

Report on

Nurse and Midwife Medicinal Product Prescribing Review of Existing Systems and Processes

Report prepared by:

Nursing and Midwifery Board of Ireland and Office of the Nursing and Midwifery Services Director Health Service Executive









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FOREWORD: PROFESSOR MARTIN BRADLEY

Commissioned by the Nursing and Midwifery Board of Ireland and the Office of the Nursing and Midwifery Services Director (Health Services Executive) we were asked to review the existing regulatory and implementation systems and processes to ensure that they were fit for purpose to support the development of nurse and midwife medicinal product prescribing.

As a result of that work a series of recommendations are made which if adopted will improve the uptake and retention of prescribers, reduce the burden of bureaucracy, strengthen and clarify the local governance and accountability arrangements and ultimately lead to a better utilisation of the skills of nurse and midwife prescribers. This will also require an enhancement of the current legislation.

It is notable that some of these issues have been the subject of review in previous years, in particular the legislative position and while a consensus between the professions and policy makers has been achieved progress on the required legislative change has not been forthcoming.

In relation to governance arrangements we were cognisant of the Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives (2014) and the recently updated Scope of Nursing and Midwifery Practice Framework (2015). These two seminal documents guide the individual's professional practice and accountability to the public and in conjunction with the programme of preparation for prescribing provide the framework for local governance. In turn the employer has a responsibility to ensure that the registrant is facilitated to apply the prescribing principles to their area of practice.

During our discussions the issue of remuneration for extended roles was raised. It was not within the remit of this review to address that area but it should be noted that it was an area of concern.

In summary, the benefits of non – medical prescribing have been consistently reported in the literature and the evidence suggests that as nurses and midwives take on new roles and responsibilities the authority and ability to prescribe has improved both the access to medicines and the timeliness of interventions for those seeking treatment. This is significant in relation to the modernisation and reform of services and provides greater scope for utilising the skills and resources of nurses and midwives particularly in the management of childbirth, chronic disease management, medicines management, mental health and palliative care.

We can expect further changes in professional roles and boundaries, with the introduction of new technologies and innovative treatments, a shift to more care in the community and at home and increasingly shared responsibility for the delivery of care from individuals to teams. These changes will be the hallmarks of a progressive and dynamic health care system and it is inevitable that more skilled self-care and self-management will be the only way to meet the inevitable increase in demand for health and care. The scope for competent and confident prescribers to deliver timely interventions will contribute greatly to these necessary developments.

Finally I would like to take this opportunity to thank the Advisory Group and all those who contributed so willingly to our consultation events. We were greatly aided by the professionalism, knowledge and expertise of our working group who so ably pulled together the recommendations and organised the consultation events.

On behalf of the Advisory Group I thank them – Kathleen Walsh, Clare MacGabhann and Annette Cuddy.

Professor Martin Bradley FRCN. FQNI.

Chair of the Advisory Group

Matin E. Prolley

EXECUTIVE SUMMARY

Background

The nurse midwife medicinal product prescribing initiative has been in place since 2007, and there are now 851 nurses and midwives registered with the Nursing and Midwifery Board of Ireland (NMBI) as Registered Nurse Prescribers (RNPs) (October 2015). A total of 1217 (June 2015) nurses and midwives from the voluntary and statutory services of the Health Service Executive (HSE) have been funded by the Office of the Nursing and Midwifery Services Director (ONMSD) to undertake the education programme. The candidate and RNPs are from 112 clinical specialties and 180 health service providers (49 acute hospitals, 124 community health organisation and 7 prison services). There are also 41 RNPs from private health service providers.

The nurse and midwife prescribing initiative has significant potential to contribute to the current restructuring of the health services. This includes further developing integrated services to ensure delivery of optimum care and cost effective outcomes in acute and community services. The introduction of this initiative continues to be a key priority for the ONMSD and forms a central component of government policy for the expansion of the nursing and midwifery role. The role of the nurse midwife prescriber is exercised in an interdependent system which recognises the expertise of the RNP and avails of the professional knowledge of medical, nursing and pharmacy colleagues.

Context

Since 2011, the number of applicants to undertake the education programme (provided by 5 higher education institutions) has been decreasing, as evidenced in the National Implementation Report on the Nurse and Midwife Medicinal Product Prescribing Initiative (June, 2015) (Appendix 1). Numerous factors have contributed to this decline, including:

- 1. The public service moratorium in place since 2008 resulting in no recruitment, no replacement of retired/resigned and allowing only mandatory training.
- 2. Regulatory requirements related to the Collaborative Practice Agreement (CPA) arrangements, including:
 - a. Requirement for annual and biannual review
 - b. Access to and role and function of Drugs and Therapeutics (D&T) committee for authorisation of Attachment B of CPA.
- 3. Requirements for inputting prescriptions into the *Nurse Midwife Prescribing Data Collection System* (HSE).

As a consequence of these factors, a collaborative approach was established between the NMBI and the ONMSD HSE to review the regulatory and implementation systems and processes.

Aim of Review

The aim was to review the existing regulatory and implementation systems and processes in place to support nurse and midwife medicinal product prescribing.

Advisory Group

To support this project, an advisory group and collaborative working group consisting of relevant key stakeholders was established. The collaborative working group reported to the advisory group.

This report presents the findings from the review.

Advisory Group Terms of Reference

An Advisory Group was established to advise on the review and to agree recommendations identified. Advisory Group Terms of Reference:

- 1. To review Collaborative Practice Agreement (CPA) Requirements, including:
 - a. Initial registration as Registered Nurse Prescriber [with NMBI]
 - b. Renewal and requirement for annual/biannual review of CPA.
- 2. To review requirement for authorisation of Attachment B of CPA (medicines listing) by Drugs and Therapeutics Committees.
- 3. To review current function and propose future role and function for Drugs and Therapeutics Committees specific to nurse midwife prescribing.
- 4. To explore HSE mandatory requirement for inputting of prescriptions into the *Nurse Midwife Prescribing Data Collection System*.
- 5. To explore extending prescriptive authority to Registered Nurse Prescribers to prescribe exempt (unauthorised) medicinal products.
- 6. To provide final report and recommendations to NMBI Board and ONMS Director for review and action as necessary.

