DISCUSSION PAPER

NURSE PRESCRIBING IN SPECIALIST PALLIATIVE CARE

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This draft discussion document was prepared for the Working Group of the National Clinical Programme for Palliative Care by a sub-group of the working group, together with members of the Nurse and Midwife Medicinal Product Prescribing Team, and a practicing registered nurse prescriber working as a member of the specialist palliative care team in HSE West.

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1. Introduction

A working group has been established to review the current level of prescribing by Registered Nurse Prescribers (RNP) in specialist palliative care services and to explore the potential and possible barriers that may exist to full participation in prescribing. The need for this working group was identified by specialist palliative care (SPC) nurses including RNPs, who want nurse prescribing used to its maximum potential to benefit service users and to build capacity of RNPs within SPC services. This report will be submitted to the Clinical Lead of the National Clinical Programme for Palliative Care and the HSE Office of Nursing and Midwifery Services Director for review and action.

2. Background

Primary legislation was introduced in May 2006 to provide for prescriptive authority for nurses and midwives, with the necessary legislative amendments signed into law on May 1st 2007. The introduction of nurse and midwife medicinal product prescribing is underpinned by a twin-track approach encompassing amending the Irish legislation and the introduction of new professional nursing regulations (appendix 1). The *Irish Medicines Board (Miscellaneous Provision) Act 2006* and its associated regulations the *Misuse of Drugs (Amendment) Regulations 2007, Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007* and the *New Nurses Rules 2007* form the basis on which nurse and midwife prescribing evolved in 2007.

The regulations associated with the Act include:

- The nurse or midwife must be employed by a health service provider in a hospital, nursing home, clinic or other health service setting (including any case where the health service provider is delivered in a private home).
- The medicinal product is one that would be given in the usual course of service provided in the health service setting in which the nurse is employed.
- The prescription is issued in the usual course of the provision of that health service.
- The prescriber's Nursing and Midwifery Board of Ireland (NMBI) Personal Identification Number (PIN) must be inserted on all prescriptions.

Since the legislative amendments in 2007 the main focus has been on successfully implementing the initiative by supporting health service providers to introduce medicinal product prescribing. A national standardised framework has been developed to support this and ensure consistency across the HSE. This approach, coupled with ministerial commitment (a ministerial initiative) has contributed to the overall success of the introduction and implementation of nurse/midwife prescribing in Ireland.

The State Claims Agency Clinical Indemnity Scheme

The Clinical Indemnity Scheme (CIS) was established in July 2002 and is managed by the State Claims Agency. Under the scheme, the state assumes full responsibility for the indemnification and management of all clinical negligence claims against enterprises and practitioners covered by the scheme.

- In relation to nurse and midwife medicinal product prescribing, the CIS provides vicarious indemnity cover to all health practitioners providing professional services for and on behalf of the hospital/enterprise (i.e. Candidate/Registered Nurse/Midwife Prescribers, medical mentors, collaborating medical practitioners, pharmacists).
- Registered nurse prescribers are individually and professionally accountable to the NMBI and their employer for all decisions pertaining to their medicinal product prescribing practice.
- The State Claims Agency has issued a statement in relation to clinical indemnity in respect of nurse or midwife medicinal product prescribing in the public health services (see appendix 2).

The State Claims Agency has also issued a statement in respect of clinical indemnity in relation to unauthorised (exempt) and authorised medicines prescribed for an unauthorised indication (off label).

Collaborating medical practitioners or mentors who are General Practitioners are not covered by this scheme and therefore should inform their insuring body that they are supporting nurse or midwife medicinal product prescribing and that appropriate indemnity cover is in place.

3. Specialist Palliative Care Registered Nurse Prescriber

In order to become a RNP a nurse must have:

- Successfully completed a designated nurse and midwife medicinal product prescribing education programme.
- Registered with the Nursing and Midwifery Board of Ireland (NMBI).
- Have an agreed valid Collaborative Practice Agreement (CPA) in place (see appendix 4 and section 10 of this document).
- Participate in monitoring, audit and evaluation of their practice.

The six-month education programme for nurse/midwife medicinal product prescribing is provided in 7 Higher Education Institutions across the country, at a cost of \notin 3,000 per candidate. In order to undertake the education programme, the candidate must have appropriate clinical experience (three years recent, post registration in the past five years with the equivalent of one year full time experience in the specific area of practice).

The education programme is determined at Level 8 of the National Qualifications Authority of Ireland, consists of three core modules and one clinical practice module:

Core module 1: Professional Accountability in Nurse/Midwife Prescribing: Incorporates regulatory framework, legal, ethical, risk management and quality assurance issues, patient assessment, diagnosis and prescription writing and evidence based practice.

Core module 2: Pharmacology and Prescribing: Fundamental principles of clinical pharmacology, standard pharmacy, prescription and dispensing practice.

Core module 3: Systematic Assessment and Evaluation in Patient Care: Patient assessment, diagnosis and prescription writing. Evidence based practice.

Clinical Practice Module: Integration of theory and practice: 12 days (96 hours), requires medical mentor (consultant/GP).

