finally, 87% of participants reported that the community location increased their likelihood of receiving a bone mineral density scan, indicating that pharmacy accessibility and availability may be a key advantage in health screening. This has also been shown in men's health screening, where there may be a reluctance to regularly seek medical care for health advice.<sup>22</sup>

**Example: Chronic Obstructive Pulmonary Disease (COPD)**

COPD affects up to 10% of the population and is associated with high morbidity, mortality and healthcare cost.<sup>20,21</sup> The vast majority

of COPD in the community remains undiagnosed.<sup>20</sup> However, many initial referrals for COPD diagnosis come from community pharmacy referrals because of the strong association with smoking and symptoms such as cough.

In summary, despite the acknowledged health need for improved health screening and chronic disease prevention, there is no HSE policy on the development of the role of pharmacy in this regard. As a result, health screening services in Irish pharmacies are uncoordinated, ad-hoc, not resourced and not aligned to the Health Strategy and HSE Service Plan. There is no frontline health service in Ireland with a higher throughput of the general population than community pharmacy, and yet there appears to be a lack of awareness of the potential for community pharmacy to deliver frontline healthcare services such as health screening. This is analogous to the pre-1986 Nuffield Report on Community Pharmacy in the UK.<sup>26,27</sup> More than 21 years ago, the NHS began to develop policies which utilise community pharmacy as a frontline professional health service rather than medication supply outlets. A similar transition has occurred in most other developed countries such as the US, Canada and Australia, but is yet to begin in Ireland.

**BENEFITS TO PATIENT AND HEALTHCARE PROVIDER**

The benefits to the healthcare provider and patient of co-ordinated healthcare screening services in pharmacy include:

1. Pharmacy is the primary care service with the greatest reach into the general population.
2. Pharmacies are open on average for 60 hours per week and may be more accessible than other primary care services.
3. There is a continuous availability of highly trained health professionals in pharmacies.
4. Pharmacy is the healthcare service with most frequent contact with high-risk chronic disease patients and is ideally placed to screen for disease development and progression.
5. There is broad acceptability of healthcare screening in pharmacies, with 92% of the general population agreeing that services such as diabetes screening should be available in this setting.<sup>3</sup>
6. Minimal capital expenditure required in rolling out programmes in the existing pharmacy network.
7. Easy access to identifier data for high risk patients through medication databases.

## CONCLUSIONS

Pharmacy currently provides health screening as a front-line primary care service although there are currently no defined structures and standards in place. Community pharmacies are an appropriate place for the development of structured population health screening initiatives and a formalised policy around health screening should be developed.

Structured population health screening initiatives should capitalise on the fact that pharmacy is the frontline healthcare service with the highest population throughput on a monthly basis. Other advantages of pharmacy in health screening include:

- Availability and accessibility of the current pharmacy network.
- Availability of highly trained health professionals in the community pharmacy network.
- Very favourable public view of health screening in community pharmacy. Screening services in community pharmacy should include improving detection and prevention of chronic diseases such as diabetes, cardiovascular disease, heart failure, COPD, arthritis, as well as certain types of infections and cancers.

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## **9. Pharmacist Vaccination Clinics**

**Ready Access Increases Uptake and  
Improves the Health of the Nation**



## 9. Pharmacist Vaccination Clinics

Prevention of illness, rather than necessary treatment of the patient once illness has occurred, is the primary focus of all forms of vaccination whether this occurs at a local, national or global level. The WHO Global Immunisation Vision and Strategy 2000-2015 identifies four strategic areas with 24 underlying components which envisage the creation, facilitation and development of national policy to deliver their stated vision for 2015.<sup>1</sup>

It has been stated that death is reported in 0.5 - 1 per 1000 cases of influenza. The majority of deaths occur in those over the age of 65.<sup>2</sup> Even in winters when the incidence of influenza is low, 3,000-4,000 excess deaths may be attributable to influenza in the UK.<sup>3</sup> The current best Irish national estimate of the number of deaths annually from influenza and its complications is 300-400 deaths per year, and is based on extrapolation of studies done in the UK and the US.<sup>4</sup> It can also put pressure on health and other services. Influenza immunisation is an effective way to prevent or ameliorate influenza, and it reduces complications. It also reduces hospital admissions as a result of influenza by as much as 60% and morbidity by 40%.<sup>5</sup>