Existing HSE Governance and NMBI Regulatory Framework

A robust framework is in place to support the introduction of nurse midwife prescribing nationally. This includes guidance from the NMBI and the ONMSD HSE prescribing team. A suite of supporting documents and structures has been provided by the NMBI and the ONMSD in this regard, ensuring good governance is maintained. This includes:

NMBI:

- Collaborative Practice Agreement for Nurses and Midwives with Prescriptive Authority 3rd edn (An Bord Altranais, 2012).
- Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority, 2nd edn (An Bord Altranais 2010)
- Requirements and Standards for Education Programmes for Nurses and Midwives with Prescriptive Authority (An Bord Altranais, 2007)

ONMSD:

• Guiding Framework for the Implementation of Nurse and Midwife Prescribing in Ireland (Office of the Nursing Services Director, 2008)

- Nurse and Midwife Medicinal Product Prescribing Application Guidelines for the Education Programme: Information for Health Service Providers, Nurses and Midwives and Mentors, 2nd edn (Office of the Nursing and Midwifery Services Director, 2011)
- Medicinal Product Authorisation Information and Frequently Asked Questions for Registered Nurse Prescribers (Office of the Nursing and Midwifery Services Director, 2011)
- Information and Guidance on the Introduction of Nurse and Midwife Medicinal Product Prescribing in General Practice (Office of the Nursing and Midwifery Services Director, 2011)
- Patient Information Leaflets, Adult and Children (Office of the Nursing Services Director, 2008: available at http://www.hse.ie/go/nurseprescribing)
- National Policy for Nurse and Midwife Medicinal Product Prescribing (Office of the Nursing and Midwifery Services Director, 2012)
- Nurse and Midwife Medicinal Product Prescribing: Toolkit for Implementation (Office of the Nursing and Midwifery Services Director, 2014)
- Continuing professional development initiatives for RNPs

In order to be accepted onto the education programme a signed Site Declaration Form must be submitted together with the application form to the relevant higher education institution. The purpose of the Site Declaration Form, which is signed by the Director of Nursing/Midwifery/Public Health Nursing/Services and the medical mentor, is to provide a firm commitment from the health service provider that the introduction of nurse midwife prescribing will be supported in their service. It identifies the essential criteria for site selection for the initiative.

The supporting structures and processes outlined above will be maintained and further enhanced following this review, to meet the future needs of this initiative. It is envisaged that the implementation of the recommendations of the review will result in a leaner, less cumbersome process into the future. The NMBI and the ONMSD HSE prescribing team will continue in their roles to support registrants and health service providers in the ongoing implementation of the initiative.

Recommendations

The Recommendations are based on the terms of reference of the Advisory Group and the findings of the various activities conducted by the Collaborative Working Group over the project lifetime. These activities included stakeholder meetings and interviews, workshop with Directors of Nursing/Midwifery/Public Health Nursing, a survey with RNPs and candidates and critical analysis of NMBI documents and review of relevant Irish research articles for nurse and midwife prescribing. The recommendations numbered 1 to 10 are linked to the specific term of reference. The accompanying rationale identifies the stakeholder with primary responsibility for implementation. Recommendations 11 to 14 are additional recommendations that emerged from the activities of the Collaborative Working Group.

Collaborative Practice agreement (CPA) for Nurses and Midwives with Prescriptive Authority [Key Findings: Section 3.2, page 18]

Recommendation 1: The CPA is retained as a governance tool which must be completed at the point of application for registration with NMBI as a Registered Nurse Prescriber (RNP).

ToR 1

Responsibility Recommendation 1: Nursing and Midwifery Board of Ireland (NMBI), HSE Office of Nursing and Midwifery Services Director (ONMSD, HSE) [Rationale: Section 3.3, page 19].

Recommendation 2: The governance for the ongoing review of RNP prescribing practices should be managed through local health service provider policy as directed by the NMBI and HSE. NMBI will continue to require the RNP to attest to having a valid CPA in the short term through individual communication and subsequently linked to the Annual Retention Notification, and in the future through the NMBI continued competency scheme for nurses and midwives. **The NMBI requirement and notification for annual and biannual CPA review will cease.**

Responsibility Recommendation 2: NMBI and local health service providers [Rationale: Section 3.3, page 19].

Recommendation 3: The CPA form should be maintained. However the NMBI should provide more clarity and guidance for the development of Attachments A, B and C.¹

ToR 1

Responsibility Recommendation 3: NMBI [Rationale: Section 3.3, page 20].

Authorisation of Attachment B of CPA by Drugs and Therapeutics (D&T) Committee [Key Findings: Section 4.2, page 21]

Recommendation 4: The Drugs and Therapeutics Committee is to review and advise on attachment B of the CPA and provide support to the DON/M/PHN who authorises the CPA on behalf of the health service provider. This reflects its advisory and supportive role with regard to nurse midwife medicinal product prescribing.

The framework in place for use of authorised medicines prescribed for unauthorised indications (off label) as currently established should be retained.

ToR 2

Responsibility Recommendation 4: NMBI, ONMSD HSE [Rationale: Section 5.3, page 24].

¹ 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 the RNP is authorised to prescribe Attachment C - details any conditions of the RNP's prescriptive authority and a description of the review and audit of prescriptive practices

Role and Function of Drugs and Therapeutics Committee

Recommendation 5: The D&T Committee or the relevant review group is provided with clear directions regarding its role and function specific to nurse midwife prescribing. This will provide for a national consistent standard involving a tripartheid approach from the Department of Health (DoH), healthcare regulation and HSE.

ToR 3

Responsibility Recommendation 5: ONMSD HSE, DoH, NMBI [Rationale: Section 5.3, page 24].

Revision of NMBI and HSE Guidance

Recommendation 6: In view of Recommendations 1-5 the NMBI should revise its professional guidance documents on prescriptive authority. The ONMSD should revise its National Policy for Nurse and Midwife Medicinal Product Prescribing (2012) and accompanying guidelines.

ToR 1, 2, 3

Responsibility Recommendation 6: NMBI and ONMSD HSE

HSE requirement to input prescriptions to Nurse Midwife Prescribing Data Collection System [Key Findings: Section 6.2, page 27]

Recommendation 7: Each health service provider should have an agreed schedule for routine audit of nurse midwife prescribing as part of its overall organisational audit programme for prescribing and medicines management. The Nurse Midwife Prescribing Data Collection System(NMPDCS) should continue to be available for local use as a support for monitoring and clinical audit of RNP prescribing practices. The HSE national mandatory requirement for RNPs to input their prescriptions into this system should be removed.