SPC Nurse Prescribers may work in a variety of settings including the community, outpatient clinics, acute hospitals and specialist palliative care in-patient units and must:

- Practice in accordance with legislation and professional guidance.
- Practice within the limits of their own competence.
- Practice within the framework of professional accountability and responsibility.
- Conduct a systematic holistic assessment of the patients needs.
- Plan care in consultation with the patient taking interventions of the multidisciplinary team into consideration.
- Demonstrate and integrate knowledge of medicinal products for safe medication management and prescribing practice.
- Establish and maintain a caring therapeutic interpersonal relationship with service users and families.
- Collaborate with all relevant members of the health care team and document relevant information.
- Evaluate the patient's progress.
- Undertake audit and monitoring of prescribing in accordance with their CPA.
- Undertake continuing professional development.

4. Collaborating Medical Practitioner

The Collaborating Medical Practitioner(s) is the medical practitioner or group of medical practitioners with whom the RNP has a written CPA as part of the requirements to prescribe medicinal products within their scope of practice. The support of the collaborating Medical Practitioner is crucial to the implementation process (see appendix 5).

5. Scoping Exercise

Current situation

A total of thirteen nurses, either directly employed by SPC organisations or as part of a HSE Public Health Nursing team, have been funded to undertake the nurse/midwife prescribing education programme. Eight of the thirteen nurses are registered with the NMBI as RNPs and five are currently prescribing (see Table 1. for breakdown of HSE area, service, and numbers registered).

No	HSE Area	Area	Registered	Prescribing	Community	Acute Hosp	Hospice
			yes/no	yes/no			
1.	HSE West	Dept. of PHN Roscommon	Yes	Yes	1		
2.	HSE West	Roscommon General Hospital	Yes	Yes		1	
3.	HSE South	Cork University Hospital	Yes	No		1	
4.	HSE South (Tipperary)	Dept. Public Health Nursing	No	No	1		
5.	HSE South (Kerry)	Dept. Public Health Nursing Kerry	Yes	No	1		
6.	Dublin	St. Luke's Hospital	No	No		1	
7.	Dublin	St. James Hospital	Yes	No		1	
8.	Dublin SC	Our Lady's Hospice & Care Services	Yes	Yes			1
9.	Dublin SC	Our Lady's Hospice & Care Services	Yes	No			1
10.	Dublin ML	Dept. of PHN Laois /Offaly	Yes	Yes	1		
11.	Dublin ML	Dept. of PHN Laois /Offaly	Yes	Yes	1		
12.	Dublin ML	Dept. of PHN Laois /Offaly	No	No	1		
13.	Dublin ML	Dept. of PHN Laois/Offaly	No	No	1		

Table 1. Nurse prescribers and national sites

6. Facilitators and enablers of nurse prescribing within specialist palliative care

An independent survey was undertaken by UCD (Drennan et al, 2009) with the aim of addressing three key questions: 1) to evaluate nurse and midwife prescribing from a service perspective; 2) to evaluate the current and potential outcomes of nurse and midwife prescribing in terms of patient/client benefits, safety and satisfaction; 3) to take into account the views of key stakeholders, particularly employers, nurses and midwives, medical and pharmacy professions and the regulatory bodies. The evaluation involved key stakeholders including employers, nurses and midwives (prescribers and non-

prescribers), the medical and pharmacy professions, regulatory bodies, and patients and clients using an in-depth sampling process. Evaluation theory and methodology was used combining quantitative and qualitative research approaches.

The overall findings from the report indicated that the extension of prescriptive authority to nurses and midwives has been a positive development to the care they provide, to service users and their families and to enhancing the provision of holistic care. It has increased professional development in relation to better use of skills, greater autonomy and increased job satisfaction. There was a high level of support towards the introduction of nursing and midwifery prescribing by the majority of key stakeholder groups with general agreement that it has enhanced care and that it met the needs of service users. There was also general agreement that nurse and midwife prescribing was safe and that RNPs had the knowledge and capacity to prescribe correctly. This report is available on: http://www.hse.ie/eng/services/publications/Hospitals/prescribing initiative.pdf

The HSE website featured an acknowledgement of the review of the UCD Report acknowledging the success of phase 1 of nurse and midwifery prescribing and acknowledged the benefits to service users and staff across the healthcare system. In the HSE feature a number of acknowledgements were cited including one from Professor Seamus Cowman, Head of the School of Nursing at RCSI who commented "*The evaluation report identifies that Nurse and Midwife Prescribing has been a great success in terms of patient care access and efficiencies in health services. RCSI developed the first education programme in Nurse and Midwife Prescribing and I look forward to continuing to work with the HSE on this important project.*" available on:

http://www.hse.ie/eng/services/news/newsarchive/200920082007Archive/Oct_2009/nursep rescribingevaluation.html

In a recent Irish survey, Clinical Nurse/Midwife Specialists (CN/MS) who are RNPs have identified the introduction of nurse midwife medicinal product prescribing as overwhelmingly positive. They identified "enhanced patient care, timeliness, streamlining of services", and the opportunities for their own continuing professional development as the top benefits and efficiencies for them since they commenced prescribing of medicinal products. This survey was undertaken by Office of Nursing and Midwifery Services Director (2014) titled *Nurse and Midwife Medicinal Product Prescribing. Clinical Nurse/Midwife Specialist Registered Nurse Prescriber Survey.* It explored RPNs opinions on the benefits of prescriptive authority to CN/MSs, with a view to building capacity of nurse and midwife prescribing amongst this grade. This report is available on:

http://www.hse.ie/eng/about/Who/ONMSD/practicedevelopment/NursePrescribing/CNM S RNP Survey Report.pdf

Other positive drivers for nurse/midwife prescribing include:

- Positive national experience of nurse/midwife prescribing (as above)
- An educated knowledgeable SPC nurse workforce: SPC nurses have specialist knowledge, skills and education in accordance with their particular roles within

palliative care services. This knowledge can be further utilised through nurse prescribing.