It is widely accepted that annual vaccination remains the best protection against influenza, especially in people who are at high risk of complications from influenza. Influenza can affect all ages, however it has more severe consequences in the older person or people defined as being high risk. There are guidelines set out by the Royal College of Physicians of Ireland Immunisation Advisory Committee.<sup>6</sup> Two groups are identified:

- 1) Any individual over the age of six months who is at risk of influenza related complications.
- 2) Those at increased risk of transmitting influenza to a person who is at high risk of influenza related complications.

These categories include:

- All persons over the age of 65.
- People with chronic illness such as chronic heart disease, chronic lung disease, diabetes mellitus.
- People who are immunosuppressed due to disease or treatment, including asplenia or splenic dysfunction.
- Children and teenagers on long-term aspirin therapy.
- Residents of nursing homes, residential care settings for older people and other long stay facilities where rapid spread is likely to follow introduction of infection.

In addition to these groups, vaccination should also be considered for health care workers both for their own protection, as these are a group likely to come into contact with influenza during outbreaks, and for the protection of their patients.

In residents of nursing homes, the vaccine is effective in preventing

severe complications and deaths. Studies have shown that hospitalisation rates, cases of pneumonia and respiratory illness, and death rates were reduced by over 50% in elderly residential populations that were vaccinated.<sup>7,8,9,10,11</sup>

A future pandemic is likely to spread rapidly to all parts of the globe and cause sudden and sharp increases in illness over a matter of weeks. A pandemic has the potential to overwhelm health and other services rapidly. Contingency plans are being made in which a tiered approach to immunisation is proposed, immunising sections of the population in stages according to the availability of vaccine. One of the challenges in responding to a pandemic will be to develop a safe, immunogenic vaccine that protects against the pandemic strain of virus, and then immunising large numbers of individuals who may be key workers or in "at-risk" groups. Within this context, additional opportunities for providing immunisation will be essential and the community pharmacy network provides an existing and readily accessible solution. Pharmacy based vaccination services are available in 46 states of the US and are being developed in the UK, in both Scotland and England. The concept of effective and appropriate vaccination for the individual, and the effective operation of vaccination programmes, is an essential component of an effective health care system. The aim of reducing morbidity and mortality due to the impact of vaccine preventable diseases, through a structured system of vaccine delivery to the general population, must take account of the sociological context. Ensuring ease of access to both systems of administration and quality vaccines, ensuring systems of information provision and ensuring that systems are in place to monitor and sustain delivery of agreed health service policy, is prerequisite to effective operation of vaccination schemes. The network of community pharmacy practices spread throughout the country offers accessible locations for delivery of vaccination, and for the provision of reminders to ensure booster doses when necessary.

### EVIDENCE BASE FOR CLINICAL PHARMACY PRACTICE

The provision and delivery of vaccination services through the network of community pharmacies has occurred in other jurisdictions. In 1998, pharmacists in 25 states in the US were authorised to administer immunisations with over five million doses of influenza vaccine administered in pharmacies.<sup>12</sup> By 2003, 35 states in the US had legalised the administration of vaccines by pharmacists on the basis of certain training requirements and specific protocols.<sup>13</sup> A study undertaken by the Medical University of South Carolina has indicated that individuals aged 65 years and older who live in states where pharmacists can provide vaccines had significantly higher influenza vaccine rates than individuals of this age who reside in states where pharmacists can not provide vaccines.<sup>14</sup>

In the UK the utilisation of Patient Group Directions in the NHS Grampian pharmacy influenza immunisation scheme facilitated its introduction in late 2002. This scheme had a patient focus, in that it was envisaged that it would increase patient choice and increase influenza vaccine uptake in at risk groups who are under 65 years of age. Although the number of pharmacists and pharmacies involved was small – 10 pharmacies participated in year three with seven of those subsequently running clinics – a review over three years of provision indicated that community pharmacy has the ability to provide influenza immunisation in rural and city settings. Patient satisfaction was high with just one of the 898 patients from year two not indicating that they would use the pharmacy to have other vaccinations.<sup>15</sup>