ToR 4

Responsibility Recommendation 7: ONMSD HSE and local health service providers [Rationale: Section 6.3, page 28]

Recommendation 8: The ONMSD HSE to engage with HSE ICT regarding the potential to further develop the NMPDCS to generate electronic prescriptions. This would be in collaboration with relevant stakeholders involved in eHealth strategy, such as DoH/HSE.

ToR 4

Responsibility Recommendation 8: ONMSD HSE [Rationale: Section 6.3, page 28].

RNP authority to prescribe exempt (unauthorised) medicines [Key Findings: Section 7.3, page 31]

Recommendation 9: The DoH to amend the legislative authority for RNPs to prescribe exempt (unauthorised) medicines and draft regulations to enable this. The health service provider should utilise the existing HSE and NMBI guidance frameworks for the use of medicines for unauthorised indication for managing the implementation of exempt (unauthorised) medicine prescribing by RNPs.

ToR 5

Responsibility Recommendation 9: DoH [Rationale: Section 7.4, page 32]

Additional Recommendations

Recommendation 10: Based upon findings of consultation activities regarding exempt and off label products, communication should be circulated to stakeholders regarding:

- **a.** The provision of information updates about exempt medicines and unauthorised indication medicine usage (off label).
- **b.** RNP use of Irish medicine references such as HPRA and the Irish Medicines Formulary vs reliance on UK sources (British National Formulary (BNF)).

ToR 5

Responsibility Recommendation 10: NMBI/ONMSD HSE [Rationale: Section 7.4, page 32]

Recommendation 11(a): NMBI to examine a process for competency assurance for addressing the current issue of long term candidate nurse prescribers (i.e. candidates who have successfully completed the education programmes but not yet registered as RNP).

Recommendation 11(b): NMBI to examine a process for competency assurance for addressing the current issue of RNPs who have not utilised their prescriptive authority, i.e. those returning from long term leave /maternity leave/career break etc.

Responsibility Recommendation 11: NMBI [Rationale: Section 8, page 33]

Recommendation 12: The Director of Nursing/Midwifery/Public Health Nursing/Services must have overall responsibility and authority for the governance of nurse midwife prescribing to ensure due diligence in their health service provider. This should be in collaboration with the Chief Executive Officer (group hospitals), Chief Officer (Community Health Organisations) or equivalent, Superintendent Pharmacist and Clinical Directors as appropriate.

Responsibility Recommendation 12: Directors of Nursing/Midwifery/Public Health Nursing/Services [Rationale: Section 8, page 33]

Conclusion

Since the introduction of nurse midwife prescribing in 2007 the NMBI, ONMSD HSE, health service providers, higher education institutions have worked together to forge a strong robust system of education, registration, regulation and governance to support the initiative. It is time to reconsider and reconfigure the "belt and braces" approach, introduced eight years ago for the commencement of nurse midwife prescribing. It should be acknowledged by stakeholders that health service providers have advanced their corporate and clinical governance, risk management, quality safety and audit structures and processes since 2007.

Value for money and skills utilisation is critical in maintaining a health service which has finite resources and infinite demand in the current Irish health economy. Nurses and midwives are ideally placed to deliver a more efficient service which supports early intervention of care, early discharge and management of patients in the community and indeed at home where possible. In a climate of increasing demand, nurses and midwives are expected to become more autonomous practitioners themselves.

In the future, as nurse midwife prescribing becomes more embedded in the Irish healthcare system and with the introduction of continued competency schemes by the NMBI, it may be applicable to transition the CPA criteria into the continued competency scheme.

Nurse midwife prescribing is uniquely suited to the current and future developments in the Irish healthcare system. In encouraging and supporting nurses and midwives to become RNPs, it is critical that the process is as lean and efficient as possible. This review has taken into account the experiences of the past seven years. It is anticipated that implementation of the recommendations will result in a more rationalised effective system and processes which will support the building of capacity of RNPs. Emphasis on the collaborative nature of this initiative among service providers and practitioners along with acknowledging individual and collective responsibility and accountability is a key message with these recommendations.

SECTION 1 INTRODUCTION

1.1 Background

The Report of the *Commission on Nursing: A Blueprint for the Future* (Government of Ireland, 1998) identified

"A needs to allow greater flexibility for nurses and midwives in the administration of non-prescribed drugs according to agreed protocols with medical practitioners" (page 37).

Three years later in 2001 the NMBI (formerly An Bord Altranais, (ABA)) with the National Council for the Professional Development of Nursing and Midwifery (NCNM) jointly conducted a project to review the prescribing and administration of medicinal products by nurses and midwives. The project included an examination of international developments in nursing and midwifery prescribing and a series of activities (as well as consultation) exploring the implementation of nurse midwife prescribing in Ireland. The Review summarised international research studies on nurse midwife prescribing, identifying numerous benefits for patients including:

- patient satisfaction
- appropriate safe prescribing
- convenience and greater accessibility for patients
- cost effectiveness
- improved patient compliance with medicines
- fewer pharmacological interventions considered
- nurses and midwives as providers of education
- appropriate clinical decision-making.

The project was completed in 2005 with the publication of The Review of Nurses and Midwives in the Prescribing and Administration of Medicinal Products (ABA and NCNM). The report contained five recommendations, with one stating that prescriptive authority be extended to nurses and midwives subject to regulation.

Subsequently legislation and associated regulation were enabled by the Government providing the legislative framework for nurse midwife prescribing.

The nurse midwife medicinal product prescribing initiative has been in place since 2007, and there are now 851 nurses and midwives registered with the Nursing and Midwifery Board of Ireland (NMBI) as Registered Nurse Prescribers (RNPs) (October 2015). A total of 1217 (June 2015) nurses and midwives from the voluntary and statutory services of the Health Service Executive (HSE) have been funded by the Office of the Nursing and Midwifery Services Director (ONMSD) to undertake the education programme. The candidate and RNPs are from 112 clinical specialties and 180 health service providers (49 acute hospitals, 124 community health organisation and 7 prison services). There are also 41 RNPs from private health service providers.