- SPC nurses have developed collaborative working relationships with medical practitioners in their areas. This relationship can be further developed and enhanced through the nurse prescribing process and development of their CPA.
- Open communication where SPC nurses maintain close contact and liaison with the consultant, GP and community pharmacist, facilitating information transfer of medication alteration. The RNPs required communication process is outlined in their CPA.
- Enhances existing communication and collaboration systems and structures between consultant, GP, nurse, patient and his/her family.
- Enhance opportunities for service user and family education on correct medication management and administration.

7. Barriers to nurse prescribing

Both the UCD and ONMSD reports cite difficulties with gaining support for their participation in prescribing from a minority of professional key stakeholders even though it was acknowledged that nurse/midwife prescribing was safe and the education programme was comprehensive. Other difficulties that have since been encountered and that are specific to palliative care include the following:

- SPC services commonly adopt a collaborative model of care where their input is advisory to and supportive of the primary care provider (whether that be in the hospital or community setting). In most services, doctors provide advice on medication management to the Most Responsible Physician, rather than actually prescribing the medications themselves. Specialist palliative care physicians commonly only prescribe medications for patients who are admitted to SPC In-Patient Units. The prescribing role for SPC RNPs most commonly lies in acting as a bridging capacity to facilitate earlier access to medications to treat symptoms.
- RNP cannot prescribe unauthorised (exempt) medications. There remains lack of clarity regarding mixing of preparations for syringe drivers/pumps, and whether this combination constitutes a new unlicensed product e.g. the mixing of morphine sulphate and Midazolam. RNP cannot prescribe medications for subcutaneous delivery via a syringe driver/pump where there is more than one medication (please see appendix 3).
- SPC has a small cohort of nurses and challenges in recruiting candidates due to the increased responsibility and workload associated with nurse midwife prescribing have been encountered.
- Resistance to change and fears around impact on roles and relationships has been noted.

In view of the difficulties noted, the following good practice steps have been distilled from the experience of successful nurse prescribing sites.

^{8.} Good practice steps to consider before embarking on the process to introduce nurse prescribing

- 1. Identify the patient need for nurse prescribing by undertaking a service needs analysis. Without an identified patient need nurse prescribing will not be implemented successfully.
- 2. Key stakeholders (relevant medical consultants and general practitioners, relevant nursing leads, the prescribing site co-ordinator, representative of the Pharmacy Dept., Chair of Drugs and Therapeutics Committee and any palliative care nurses interested in prescribing) need to understand the process outlined in *A Guiding Framework for the Implementation of Nurse and Midwife Prescribing in Ireland.* Confirm the key stake holders commitment and on going support before proceeding.
- 3. Seek support from the Office of the Nursing and Midwifery Services Director (see table 2 for nurse leads in 4 HSE areas) and other specialist palliative care services who may have implemented nurse prescribing in a similar setting. Appendix 7 outlines material and processes developed by the ONMSD to support nurse/midwife prescribing.
- 4. Establish awareness of the resources/requirements necessary to introduce nurse prescribing
 - i. The development of a business case.
 - ii. The establishment of governance mechanisms e.g. access to a Drugs & Therapeutics Committee?
 - iii. Identification and confirmation of a mentor.
 - iv. Identification of a prescribing site co-ordinator (PSC).
 - v. Identification of appropriate nurse(s) to undertake the course.
 - vi. Consideration of the continuing professional development requirements.
 - vii. Access to organisational medication record (Kardex or prescription pad) or access to a GMS prescription pad for those working in community services.
 - viii. Access to the internet and IT equipment to comply with the data collection requirement (National Nurse and Midwife Prescribing Data Collection System).
- 5. Identify how nurse prescribing integrates with the model of palliative care delivery provided so as to benefit service users and complement the delivery of care between primary, secondary and tertiary services rather than detracting from, or undermining existing effective models of care. E.g. in community settings the bridging prescriptions enable patients to commence mediations, and then arrange to see their GP for consultation.

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Table 2. Nurse Prescriber Leads

9. The process to implementing nurse prescribing - from a specialist palliative care perspective

The structures, processes, education, regulations, auditing and monitoring of nurse/midwife prescribing has been extensively negotiated with all key stakeholders and are now in legislation. There are four stages to the implementation of nurse prescribing: Initiation, Planning, Implementation and Mainstreaming. Engagement and consensus is required with key stakeholders within the organisation in order to proceed through each stage. The four stages are guided by fifteen steps that ensure all requirements to the implementation of nurse/midwife prescribing are met.