Community pharmacists in England are set to play a bigger role in delivering the seasonal influenza programme following an independent report commissioned by the Department of Health.<sup>16</sup> The report was commissioned following delays and shortages during 2005/2006. It recommended that the Department of Health examine the potential role of community pharmacy to promote the programme by identifying patients to GPs; to enable the targeting of at-risk and hard-to-reach groups; to increase the primary care capacity for delivering immunisation; and to increase patient choice and accessibility.

The report said that the reform of primary care, including the new contractual framework for community pharmacy and the expansion of pharmacist and nurse prescribing, provides opportunities for new ways of working. However, the report warns that introducing alternative providers may increase the complexity of calculating flu vaccine requirements. It may also require new incentive and reward systems to encourage collaborative working.

Pharmacists working within City and Hackney Primary Care Trust (PCT), in London, were trained to administer influenza vaccines, in an attempt to improve uptake of the vaccine in east London during the annual flu campaign. The PCT had achieved only a 59 per cent uptake of flu vaccination among its 20,000 target patients, the worst result in the UK. It was clear that the PCT had to do something different to get these patients immunised and they considered pharmacists ideally placed.<sup>17</sup>

The PCT used two approaches to capture patients. Accredited community pharmacists identified at-risk patients who brought in prescriptions for dispensing and checked if they had received the vaccine. If they had not received it, pharmacists offered to administer the vaccine in a private consultation area in their pharmacy. In addition, the PCT commissioned pharmacists to run clinics in GP practices that had been particularly poor performers.

A service level agreement for this enhanced service was developed, and pharmacists received a retainer fee to cover the campaign, training, records and audit, and a fee for each vaccine administered. As part of the agreement, records of who had been vaccinated were given to the GP practice on the day of vaccination where this was feasible. A total of 54 pharmacists undertook the one-day training course. It included recognition of anaphylaxis, the principles of immunisation and practical vaccination skills.

Ease of accessibility of the community pharmacy with convenient locations and hours of operation are factors which would favour patient uptake and participation in any immunisation programme. Adult prescription recipients' choices of vaccine provider were evaluated in a study examining a cluster sample from 24 community pharmacies. From this it was identified that for the purpose of the study, two key considerations were important to patients: convenience and provider experience.<sup>18</sup> This reflected the results produced in 2001 from a study which described the demographic, clinical and attitudinal characteristics of patients vaccinated by pharmacists – a cross sectional survey of 1730 adults vaccinated at 21 community pharmacies in 10 states concluded overall satisfaction with the experience and a willingness to recommend it to others.<sup>19</sup>

Vaccination has unquestionable benefits for both the individual and for public health as a whole. However, barriers exist both at a sociological and practical level which impact on patient uptake and participation in immunisation programmes. For example the HSE, in an information booklet addressing influenza vaccination, identified a number of factors which could possibly prevent or inhibit people at risk from seeking or accepting vaccination.<sup>20</sup> All of the factors identified, which may act as barriers, may be managed through a mechanism of information provision and counselling by a trained accessible healthcare professional.

The community pharmacist is ideally situated to provide such information and encouragement and the community pharmacy is an ideal location from which to conduct an immunisation clinic, provided it has a private consultation room.

## **BENEFITS TO PATIENTS AND HEALTHCARE PROVIDER**

There are many potential benefits to pharmacy based vaccination clinics.

1. Pharmacy is the primary care service with greatest reach into the general population with typically long hours providing ease of accessibility.
2. The pharmacist has the most frequent contact of any healthcare professional in Ireland with the population as a whole.

3. The pharmacist is ideally placed to assess, identify, contact and encourage at risk individuals in the population as a whole and initiate an intervention which would result in vaccine uptake.
4. Continuous availability of highly trained and educated health professionals.
5. Increased demand for immunisation services with concomitant increased national vaccination coverage.
6. Minimal capital expenditure in rolling out programmes in existing pharmacy network.