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1.2 Context

Since 2011, the number of applicants to undertake the education programme (provided by 5 higher education institutions) has been decreasing, as evidenced in the *National Implementation Report on the Nurse and Midwife Medicinal Product Prescribing Initiative* (June, 2015) (Appendix 1). Numerous factors have contributed to this decline, including:

- 1. The public service moratorium in place since 2008 resulting in no recruitment, no replacement of retired/resigned and allowing only mandatory training.
- 2. Regulatory requirements related to the Collaborative Practice Agreement arrangements, including:
 - a. Requirement for annual and biannual review
 - b. Access to and role and function of Drugs and Therapeutics (D&T) committee for authorisation of Attachment B of CPA
- 3. Requirements for inputting prescriptions to *Nurse Midwife Prescribing Data Collection System* (HSE).

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This report presents the findings from the review.

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 - a. Initial registration as Registered Nurse Prescriber [with NMBI]
 - b. Renewal and requirement for annual/biannual review of CPA.
- 2. To review requirement for authorisation of Attachment B of CPA (medicines listing) by Drugs and Therapeutics Committees.
- 3. To review current function and propose future role and function for Drugs and Therapeutics Committees specific to nurse midwife prescribing.
- 4. To explore HSE mandatory requirement for inputting of prescriptions to Nurse Midwife Prescribing Data Collection System.
- 5. To explore extending prescriptive authority to Registered Nurse Prescribers to prescribe exempt (unauthorised) medicinal products.
- 6. To provide final report and recommendations to NMBI Board and ONMS Director for review and action as necessary.

1.6 Existing HSE Governance and NMBI Regulatory Framework

A robust framework is in place to support the introduction of nurse midwife prescribing nationally. This includes guidance from the NMBI and the ONMSD HSE prescribing team. A suite of supporting documents and structures has been provided by the NMBI and ONMSD in this regard, ensuring good governance is maintained. This includes:

NMBI:

- Collaborative Practice Agreement for Nurses and Midwives with Prescriptive Authority 3rd edn (An Bord Altranais, 2012).
- Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority, 2nd edn (An Bord Altranais 2010)
- Requirements and Standards for Education Programmes for Nurses and Midwives with Prescriptive Authority (An Bord Altranais, 2007)

ONMSD:

- Guiding Framework for the Implementation of Nurse and Midwife Prescribing in Ireland (Office of the Nursing Services Director, 2008)
- Nurse and Midwife Medicinal Product Prescribing Application Guidelines for the Education Programme: Information for Health Service Providers, Nurses and Midwives and Mentors, 2nd edn (Office of the Nursing and Midwifery Services Director, 2011)

- Medicinal Product Authorisation Information and Frequently Asked Questions for Registered Nurse Prescribers (Office of the Nursing and Midwifery Services Director, 2011)
- Information and Guidance on the Introduction of Nurse and Midwife Medicinal Product Prescribing in General Practice (Office of the Nursing and Midwifery Services Director, 2011)
- Patient Information Leaflets, Adult and Children (Office of the Nursing Services Director, 2008: available at http://www.hse.ie/go/nurseprescribing)
- National Policy for Nurse and Midwife Medicinal Product Prescribing (Office of the Nursing and Midwifery Services Director, 2012)
- Nurse and Midwife Medicinal Product Prescribing: Toolkit for Implementation (Office of the Nursing and Midwifery Services Director, 2014)
- Continuing professional development initiatives for RNPs

In order to be accepted to the education programme a signed Site Declaration Form must be submitted together with the application form to the relevant higher education institution. The purpose of the Site Declaration Form, which is signed by the Director of Nursing/Midwifery/Public Health Nursing/Services and the medical mentor, is to provide a firm commitment from the health service provider that the introduction of nurse midwife prescribing will be supported in their service. It identifies the essential criteria for site selection for the initiative.

The supporting structures and processes outlined above will be largely maintained and further enhanced following this review, to meet the future needs of this initiative. It is envisaged that the implementation of the recommendations of the review will result in a leaner, less cumbersome process into the future. The NMBI and the ONMSD HSE prescribing team will continue in their roles to support registrants and health service providers in the ongoing implementation of the initiative.

SECTION 2 METHODOLOGY

2.0 Methodology

The Collaborative Working Group (composed of members of NMBI staff and members of the ONMSD HSE Prescribing team) employed a suite of qualitative and quantitative approaches for data collection with stakeholders. The approaches are outlined below as they correspond to the particular terms of reference. The stakeholders included RNPs, candidate RNPs, Prescribing Site Coordinators (PSC), Directors of Nursing, Midwifery, and Public Health Nursing/Services, HSE Medicines Management Programme, Drugs and Therapeutics Committee members.

Terms of Reference 1 to 4:

- Meetings with members of the Advisory Group and other stakeholders seeking their feedback (total number of meetings 8).
- Critique of NMBI CPA guidance from RNPs and PSCs.
- Communication from the ONMSD HSE prescribing team to HSE service providers to ascertain why
 certain identified candidates had not registered.
- Analysis of correspondence received from individuals and health service providers.
- Workshop held with Directors of Nursing/Midwifery/Public Health Nursing/Services seeking their views for each Term of Reference.
- Examination of registration issues was undertaken with the Registration Department of the NMBI, in particular regarding the processes for annual and biannual renewal of CPA.
- Content analysis of *Collaborative Practice Agreement Guidance for Nurses and Midwives with Prescriptive Authority* (NMBI, 2012) focusing on its terminology, language and clarity of instruction.
- SWOT (Strengths Weaknesses Opportunities Threats) analysis of CPA was undertaken (Appendix 4).
- Review of the medicines legislation authorising nurse midwife prescribing.

Term of Reference 5:

Following discussion with the Medicines Division Unit, the Chief Nursing Office, DoH and the HPRA, a survey was conducted with candidates/RNPs regarding their views on the authority to prescribe exempt (unauthorised) medicines including identification of specific exempt medicines.

In addition, the first 5 terms of reference were tested against the *Guiding Principles for Clinical Governance Development* (Health Service Executive, 2012). See Appendix 3 for the analysis by the Collaborative Working Group.