Stage 1: Initiation

	Steps	Actions	Suggestions	Suggestions For Palliative Care Settings
TION	Step 1	Prepare to lead the development.Source documents.Share the information.	 NMBI http://www.nursingboard.ie HSE <u>http://www.hse.ie</u> Legislation. <u>http://www.nirishstatutebook.ie</u> Colleges http://www.rcsi.ie or http://www.ucc.ie 	Talk with Prescribing Team (ONMSD). Talk with other similar services that have gone through the process.
VILINI	Step 2	Initiate local discussions with key influencers and stake holders	 Relevant medical consultants/GPs Relevant members of the nursing Team- DoN, Potential Prescribing Site Co- ordinator Pharmacy Dept. D&TC Chair 	Available D&TC or access to one Or Does the service need to create one

Stage 2: Planning

	Steps	Actions	Suggestions	Suggestions for palliative care settings
PLANNING	Step 3	Undertake a service needs analysis.	 Reflective diary/gap. analysis/process maps. Focus groups/team meetings. Review key statistics/reports/service plan. Link with other services who have gone through the process. Assess readiness and capacity for prescribing. 	Use Prescribing Toolkit Needs Assessment document Role Delineation Framework E.g. in the case of community patients, nurse prescribing affords earlier access to medication by providing a bridging prescription until they get to their GP.
	Step 4	Prepare and discuss business case.	 Identify target clinical areas and required number of RNP's. Assess initial resource requirement. Identify deliverables for patient/family. Obtain a mandate to proceed from Senior Management. 	IT equipment and internet access, reference material.

	Step 5	Establish governance mechanisms.	• Define health service provider's requirement (outlined in the CPA).	Governance, communication, practice area etc.
	Step 6	Identify and confirm mentor(s).	Outline and agree commitment of mentor role.Agree communication with relevant colleagues.	
	Step 7	Identify a prescribing site coordinator.	 Responsibility may be delegated by the director. Liaison and lead role for the introduction of prescriptive authority for nurses and midwives. 	
	Step 8	Identify suitable and interested nurses/midwives who wish to undertake course and submit application to education establishment.	 Staff briefing sessions. Internal advertising of the course. Application form signed by the candidate, mentor & director. Site Declaration Form: signed by mentor and director. 	Ensure <u>everyone</u> is on board before moving forward.

Stage 3: Implementation

	Steps	Actions	Documents	What is required	Suggestions for palliative care settings
	Step 9	Six month education for prescriptive authority programme.	Collaborative Practice Agreement developed	Nurse Prescribing Policy developed	Use national policy and adapt it to the service
ITATION	Step 10	Successful completion of programme.	Medicinal products approved by Drug and Therapeutics Committee.	Approval of Nurse Prescribing Policy	
IMPLEMENTATION	Step 11	Registration with NMBI.	 Registration application form CPA Attachments A,B&C, Application fee 	Authorise Collaborative Practice Agreement	
	Step 12	Commencement letter.	Authorisation date to prescribe.	Provide a prescription pad to RNP	

Stage 4: Mainstreaming.

	Steps	Actions	Suggestions	Ongoing actions	Suggestions for
					palliative care settings
MAINSTREAMI NG	Step 13	Communicate to organisation.	 Brief MDT Update patient information leaflets. Update web information on service 	Annual review of Collaborative Practice Agreement.	Allows for change, review & reflection.

Step 14	Implement Monitor- Audit-Evaluate system as per national structure.	Information on all prescriptions input to the Nurse and Midwife Prescribing Data Collection System.	Quarterly audit RNP practice for 1 st year and then biannually	Chart & prescription audits, review of the RNP data NMPDCS
Step 15	Build capacity in SPC service according to identified need, identify nurses with interest in undertaking course, start at step 1.			

Adapted from Office of Nursing Director, HR Directorate, Health Service Executive (2008)

10. Safety and governance

The NMBI provides for the registration, control and education of nurses/midwives and for other matters relating to nurses/midwives and the practice of nursing/midwifery and sees its overall responsibility to be in the interest and protection of the public. Prescribing is an expansion of a nurse's/midwife's scope of practice, beyond the skills, competence and knowledge an individual practitioner possesses at the point of registration.

- The Requirements and Standards for the Education Programme for Nurses and Midwives with Prescriptive Authority (2007) define the competencies that must be attained through successful completion of the programme. Building upon these foundations are the remaining elements of the Board's framework, which are:
- The Decision-Making Framework for Nurse/Midwife Prescribing (2007) is a graphic representation of the structures and processes that should be in place for the nurse or midwife to prescribe. The diagram illustrates a rational step-by-step approach in which to consider the context and appropriateness of prescribing and the necessary clinical governance supports
- **The CPA** is a written agreement between the nurse, registered medical practitioner(s) and health service employer outlining the parameters of the prescriptive authority of the nurse.
- The Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority (2010). The professional responsibilities of the nurse's/midwife's prescriptive authority are addressed in the Practice Standards and should be viewed as the overarching mechanism with which a nurse/midwife is expected to practice.
 - **The Drugs & Therapeutics Committee** is responsible for reviewing Attachment B (listing of medications the RNP is proposing to prescribe) of the CPA.
 - Audit requirements are quarterly for the first year and then biannually. The audit responsibility is outlined in the CPA. The audit may include chart audits, review of the RNP's prescribing history from the National Data Collection System, review of the prescriptions, and review of information sent to the GP/Hospital doctor.

• Nurse Midwife Prescribing Data Collection System is the only national system for recording of prescriptions written. It assists audit, identify trends in prescribing, demonstrates CPA adherence.

11. Examples from practice

The following are two exemplars taken from two different practice settings which demonstrate the circumstances and communication processes used by registered nurse prescribers in palliative care services and a testimonial provided by a GP in HSE West who has experience of supporting nurse prescribing.