## CONCLUSIONS

A policy and strategy for maximising the use of vaccines, which takes account of the huge potential of the community pharmacy network, to improve patient outcomes and take pressure off other frontline services should be developed.

National standards and protocols for the delivery of vaccination and immunisation programmes through community pharmacy should be developed, as well as national training programmes to address the requirement for additional skills and specialisations of currently registered pharmacists.

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## Conclusions

**THE MAIN CONCLUSIONS OF THIS INTERIM REPORT ARE SET OUT BELOW:**

**Pharmacy and Drug Safety**

1. There is a growing evidence base supporting the clinical benefits and cost-effectiveness of pharmacy based chronic disease management programmes to address adherence, self-care and guideline goal achievement by patients. A multidisciplinary approach involving pharmacy would be more effective than current models of care. A national policy for the utilisation of the existing community pharmacy network to deliver clinical and cost benefits in the care of chronic disease is necessary.
2. The pharmacist's role in minimising drug errors has been shown to be clinically effective and cost effective. As the evidence-based drive to greater polypharmacy results in greater drug-drug and drug-disease interactions, the pharmacist's role in pharmaceutical care of patients should be recognised and developed. A collaborative pharmacist/physician model is most effective in this regard, and an open, "no-blame" culture of medication error reporting should be developed in order to address chronic under-reporting of events. The establishment of an independent body with responsibility for a centralised, cross-sector/profession reporting mechanism for medication error reporting, would be desirable.
3. Furthermore, a more central role in ADR reporting for the pharmacist should be found as a potential remedy for the current under-reporting of ADRs to regulatory authorities. This should be a compulsory element of the contractual work of the pharmacist within the HSE. These data should be provided not only to the Irish Medicines Board (IMB), but also should be co-ordinated by the Health Information Quality Authority (HIQA) as part of its remit in improving patient safety systems.
4. Funding, channelled through an agency such as the Health Research Board, could be made available to fund clinical pharmacy research and the development of pilot schemes in pharmacy practice.
5. A national policy for the fuller utilisation of clinical pharmacy services in hospitals should be developed.

**Re-Classification of Medicines**

6. A national policy should be developed with regard to POM to P switching, and the introduction of a "pharmacist prescribed" category given serious consideration.

7. The immediate introduction of a national Minor Ailments Scheme would provide a cost effective, easily accessible service for patients with minor conditions, thus reducing the time and resources GP services have to spend on more minor ailments.
8. Standards would need to be established for the scheme including the type and range of ailments that can be treated, the protocols to aid diagnosis, the development of a minor ailments formulary, private consultation areas, audit procedures and inspection validation procedures. Pharmacy pilot sites could be used to develop, evaluate and refine the scheme.

**Pharmacist Prescribing**

9. Prescribing by specially trained pharmacists should be examined and a national standard for prescribing competencies be developed for those involved in prescribing.
10. A system for allowing all healthcare professionals access to patients medication records should be developed in Ireland to facilitate safe and effective prescribing.

**Health Screening**

11. There is an acknowledged health need for improved detection of chronic diseases such as diabetes, cardiovascular disease, heart failure, certain infections and cancers. These are considered by the HSE to be priority areas for the management of increased demands on existing healthcare resources. There is a growing evidence base supporting the clinical and cost benefits of targeted health screening in community pharmacy. Despite the existing health screening activity and service potential, there is no current national policy on implementation of health screening initiatives in community pharmacy, and this needs to be urgently addressed.
12. A national policy and strategy for maximising the use of vaccines, which takes account of the huge potential of the community pharmacy network, to improve patient outcomes and take pressure off other frontline services should be developed.

**Education and Training**

13. In order to achieve consistently high levels of service delivery, there is a need to provide conversion training and ongoing accreditation for pharmacists in areas such as chronic disease management, health screening etc. This accreditation and development of specialisations should be through the PSI and provided within the three Schools of Pharmacy.