SECTION 3 COLLABORATIVE PRACTICE AGREEMENT (CPA) FOR NURSES AND MIDWIVES WITH PRESCRIPTIVE AUTHORITY

3.1 Introduction

The NMBI was charged by the Minister for Health and Children in 2006 with devising professional regulation and guidance to augment the medicines legislation authorising a nurse or midwife to prescribe medication. In fulfilment of this responsibility, the Collaborative Practice Agreement (CPA) was drafted. It is underpinned by the principles of professional accountability, responsibility, competence and clinical governance. Historically the CPA has been viewed as the critical building block of the professional regulatory framework for prescriptive authority for nurses and midwives. It has been a primary mechanism to ensure that good clinical governance structures are in place in the clinical setting and health service provider. This supports the RNP in the provision of safe and appropriate prescribing within his/her scope of practice. The CPA is a written agreement between RNP, registered medical practitioner and health service employer outlining the parameters of the scope of practice of the RNP.

The underlining principles of the CPA include:

- NMBI standard developed to ensure that the requirements as outlined in the medicines legislation
 are upheld and that clear lines of communication have been identified within the health care
 setting.
- Serves as a tool to ensure that communication structures have been established between the RNP
 and the medical practitioner regarding the care of their patients and agreed by the health service
 employer.
- Defines the parameters of the RNP's scope of practice. While recognising the responsibility of the
 medical practitioner to the patient, the individual RNP is accountable for their practice. This means
 that they are professionally accountable as an individual for their prescribing decisions. This
 encompasses the consultation and referral arrangements when a patient's care extends beyond
 the RNP's scope of practice.

The CPA is established with the agreement of the RNP, the medical practitioner/s and the health service employer outlining the parameters of the RNP's prescribing authority (i.e. her/his scope of practice). The document provides specific guidelines and criteria for the development and approval process of the CPA that were drawn from the review of the literature and international experiences.

The CPA form requires the RNP to declare how they have met the following criteria:

Attachment A:

A general description of the practice setting to include population and conditions for which the RNP has responsibility.

Attachment B:

A listing of the specific medicines (generic name) and/or categories of medications the RNP is authorised to prescribe as per the drugs and therapeutics committee.

Attachment C:

- 1) A description of the conditions, if any, the health service provider/employer has placed on the RNP's prescriptive authority
- 2) An outline of the requirements for the review and audit of RNP prescriptive practices. If a drugs and therapeutics committee is involved or needs to review either or both of these requirements, it should be noted.

3) If the registrant is intending to prescribe in other practice locations outside the primary health service provider or practice setting detailed, this information should be listed.

The NMBI requires all newly registered RNPs to review and renew their initial CPA after one year and every two years thereafter. The RNP registration details include the status of the CPA – valid or invalid. Invalid status of a CPA is a consequence of RNP termination of the CPA in the health service provider. The CPA status is accessible to the public on the NMBI website.

The RNP is required to notify the NMBI of the commencement of a CPA and of its termination. Because the CPA is directly linked to (1) the RNP's clinical practice area and (2) agreement with a named collaborating medical practitioner. Any changes to these two elements nullify the CPA.

The CPA and its relationship to the registration and clinical governance processes for nurse midwife prescribing have been included in the Advisory Group terms of reference because of various factors. These include:

- Time delays for the development and approval processes for the CPA
- Identification of the administrative burden on the RNP and health service provider for annual and biannual renewal process.
- Administration burden on NMBI with notifying and maintaining the CPA renewal process for the individual RNP the increasing number of RNPs.
- Identification of additional health service providers clinical governance structures for nurse midwife prescribing (e.g. health service provider policy)
- Stakeholder views are mixed regarding whether the CPA in its current form and criteria are overly
 prescriptive and restrictive, thus dissuading nurses and midwives from expanding their scope of
 practice to prescribing medicines.

3.2 Key Findings

- Risk of practising without a valid CPA may result in RNP working outside regulatory guidance.
- Time delays/resource intensiveness with regard to NMBI processing CPA renewal notifications and acknowledgements.
- Delay and time consuming process for annual and biannual revalidation.
- Word "authorise" for Attachment B and interpretation of this has caused confusion with some Drugs and Therapeutics Committees.
- Overall the CPA provides good governance for the RNP's parameters and scope of practice. Enables collaborative working and outlines communication process.
- No legislative requirement for CPA.
- Feedback was received regarding the requirement for multiple collaborating medical practitioner signatures on the Collaborative Practice Agreement, particularly in certain community areas, for example public health nursing. In some urban areas there may be up to 40 GPs collaborating with the RNP.

3.3 Recommendations

Recommendation 1: The CPA is retained as a governance tool which must be completed at the point of application for registration with NMBI as a Registered Nurse Prescriber (RNP).

Rationale: The CPA provides good governance for the RNP's parameters and scope of practice. It enables collaborative working with the multidisciplinary team and outlines the communication process between the RNP and collaborating medical practitioner(s). Feedback from the DON/M/PHN/Services workshop supported the continued use of the CPA as the primary governance tool for health service providers. As part of this recommendation, consideration will be given to areas where multiple medical practitioner signatures are required, in particular in certain community health organisations.

Responsibility Recommendation 1: NMBI, ONMSD HSE.

Recommendation 2: The governance for the ongoing review of RNP prescribing practices should be managed through local health service provider policy as directed by the NMBI and HSE. NMBI will continue to require the RNP to attest to having a valid CPA in the short term through individual communication and subsequently linked to the Annual Retention Notification, and in the future through the NMBI continued competency scheme for nurses and midwives. The NMBI requirement and notification for annual and biannual CPA review will cease.

TOR 1

Rationale: Overall the CPA provides good governance for the RNP's parameters and scope of practice. It enables collaborative working and outlines communication processes. However, the current requirement from NMBI for the annual review of newly registered RNPs, followed by subsequent biannual review is viewed as time consuming for the RNPs and health service providers. As a result of delays in processing the CPA through the approval channels locally a CPA may be invalidated. The CPA renewal notification and updating processes are resource intensive for the regulator. Feedback from stakeholders identified that there is minimal change of the RNP's CPA from year to year, with most changes relating to the addition of medicines (Attachment B). These additions are best addressed at health service provider level.

Responsibility Recommendation 2: NMBI and health service provider



Recommendation 3: The CPA form should be maintained. However, the NMBI should provide more clarity and guidance for the development of Attachments A, B and C.²

Rationale: Local health service providers have sought direction from the NMBI and the ONMSD for developing the CPA attachments. While the nurse midwife prescribing initiative may be well established in numerous health service providers there are some introducing prescribing for the first time. Providing clarity on the criteria for the CPA attachments may assist in expediting the development and approval process at health service provider level. It may also facilitate monitoring and audit of prescriptive practices within the health service provider.