Exemplar 1 – Nurse led palliative care clinic

On Monday afternoon Mr X attended the nurse lead palliative care clinic for a breathlessness management programme. He had COPD stage 4 and had been referred by his respiratory team in the acute hospital. After the initial assessment the nurse had generated a letter to both the GP and the referrer explaining what the breathlessness management programme involved. The six week programme primarily focused on non pharmacological interventions to assist Mr X to better manage his breathlessness but if low dose opiates were indicated these would be considered. On week four of the programme the nurse introduced the concept of using Oramorph to ameliorate symptoms of breathlessness. Mr X was eager to trial it. His history was taken including drug allergies and adverse reactions, medication list reviewed and an examination was carried out. Mr X had no known drug allergies.

The RPN contacted the GP who agreed with this plan and agreed to the RNP prescribing the initial trial dose and a laxative to prevent constipation. Oramorph for breathlessness is an off label use of morphine. It had been passed by the Drugs & Therapeutics Committee for use in breathlessness and was on the RNP CPA. Mr X consented to the RNP writing the prescription. He was given the HSE Nurse Prescriber Patient Information Leaflet. The RPN went through the 'Oramorph for breathlessness' patient information leaflet (developed in conjunction with the hospice pharmacist) which explained why it is used, how much to use, how often, common side effects and the included RPN's contact details. It also addressed frequently asked questions. All of the above was recorded in the patient's healthcare record. The RPN wrote the prescription, one copy was given to the patient, one copy was faxed to the GP, one copy was filed in the patient's healthcare record and one remained in the RNP's prescription pad for audit purposes. The prescription was entered onto the Nurses Midwife Prescribing Data Collection System. He was advised to take a regular laxative and chose to use Senokot. The RNP telephoned Mr X on Wednesday to check how he was getting on. He found the Oramorph helped the sensation of breathlessness and helped him feel more relaxed, he was using it twice or three times a day. Mr X was reviewed the following Monday in the nurse led clinic. His GP was sent an update on the trial. Mr X saw his GP and he agreed to continue prescribing Oramorph 2.5mg prn for breathlessness.

Exemplar 2 – Community CNS SPC

Ms C is a 64 year old woman known to the specialist palliative care service. She was being treated by her oncology team for ovarian cancer with widespread retroperitoneal lymph node involvement. She had progression of her disease on recent scans. Ms C had been discharged from hospital the previous week on Morphine Sulphate tablet 5mg bd which maintained her comfort up to the few days prior to my visit. She needed to take Oramorph 2.5 mgs twice over night and had been requiring a total of three or four breakthrough doses in a 24 hour period, over the last two days.

On assessment Ms C described some 'discomfort' at rest in her left lower quadrant. She described her 'discomfort' as aching and throbbing in nature, 7 out of 10 in intensity, it lasted for 20 minutes or more, but when she took Oramorph it went away. The pain wasn't associated with any aggravating factors. On examination her colour was good; she had a large palpable mass that was tender to touch. Her bowel had opened well that morning. She described a regular daily bowel habit passing type 3 stools (Bristol Stool Scale) with comfort. No cramps. She experienced no nausea or vomiting. There were no signs of opiate toxicity.

I advised using a breakthrough of 2.5 mgs Oramorph for her discomfort, while I was there. She had a good response to the breakthrough after 20 minutes. As Ms C was well known to me I was aware of her sensitivity to opioids. She usually had a very good response to small doses of opioids. I discussed my assessment with the palliative care consultant and we agreed to increase to MST® 10mgs bd. I then contacted the patient's GP who concurred with this advice and was agreeable to my prescribing these medications as Ms C required a new prescription. I prescribed the morphine sulphate SR tablets and morphine sulphate liquid for breakthrough as we had discussed.

If I had not written the prescription Ms C's husband would have had to drive 15 miles to the doctors surgery, wait for the prescription and then drive another 10 miles to the pharmacy to fill the prescription. This would mean that Mr C would be away from the house a lot longer than he would like.

I followed up Ms C the next day. I assessed her pain/discomfort and her response to the increase in medications. She described feeling comfortable. Prescriptions were loaded into the minimum data set.

Testimonial from GP

My name is (name supplied to authors but withheld) and I am a GP in Co Roscommon. When I have patients with complex palliative care needs I generally refer to our local consultant-led specialist palliative care team. The specialist palliative care community team follow up my referrals with a visit to patients' homes and make recommendations regarding appropriate treatment/medication. After that if there are problems encountered when the homecare nurse is visiting she will often contact me from the patient's home and discuss medication options. At this stage I am happy for the nurse to issue a prescription on what we have agreed until the patient needs to renew their prescription which is then issued from the surgery.

Nurse prescribing is both convenient for patients and their family who are saved the inconvenience of travelling to the surgery and waiting for a prescription to be issued, and it is convenient for my practice as it avoids unnecessary delays and possible duplication. There are numerous cases that come to mind that reflect these positive points on palliative care nurse prescribing.

12. Key questions for discussion

Nurse/midwife prescribing has been proven to benefit service users and families as well as the healthcare service in general (ONMSD Report, 2014; Watson and Gethin, 2012; DoH&C, 2011; HSE, 2009; O'Connell et al, 2009; Naughton et al, 2009; Hall et al, 2006; Berry et al, 2006; Drennan et al, 2007, Bradbury and Nolan, 2007; Lockwood and Fealy, 2008; An Bord Altranais, 2005; Luker et al, 1998).