**Proposed Governance and Implementation Framework**

14. The establishment of a Strategic Policy Advisory Group (SPAG) to examine the conclusions outlined in the Interim Report should be considered. This SPAG would be appointed by the Minister for Health and Children and be representative of all stakeholders. Proposed Terms of Reference for this group are attached in Appendix 1 to this document.
15. The Interim Report also proposes the establishment of a Resource Implementation Group (RIG) by the Minister for Health and Children, on the nomination of key service providers and regulators, to oversee the implementation of any initiatives over the next two to three years, having due regard to the constraints on resources available to the health system. Proposed Terms of Reference of this group are attached in Appendix 2 to this document. The RIG would report to the SPAG and the Minister for Health and Children on a regular basis on the implementation process.
16. The key responsibilities of the SPAG and RIG would be to evaluate the progress being made regarding the performance of pharmacy services, and their contribution to minimising the impact of bottlenecks currently of concern to senior decision and policy makers.
17. An implementation plan would need to be put in place by the RIG to co-ordinate the various initiatives. The working group believe that sections 1-5 of this Interim Report could be implemented immediately, and represent an opportunity for more cost effective delivery of care and treatment. They also represent a real opportunity to deliver some cost savings from the point of view of public and private service. However, further work is necessary to carry out sections 6-9 of this Interim Report which would require the reallocation of health service resources in both the public and private sector, and a lead time of up to 18 months would be necessary to implement these proposals.
18. The RIG should establish sub-groups consisting of stakeholders to develop a national policies on:
  - I. Chronic disease management.
  - II. Medication error reporting.
  - III. Pharmaceutical care.
  - IV. Medicines management.
  - V. Medication use review.
  - VI. The development of a national Minor Ailments Scheme.
  - VII. The development of national training programmes to address the requirement for additional skills development for currently registered pharmacists to implement the recommendations.

- VIII. Re-classification of medicines.
- IX. Prescribing competencies for pharmacists with prescriptive authority.
- X. The further utilisation of clinical pharmacy services in hospitals.
- XI. The delivery of vaccination and immunisation programmes through community pharmacy.

19. The RIG would be responsible for monitoring and reporting on the introduction of these schemes, and also monitoring them on an on-going basis, including undertaking a cost effective analysis and a pharmaco-economic assessment on an annual basis.

In order to facilitate the implementation of the initiatives proposed in the Interim Report, a strong partnership needs to be developed between service providers both public and private and the representative bodies of pharmacists in community and hospital. This Interim Report also deals with the resource implications and how best to implement the necessary changes in a structured and systematic way.

The PSI is strongly supportive of maintaining the highest possible standards of pharmacy practice in Ireland. The major beneficiaries of advancing pharmacy services and delivering value for money will be the patients, and the health service in general. The PSI is strongly of the view that the new direction for pharmacy service provision should be subjected to regular pharmaco-economic assessment and cost analysis.



## **Abbreviations**

ACE	Angiotensin-Converting Enzyme
ADA	American Diabetic Association
ADR	Adverse Drug Reaction
ADWE	Adverse Drug Withdrawal Event
AF	Atrial Fibrillation
AIDS	Acquired Immunodeficiency Syndrome
ARB	Angiotensin Receptor Blocker
BCSH	British Committee for Standards in Haematology
BNF	British National Formulary
CDAD	<i>Clostridium difficile</i> -Associated Disease
CDC	Centre for Disease Control and Prevention (US)
CHD	Coronary Heart Disease
CIBIS-II	Cardiac Insufficiency Bisoprolol Study II
CMP	Clinical Management Plan
CMS	Chronic Medication Service
CNS	Central Nervous System
CODEIRE	Cost of Treating Diabetes in Ireland Study
COPD	Chronic Obstructive Pulmonary Disease
CVA	Cerebral Vascular Accident
DM	Diabetes Mellitus
DOT	Directly Observed Therapy
DUMP	Disposal of Unwanted Medicines Campaign
DVT	Deep Vein Thrombosis
ENT	Ear, Nose and Throat
FDA	Food and Drug Administration (US)
FEV <sub>1</sub>	Forced Expiratory Volume
GMS	General Medical Services
GP	General Practitioner
GSL	General Sale
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HDL	High Density Lipoprotein
HIPE	Hospital In-Patient Enquiry
HIQA	Health Information Quality Authority
HIV	Human Immunodeficiency Virus
HPAI	Hospital Pharmacists Association of Ireland
HSE	Health Service Executive
ICCPE	Irish Centre for Continuing Pharmaceutical Education
ICGP	Irish College of General Practitioners
ICU	Intensive Care Unit
IDU	Injecting Drug User
IMB	Irish Medicines Board
IMMP	Intensive Medicines Monitoring Programme
INR	International Normalised Ratio
LDL	Low Density Lipid
MDR-TB	Multi-Drug Resistant Tuberculosis
MHRA	Medicines and Healthcare Regulatory Agency (UK)
MUR	Medicine Use Review
NEP	Needle Exchange Programme
NHS	National Health Service (UK)
NICE	National Institute for Health and Clinical Excellence (UK)