Responsibility Recommendation 3: NMBI

² 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 the RNP is authorised to prescribe Attachment C - details any conditions of the RNP's prescriptive authority and a description of the review and audit of prescriptive practices

SECTION 4 AUTHORISATION OF ATTACHMENT B OF CPA BY DRUGS AND THERAPEUTICS COMMITTEE

4.1 Introduction

NMBI regulation states that "Attachment B of the CPA details the listing of specific medicines the RNP is competent to prescribe as per the local D&T committee". HSE Policy states "The Drugs and Therapeutics committee is responsible for reviewing and approving the medicinal product listing (Attachment B of CPA) put forward by the candidate nurse prescriber/RNP and the Collaborating Medical Practitioner/s.

4.2 Key Findings

- There has been wide disparity in local D&T interpretation of their role and function relating to authorisation of CPA. Some Committees review Attachments A and C of CPA for clarity and context.
 Other Committees approve Attachments A and C which has led to long delays in registering as a RNP in some health service providers.
- One stakeholder suggested developing a national formulary for all RNPs, with individual CPAs referring to those medicines on that list that would be relevant to their clinical area of practice.
- One stakeholder commented that there was a perception that "the CPA provides a model for doctors to permit prescribing".
- There is no legislative basis for the CPA.
- There is a risk associated with timeframe for registration following successful completion of the education programme. This could be managed through Chief Executive Office/ Director of Nursing/Midwifery/Public Health Nursing/Services.
- It may be beneficial to establish a national advisory group which would sit within the Medicines Management Programme which would sign off medicines from a nationally approved formulary. Refer to D&T for nonstandard, exempt medicines only.
- Develop a standardised list of medicines for each speciality in collaboration with national clinical programmes.
- Feedback from PSCs and D&T representatives indicated that the standard of some CPA documentation was not of high quality, for example issues with dosage, typing errors etc.
- There is a requirement for a more local health service provider process with rigorous local guidance.
- Many RNPs refer to British National Formulary rather than Health Products Regulatory Authority or Irish Medicines Formulary.
- There should be well defined governance arrangements in place to support nurse midwife prescribing.

4.3 Recommendations

Recommendation 4: The D&T Committee is to review and advise on attachment B of the CPA and provide support to the DON/M/PHN who authorises the CPA on behalf of the health service provider. This reflects its advisory and supportive role with regard to nurse midwife prescribing.

The framework in place for use of authorised medicines prescribed for unauthorised indications (off label) as currently established should be retained.

Rationale and responsibility: Recommendation 4: See page 24

SECTION 5 ROLE OF DRUGS AND THERAPEUTICS COMMITTEE SPECIFIC TO NURSE MIDWIFE MEDICINAL PRODUCT PRESCRIBING

5.1 Introduction

Following the introduction of nurse midwife medicinal product prescribing in Ireland, there was a significant increase in the establishment or reestablishment of D&T committees across the country. Health service providers must have access to such a committee to ensure the appropriate and safe introduction and implementation of nurse midwife prescribing. The role of D&T committees was initially laid out in the Department of Health Circular 8/93 (Department of Health, 1993):

"The D&T committee is a multidisciplinary advisory committee. The committee can provide expert advice and guidance to hospital or community based staff on matters pertaining to the use of medicinal products, thus ensuring that prescribing and administration of medicines are carried out in a safe and cost effective manner".

In terms of nurse midwife prescribing, the D&T Committee is currently responsible for reviewing and approving the Collaborative Practice Agreement (CPA) medicinal product listing (attachment B of CPA) put forward by the candidate/RNP. The Site Declaration Form³ requires confirmation that this list will be submitted by the candidate to the D&T committee within 3 months of completion of the relevant education programme.

It is not required for the D&T committee to review attachments A and C of the CPA. However, these attachments may be requested by some Committees for clarity and context.

There is wide disparity in the interpretation of the role and function of D&T committees relating to nurse midwife prescribing. This may be due to the wording contained in NMBI regulation and the National Nurse Midwife Medicinal Product Prescribing Policy (HSE, 2012), together with the lack of national templates for Attachments A, B and C of the CPA. Examples of varied roles include:

- A review group to only review CPA with specific Terms of Reference for this.
- Clinical Director signs CPA on behalf of Collaborating Medical Practitioners.
- Regional primary care D&T committee that reviews CPAs from candidates/RNPs working in primary, community and continuing care.
- D&T committee in acute setting that supports review of CPA from CHO.
- Subcommittee that manages review of Attachment B and recommends approval or not to D&T committee.
- One D&T committee requires a medication protocol for each medicine on the CPA.
- Some Committees review CPA forensically and approve Attachments A, B and C of CPA.
- One D&T committee only allows 10 medicines to be included on Attachment B regardless of scope of practice or clinical area.

³ Site Declaration Form completed by DON/M/PHN/SERVICES and medical mentor, confirming governance and support for each candidate prior to undertaking education programme. Candidate not accepted on programme without it.

5.2 Key Findings

- Lack of consistency/standardisation has led to long delays in approval in some health service providers.
- Establishment of hospital groups and Community Healthcare Organisations has resulted in delays in some areas as local Committees are disbanded and RNPs must access group hospital Committee.
- Lack of understanding of governance requirements to support nurse midwife prescribing.
- Long delays caused by repeated cancellation and/or deferral of meetings or disbanding of local D&T committee meetings.
- Support of D&T committees is crucial to the initiative. However, in some instances this is labour intensive and time consuming for the Committee, and cumbersome and frustrating for the candidate/RNP.
- Overall governance and management lies with employer/Director of Nursing/Midwifery/Public Health/Services, not with the D&T committee.

5.3 Recommendations

Recommendation 5: The D&T Committee or the relevant review group is provided with clear directions regarding its role and function specific to nurse midwife prescribing. This will provide for a national consistent standard involving a tripartheid approach from the DoH, healthcare regulation and HSE.

Rationale for Recommendations 4 and 5:

The CPA should be developed and agreed by collaborating medical practitioner/s, candidate/registered nurse prescriber and senior nursing and midwifery management. Attachment B list of medicines should also be reviewed and discussed with pharmacy department personnel/pharmacist. Attachment B should then be forwarded to the D&T committee or the relevant review group for information purposes. Any additions to Attachment B by RNP should follow the same process.