In the opinion of many nurses working in SPC, nurse prescribing offers opportunities within the SPC service delivery not alone to enhance services to individuals and their families, it also provides an opportunity to strengthen and develop working relationships between GPs, SPC teams, service users and their families. Therefore the key questions raised in this discussion paper are:

- 1. How do we progress nurse prescribing to its maximum capacity in SPC for the benefit of the service?
- 2. What are the required steps necessary in order to achieve this goal?

13. Proposed action plan

- Create a resource on the National Care Programme for Palliative Care website containing key documents and resources relating to nurse midwife medicinal product prescribing.
- Present the document to the national Clinical Advisory Group for their comments.
- Establish a forum to progress Nurse Prescribing within Specialist Palliative Care with the following suggested membership:
 - RNP representatives, PHN managed and SPC managed. (In PHN managed teams RNP in SPC are clinically accountable to the consultant).
 - Working group nursing representation
 - ONMSD prescribing team representation
 - Consultant in SPC representatives (representative of diversity in service areas)
 - GP representation
 - Pharmacy representative
 - Director of Nursing PHN representative
 - Director of Nursing SPC (inclusive of variations on services)
- Agree clear terms of reference and governance.

Next steps:

- Dissemination of document to programme working group for sign-off of draft document.
- Dissemination of document to programme stakeholder groups for consultation.
- Submission of document to National Clinical Lead and HSE Office of Nursing and Midwifery Services Director for consideration of action plan.

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LEGISLATION AND REGULATORY FRAMEWORK

Medicines Legislation for Nurse/Midwife Medicinal Product Prescribing

The primary legislation - *the Irish Medicines Board (Miscellaneous Provisions) Act*, 2006 - provides for amendments to medicines regulations by Ministerial order for nurses and midwives to prescribe medications. The Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations, 2007 (Statutory Instrument, (S.I.) No. 201 of 2007) and the Misuse of Drugs (Amendment) Regulations, 2007 (S.I. No. 200 of 2007) signed into law on May 1st 2007, specify the legislative requirements/conditions for prescribing of medicinal products by nurses and midwives.

A number of conditions must be satisfied for this authority. They are summarised as follows:

- 1. The nurse/midwife must be employed by a health service provider in a hospital, nursing home, clinic or other health service setting (including any case where the health service is provided in a private home).
- 2. The medicinal product is one that would be given in the usual course of service provided in the health service setting in which the nurse/midwife is employed.
- 3. The prescription is issued in the usual course of the provision of that health service.
- 4. Nursing and Midwifery Board of Ireland (NMBI) registration number (also known as the Personal Identification Number (PIN)) must be stated on the prescription.

In addition, the 2007 regulations allow a health service provider to determine further conditions for the prescriptive authority of the nurse or midwife. The prescribing of MDA-controlled drugs, is as detailed in the Misuse of Drugs (Amendment) Regulations, 2007 which stipulates conditions for establishing a new Schedule 8 and restrictions for prescribing Schedule 4 and 5 MDAs.

NMBI Regulatory Framework

The professional regulatory framework for nurse/midwife prescribing is established through the Nurses Rules, 2007, amended by the Nurses Rules 2010, which allows for the creation of a division of the Register for Nurse Prescribers. Subject to Rule 6, *the education and training required for admission to the Nurse Prescribers Division of the Register shall be in accordance with the requirements and standards set out by the Board for that purpose, in accordance with a curriculum approved by the Board and carried out in educational institution(s) and hospital(s) approved by the Board for that purpose.*

Before admission to the programme of education and training leading to registration in the Nurse Prescribers Division of the Register, the applicant's name must already be entered in the Register. The applicant must meet the entry requirements and standards set out by NMBI and he/she must comply with any conditions set out in legislation prevailing at the time. Current entry criteria to the education programme are three years recent post registration clinical experience in nursing/midwifery (this must be within the past 5 years) with the equivalent of one year full time experience in the specific area of practice as outlined by NMBI.

Registration

In order to register as a registered nurse prescriber, the nurse/midwife prescriber the nurse/midwife must meet the entry requirements and standards set out by NMBI. Only applicants who have successfully completed an education programme for Prescriptive Authority approved by NMBI, are presently employed and have an approved Collaborative Practice Agreement (CPA) with the health service employer may apply for registration in the Nurse Prescribers Division.

NMBI regulatory documents

- The *Requirements and Standards for the Education Programme for Nurses and Midwives with Prescriptive Authority,* (NMBI, 2007) which define the competencies that must be attained through *successful* completion of the programme.
- Decision-Making Framework for Nurse/Midwife Prescribing (2007)
- Collaborative Practice Agreement (CPA) (2012)
- Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority (2010)
- NMBI guidance documents:
 - Guidance to Nurses and Midwives on Medication Management (2007).
 - Recording Clinical Practice Guidance to Nurses and Midwives (2002).
 - Practice Standards for Midwives (2010).
 - The Code of Professional Conduct for each Nurse and Midwife (2000).
 - Scope of Nursing and Midwifery Practice Framework (2000).

CLINICAL INDEMNITY SCHEME

Clinical Indemnity Scheme



Nurse & Midwife Medicinal Product Prescribing

The Clinical Indemnity Scheme (CIS) was established in July 2002 and is managed by the State Claims Agency. Under the scheme, the State assumes full responsibility for the indemnification and management of all clinical negligence claims against enterprises and practitioners covered by the scheme. This includes the voluntary and statutory services of the Health Service Executive. For more information on which enterprises are covered by the scheme, please go to <u>www.stateclaims.ie</u>.