NIH	National Institute of Health (US)
NPSA	National Patient Safety Agency (UK)
NSAID	Non-Steroidal Anti-Inflammatory Drugs
NYHA	New York Heart Association
OECD	Organisation for Economic Co-operation and Development
OTC	Over the Counter
P	Pharmacy Medicine
PBS	PHO-Brent-Scharr (diabetes population prevalence model)
PCT	Primary Care Trust
PD	Parkinsons Disease
PDS	Prospective Diabetes Study
PE	Pulmonary Embolism
POM	Prescription Only Medicine
PPI	Proton Pump Inhibitor
PSI	Pharmaceutical Society of Ireland
RCGP	Royal College of General Practitioners
RIG	Resource Implementation Group
RPSGB	Royal Pharmaceutical Society of Great Britain
SPAG	Strategic Policy Advisory Group
TB	Tuberculosis
TCD	Trinity College Dublin
UCC	University College Cork
UK	United Kingdom
US	United States of America
WHO	World Health Organisation



## Appendices

# APPENDIX 1

## **Proposed Terms of Reference of the Strategic Policy Advisory Group**

1. To support the Resource Implementation Group with appropriate advice and guidance on the development of pharmacy care, practice and treatment in Ireland.
2. To advise the Resource Implementation Group on current and relevant evidence based pharmacy care, practice and treatment.
3. To think 'outside the box' - to innovate new services which could be performed by pharmacists for patient benefit, regardless of whether a model for such pharmacy based services exists anywhere in the world or not.
4. To consider and advise on the future impact of any new proposals in respect of pharmacy care, practice and treatment and to advise on how to implement such proposals in the most cost effective and efficient manner.

## APPENDIX 2

### **Proposed Terms of Reference of the Resource**

#### **Implementation Group**

1. To identify requirements for the early implementation of new pharmacy services in Ireland.
2. To specify the actions required to put in place an effective implementation process.
3. To propose a system of voluntary enrolment in the proposed new models of pharmacy care, practice and treatment.
4. To recommend appropriate investment and revenue models to support pharmacy care, practice and treatment, having due regard to resource constraints within the overall health service.
5. To identify the areas of academic practice and research that need development in Irish pharmacy.
6. To propose a governance framework including audit systems for the new services.
7. To advise and devise models for conversion training and joint training of key pharmacy personnel in all sectors of pharmacy.
8. To present regular updates on the implementation process to the Minister for Health and Children and other stakeholders.

## APPENDIX 3

### **Parties from whom written submissions were received**

1. Irish Pharmacy Union (IPU)
2. Irish Pharmaceutical Healthcare Association (IPHA)
3. ABA (An Bord Altranais)
4. PAA (Pharmaceutical Assistants Association)
5. Prof. Owen Corrigan, TCD (personal submission)
6. Diarmuid Coughlan, UCC (personal submission)
7. Fiona Ryan, UCC (personal submission)
8. Des Treacy, community pharmacist
9. Bernadette Flood, community pharmacist







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THE PHARMACY REGULATOR

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