There are inordinate time delays for CPA approval and subsequent application for registration due to D&T Committee's role and involvement for authorising/approving Attachment B. Participants at the DON/M/PHN/Services workshop described the barriers and challenges for progressing the CPA for D&T review and authorisation. There may be delays of months for D&T meetings to review CPAs submitted. In some cases this has extended to over a year because a Committee has not convened. Some D&T Committees have extended its remit to approving the complete CPA, requiring the candidate RNP to resubmit their CPA because of required changes mandated by the D&T Committee.

The value of pharmacy and specialist input to the development of the CPA is acknowledged by stakeholders. However the process should be managed by the key participants as per Recommendation 4.

The completed CPA is approved by Director of Nursing/Midwifery/Public health Nursing/Services on behalf of the employer. The notification of an approved CPA is submitted to the NMBI as part of the application to register as a RNP.

The D&T Committee's expertise in the use of authorised medicines prescribed for unauthorised indications is recognised as best practice in the local governance regarding these medicines. Stakeholders signified the importance of the Committee in this area of prescriptive authority.

Responsibility Recommendation 4 and 5: DoH, HSE, healthcare regulation

Recommendation 6: In view of Recommendations 1-5 the NMBI should revise its professional guidance documents on prescriptive authority. The ONMSD should revise its *National Policy for Nurse and Midwife Medicinal Product Prescribing* (2012) and accompanying guidelines.

Responsibility Recommendation 6: NMBI and ONMSD, HSE

SECTION 6 HSE REQUIREMENT TO INPUT PRESCRIPTIONS TO NURSE MIDWIFE PRESCRIBING DATA COLLECTION SYSTEM (NMPDSC)

6.1 Introduction

The Nurse Midwife Prescribing Data Collection System (NMPDCS) is a web-based National Nurse and Midwife Prescribing Minimum Dataset which was established, at the request of the Department of Health, to record and monitor RNP prescribing activity across the country and to allow for an evaluation of the initiative within two years. A web-based system for data collection is used, with reports from the system demonstrating the activity of registered nurse prescribers in Ireland.

Following feedback from health service providers, a *Review of the Nurse Midwife Prescribing Data Collection System* was undertaken in 2013. The purpose of the review was to:

- Provide RNPs with an opportunity to identify the benefits and challenges of using the Nurse Midwife Prescribing Data Collection System.
- Assess compliance and non-compliance with use of the System.
- Identify modifications/improvements to make the system more user-friendly.

Overall, there were strong opinions expressed regarding the NMPDCS, regarding both benefits and challenges. While the System was regarded by some as being user friendly and of benefit to themselves and/or their organisation, others felt it had outlived its use and could not see the benefit of maintaining the System.

The main challenge appeared to be regarding the time consuming and cumbersome task of inputting the data into the System. This involved duplication or quadruplicating of recording prescribing activity. The time issue was identified as time away from patient care and clinical work, which was perceived to affect the organisation as a whole, particularly where the numbers of RNPs were high.

However, a number of RNPs requested the System remain as it stands. Interestingly, some Practice Nurses, who do not have access to the system, requested access. Most of the respondents identified the need for some modifications to the System.

The original purpose of the NMPDCS was to "allow for each individual nurse/midwife prescriber to report on the number of prescriptions written by them, and for what principle clinical indication, over a two year review period". It was recognised at the time that many organisations did not have the IT structures and processes to conduct this monitoring; hence a System was developed to collect the information. This is still the case.

It is noteworthy that a number of RNPs, whether positive or negative about the System, identified the risk of incorrect reporting at all levels of the organisation, due to some individuals not inputting at all, and the risk of inaccurate inputting. Again the most commonly cited reason for not inputting to the System was time constraints.

It was evident that the Reports section of the System is not widely used, and there appears to be a knowledge deficit surrounding this aspect. This contributed to the perception of time constraints and task orientation associated with inputting the information. Some senior nursing managers do not request any NMPDCS reports from the RNPs. This may be due to lack of awareness or understanding of the reporting functions of the System.

RNPs who only input into the System could see no benefit for themselves, the organisation or nationally. It was viewed mainly as a task with no tangible outcomes.

One of the positive findings was the use of the System as part of the audit process. This was found to be of benefit across all levels of the organisation including site visits from the Nursing and Midwifery Board of Ireland.

All of the recommended modifications have been actioned and the System is now faster and more user friendly. However, some RNPs continue to question the mandatory requirement to input prescriptions into the System. Anecdotal feedback suggests that this may be a deterrent to becoming a Registered Nurse Prescriber.

6.2 Key Findings

- The requirement to input prescriptions results in duplication of RNP workload and sometimes triplication. Other prescribers are not required to do this.
- The System is a useful tool to support audit and identify outcomes, eg timely intervention/more efficient service delivery.
- RNPs are not prescribing because of the extra workload. It takes less time to refer to medical colleagues.
- Meeting with HIQA:
 - o Recommended to retain mandatory requirement as the removal would be of no benefit to consistency of reporting at national level. Only the "champions" will continue to use it.
 - o Provide protected time for the RNP to facilitate inputting in to the System.
 - o Explore option to pilot the use of electronically generated prescriptions.
 - o Administrative support to input prescriptions.
- Meeting with Primary Care Team: Demonstration of new workload management system developed for Primary Care Teams.
- ICT systems: There are many ICT systems in development for different services. Currently there is not a national electronic healthcare record.
- Local health service providers should have well defined mechanisms for capturing all prescriptions written and reporting of prescribing activity by all healthcare professionals authorised to prescribe.

Following consultation with Dr Edwina Dunne, Assistant National Director Quality Assurance Verification, Head of Quality and Risk at Health Service Executive, regarding the value and worth of the NMPDCS, the following key questions for consideration were posed:

- What is the rationale for maintaining the NMPDCS?
- Can information from the System be linked to demonstrate a patient outcome and be of benefit to the RNP?
- Does it take time away from essential patient care?
- What is the worth of the System?
- There is a risk of the HSE being exposed due to their knowledge of the noncompliance with the mandatory requirement for RNPs to input prescriptions to the System.