In relation to nurse and midwife medicinal product prescribing, the CIS provides vicarious indemnity cover to all health practitioners providing professional services for and on behalf of the hospital/enterprise (i.e. Candidate/Registered Nurse/Midwife Prescribers, medical mentors, collaborating medical practitioners, pharmacists).

CIS indemnity is provided in respect of a suit for personal injuries brought by a person alleging negligence, statutory or at common law, in respect of the provision of, or failure to provide, professional medical services. Such a suit may be against any health practitioner, in their role regarding nurse and midwife medicinal product prescribing, whether sued alone or together, arising from the prescribing of a drug or drugs by such a registered nurse/midwife prescriber. The CIS does **not** provide cover in respect of criminal matters i.e. where the Director of Public Prosecutions (DPP) directs criminal charges against a health practitioner.

The CIS does **not** provide representation for health practitioners in relation to fitness to practice issues. In that regard, the State Claims Agency advices health practitioners to purchase additional benefits cover, specifying cover in respect of criminal and fitness to practice matters, from their relevant defence organisations.

For any queries regarding this please contact info@stateclaims.ie

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AUTHORISED MEDICINAL PRODUCTS PRESCRIBED FOR AN UNAUTHORISED INDICATION

Authorised Medicinal Product prescribed for and Unauthorised Indication (formerly "Off-label"): the use of an authorised medication outside the terms of its product authorisation, e.g. use for an indication, dose, specific patient population or specific age group which is not specified in the authorised product authorisation / summary of product characteristics (SPC) (An Bord Altranais, 2010).

2.1 Prescribing of unauthorised medicinal products and authorised medicinal products prescribed for an unauthorised indication (off-label)

- 2.1.1 Unauthorised (unlicensed) medicinal products: *Medicinal Products* (Control of Placing on the Market) *Regulations* (2007-2010), provide statutory authority for a medical practitioner to treat a patient under his/her care, using unauthorised (unlicensed) medicinal products. This authority does not extend to registered nurse prescribers.
- 2.1.2 Authorised (licensed) medicinal products prescribed for an unauthorised indication ('off-label'): it is not prohibited in the relevant legislation and regulations for a registered nurse prescriber to issue a prescription for an authorised (licensed) medicinal product in respect of an unauthorised clinical indication (i.e. 'off-label' indication). This is in accordance with Regulation 5A of the *Medicinal Products (prescription and control of supply)* regulations, 2003 as amended. Registered nurse prescribers should give careful consideration to decisions to prescribe a medication for an unauthorised indication, particularly having regard to the clinical appropriateness of the 'off-label' use and whether an alternative product is authorised to treat that indication.
- **2.1.3** The registered nurse prescriber should be knowledgeable in relation to best practice for prescribing an authorised medication for an unauthorised indication. This includes determining:
 - if there is an alternative authorised (licensed) medication that could be prescribed
 - if the medication is regularly used to treat patient/client/service users in the registered nurse prescriber's area of clinical practice
 - that the listing of the specific medication is within the health service provider's prescribing formulary and/or guidelines
- 2.1.4 The registered nurse prescriber should refer to the document, *Medicinal Product Authorisation, Information and Frequently Asked Questions for Registered Nurse Prescribers* (Office of the Nursing and Midwifery Services Director, 2011) for further support, when including off-label medications on Attachment B of their Collaborative Practice Agreement. This can be downloaded from <u>http://www.hse.ie/go/nurseprescribing</u>.

The HSE has developed a template for the statutory and voluntary services of the HSE to assist decision making in authorising a registered nurse prescriber to prescribe an authorised medicinal product prescribed for an unauthorised indication (off label). The template can be downloaded from <u>http://www.hse.ie/go/nurseprescribing</u>

COLLABORATIVE PRACTICE AGREEMENT (CPA) FOR NURSES AND MIDWIVES WITH PRESCRIPTIVE AUTHORITY

A Collaborative Practice Agreement (CPA) is a written agreement between the nurse, registered medical practitioner(s) and health service employer outlining the parameters of the prescriptive authority of the nurse.

What is the purpose of a Collaborative Practice Agreement?

It serves as a mechanism to ensure that the communication and referral process have been established between the registered nurse prescriber (RNP) and the medical practitioner(s) regarding the care of their patients and agreed by the employer.

It defines the parameters of the RNP's scope of practice. Whilst recognising the responsibility of the medical practitioner to the patient, the individual nurse is accountable for her/his prescribing practice. This means that she/he is professionally accountable as an individual for her/his prescribing decisions. This encompasses the consultation and referral arrangements when a patient's care extends beyond the RNP's scope of practice.

It provides a template for the development, audit and evaluation of the RNP's prescribing practices within the health care setting.

The principles of professional accountability, responsibility, competence and clinical governance underpin the CPA.

The candidate nurse prescriber, collaborating medical practitioner(s) and the employer work together to establish the written agreement. Each health care organization may require additional input from the prescribing site co-ordinator, Drugs and Therapeutics Committee and/or others to assist with writing the CPA.

What should be included in the CPA?

The NMBI provides a specific Application Form to be used for the CPA. The Collaborative Practice Agreement for Nurses and Midwives with Prescriptive Authority (2012) gives detailed information on the CPA criteria required by the Board. Especially important is the information required on your practice setting, including the patient/client population and conditions for which you will be responsible for.

The CPA form and attachments should be on file and stored locally by the health service employer. The RNP keeps a copy. The NMBI has the authority to review a CPA of a RNP if so required and may request and examine any CPA (current and/or previous ones) of a RNP.

What is the process for reviewing and renewing a CPA?

Newly registered RNP must review and renew their CPA with in one year. Those registered for two years or more as a RNP are required to review and renew your CPA every two years. The CPA should be reviewed by the RNP in association with the collaborating medical practitioners and any other individuals as per the organization's policy on nurse prescribing.

A new CPA form should be completed if changes have been made to any of the attachments documents (A, B and/or C). New attachments should be drafted and includes as part of the CPA renewal documentation to be approved by the health service employer. The three attachments are as follows:

• Attachment A details the description of the practice setting and the specific clinical area of the RNP.

• Attachment B details the listing of specific medications (generic names) of the medications the RNP is competent to prescribe and authorised to prescribe as per the local Drugs and Therapeutics Committee. Off label prescribing of authorised medications outside the terms of its product authorisation should also be detailed within this attachment 1.

- Attachment C details:
- The description of the conditions, if any, that the health service provider has placed on the RNP's prescriptive authority i.e. cannot prescribe for patients under the age of 18 years.
- A description of the RNP's review and audit of her/his prescriptive practices. NMBI requires all newly RNPs to review and renew their initial CPA in one year's time and thereafter every two years. A registered nurse whose name is on the RNP Division of NMBI Register for two years or more is required to review and renew her/his CPA every two years. NMBI provides written notification.

ROLE OF COLLABORATING MEDICAL PRACTITIONER (FROM NATIONAL POLICY FOR NURSE MIDWIFE MEDICINAL PRODUCT PRESCRIBING, MARCH 2011)

Where the patient/client/service user cohort involves either one or a number of medical practitioners, the responsibilities of the Collaborating Medical Practitioner(s) are as follows:

- Support the introduction of nurse and midwife medicinal product prescribing.
- Be in agreement with the list of medicinal products named in the CPA and any conditions pertaining.
- Give their written approval/signature for the collaborative practice agreement.

Where a registered nurse prescriber has a collaborative practice agreement with a group GP practice, the lead GP in the practice may discuss nurse and midwife medicinal product prescribing with their colleagues and, with their approval, may sign on behalf of the practice. The lead GP has the responsibility to inform GPs/locums of the practice's commitment to nurse and midwife prescribing.

Where a registered nurse prescriber has a collaborative practice agreement with a number of medical practitioners, the lead practitioner may discuss nurse and midwife medicinal product prescribing with their colleagues and, with their approval, may sign on behalf of the others. The lead practitioner has the responsibility to inform the other practitioners/locums of the organisation's commitment to nurse and midwife medicinal product prescribing. A listing of all collaborating medical practitioners must be maintained by the health service provider.

The collaborating medical practitioner(s) should be aware of the professional regulatory and health service provider requirements for the registered nurse prescriber's continuing competence for maintaining medicinal product prescriptive authority.

The collaborating medical practitioner(s) will report any dispute with, or breach of, the CPA to the line manager and then to the Director or as per local policy.

Where possible, the collaborating medical practitioner(s) participate(s) in the monitoring and auditing of registered nurse prescriber's medicinal product prescribing practice.

MATERIAL AND PROCESSES DEVELOPED BY THE OFFICE OF THE NURSING AND MIDWIFERY SERVICES DIRECTOR TO SUPPORT THE INTRODUCTION OF THE NURSE PRESCRIBING

A Guiding Framework for the Implementation of Nurse and Midwife Prescribing in Ireland.

A National Nurse and Midwife Prescribing Minimum Dataset.

A web based Nurse and Midwife Prescribing Data Collection System.

A patient information leaflet: *Nurse and Midwife Prescribers How they Care for You* (Translated into Irish, French, Spanish, Chinese, Russian, Polish, and Arabic).

An electronic communication mechanism for ongoing support for Prescribing Site Coordinators entitled *Irish-PSC-eNetwork*.

An electronic communication mechanism for ongoing support for registered nurse prescribers entitled *Irish-RNP-eNetwork*.

Information on Application Guidelines for the Nurse and Midwife Prescribing Initiative National Policy for Nurse and Midwife Medicinal Product Prescribing.

A DVD Nurse and Midwife Prescribing: A prescription for practice.

Medicinal Product Authorisation: Information and Frequently Asked Questions for Registered Nurse Prescribers.

Information and Guidance on the Introduction of Nurse and Midwife Prescribing in General Practice.

Nurse Midwife Medicinal Product Prescribing Toolkit.

Nurse Midwife Medicinal Product Prescribing Clinical Nurse/Midwife Specialist Registered Nurse Prescriber Survey Report (ONMSD, 2014).

Suite of bi-annual lectures to nurses and midwives undertaking the education programme.

Bi-monthly and annual reports for all key stakeholders internal and external to the Health Service Executive.

Promotion of the initiative through media, journal articles, newsletters and national and international presentations.

Bi-annual Nurse Midwife Prescribing Conference.

National Clinical Programme for Palliative Care