6.3 Recommendations

Recommendation 7: Each health service provider should have an agreed schedule for routine audit of nurse midwife prescribing as part of its overall organisational audit programme for prescribing and medication management. The NMPDCS should continue to be available for local use as a support for monitoring and clinical audit of RNP prescribing practice. **The HSE national mandatory requirement for RNPs to input their prescriptions into this System should be removed.**

Rationale: Stakeholders have identified that the mandatory requirement for RNP inputting of all prescriptions onto the NMPDCS is seen as a deterrent for some RNPs to prescribe because of the time and effort needed to retrospectively enter the data. The higher education institutions and nursing and midwifery management have communicated that nurses and midwives are hesitant to apply for the nurse midwife prescribing course as a consequence of this policy direction. Because not all RNPs in HSE services are compliant with this requirement the value of the System and reports generated at local and national levels is not realised. It does not capture real time prescribing in the organisations. Noncompliance is a serious risk management concern for health service providers, RNPs and the ONMSD HSE. Some organisations fully utilise the NMPDCS and generate reports as part of their quality and safety systems for prescribing and should continue to be supported with the System.

Local health service providers should have well defined mechanisms for capturing all prescriptions written and reporting of prescribing activity by all healthcare professionals authorised to prescribe. The Nurse Midwife Prescribing Minimum Dataset could be used to support this.

Responsibility Recommendation 7: ONMSD HSE and local health service providers.

Recommendation 8: The ONMSD HSE to engage with HSE ICT regarding the potential to further develop the NMPDCS to generate electronic prescriptions. This would be in collaboration with relevant stakeholders involved in eHealth strategy, such as DoH/HSE.

Rationale: The NMPDCS contains all the elements required for inputting and detailing of prescriptions. Another significant advantage is that the System is web-based. Thus it could be adapted as it eliminates the possible requirement for reconfiguring ICT systems across the HSE. The System has the potential to be further developed to generate electronic prescriptions.

Responsibility Recommendation 8: ONMSD HSE

SECTION 7 AUTHORITY FOR REGISTERED NURSE PRESCRIBERS TO PRESCRIBE EXEMPT (UNAUTHORISED) MEDICINES

7.1 Introduction

Evaluation of the extension of prescriptive authority to nurses and midwives has been positive both on the impact that it has had on patient care and also on the professional development of nurses and midwives. The National Independent Evaluation of the Nurse and Midwife Prescribing Initiative (Drennan et al, 2009), demonstrated that the model for nurse midwife prescribing for Ireland was safe and effective. One of the recommendations of the evaluation related to unauthorised medicines:

"Nurses and midwives should be enabled to prescribe unauthorised medications once they come within their scope of practice and nurse/midwife prescribers are cognisant of best practice in the prescribing of unauthorised medications" (page 101).

One concern consistently expressed by RNPs is the compromise of care for patients as a result of this challenge as care is not being delivered according to best practice and research. For example, a Registered Advanced Nurse Practitioner (RANP) who is also a RNP uses his/her skills to assess the patient, determine the best and safest course of treatment, including prescribing of medicinal products, and then must request a medical practitioner to prescribe the unauthorised medicine. This has safety issues and the right to timely care for that patient, as quoted by one RANP/RNP:

"Having authority to prescribe some drugs and not others in neonatal formularies is frustrating for ANPs and probably not safe for patients as the ANP who needs to prescribe an unauthorised medication for a patient in her caseload has to seek out a doctor and ask them to write a prescription for a baby the RANP has examined and diagnosed".

Schedule 1 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 includes an exemption for medical practitioners to prescribe exempt (unauthorised) medicinal products for individual patients under their direct responsibility, in order to fulfil the special needs of those patients. A RNP may not prescribe an exempt (unauthorised) medicinal product. This anomaly prevents the provision of optimum patient care to patients/clients by RNPs. For the purposes of quality and patient safety the prescribing of exempt (unauthorised) medicines should be consistent for all prescribers, regardless of profession. The same set of principles should apply to all. Under current legislation restrictions, RNPs are at risk of inadvertently prescribing medicinal products that have become exempt (unauthorised) and therefore prescribing against legislation and regulation.

The State Claims Agency Clinical Indemnity Scheme (CIS) has issued the following statement: "CIS cover applies equally to the prescription/use of licensed and unauthorised medicinal products (including the off-license use of medicinal products) providing the latter is issued with the express knowledge and consent of the enterprises management".

The increased shortages of licensed medicinal products globally, identified and regularly discussed at the Medication Safety Forum (2013), will necessitate the increasing use of exempt (unauthorised) alternatives into the future, further compounding the problem faced by RNPs.

RNPs have also requested clarity regarding:

- The prescribing by a RNP of an authorised, generic medicinal product, and subsequently an exempt (unauthorised) medicinal product is dispensed/supplied by hospital pharmacy.
- An RNP may prescribe IV Ampicillin (Penbriten®) which is licensed however an alternative brand which is not licensed (Pentrexyl®) may be dispensed/supplied.

- The prescribing of compounded and/or combined medicinal products. Currently there is ambiguity
 regarding the licensing status of these products. It is the understanding of clinical pharmacists and
 RNPs that authorised medicines, once combined or compounded into a single infusion for
 administration, become exempt (unauthorised). This includes some Schedule 8 drugs.
- The combining of medicinal products such as morphine sulphate, metoclopramide and midazolam in a single infusion is common practice in palliative care.

In the United Kingdom, legislation was amended in 2009 to allow nurse and midwife independent prescribers prescribe exempt (unauthorised) medicinal products for those in their care, on the same basis as doctors, dentists and supplementary prescribers. This approach could be considered in Ireland bearing in mind that a RNP must always work within their scope of practice and CPA.

A rigorous framework developed by the HSE is in place to support the prescribing of authorised medicinal products for an unauthorised clinical indication (off-label) by RNPs. This could be adapted for the purpose of prescribing an exempt (unauthorised) medicinal product by a RNP. The NMBI has supported this framework as it ensures the safety and quality of care for patients and service users as outlined in the *Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority* (2010).

The NMBI has also acknowledged this challenge for RNPs and seeks to support an expanded role in the prescribing of exempt (unauthorised) medicines, supported by appropriate governance structures and processes.

In 2014 a working group consisting of RANP/RNPs, the HSE nurse midwife prescribing team and the ONMSD HSE Medicines Management National Lead was established to discuss the ongoing impact of this restriction on RNPs, with a view to proposing an amendment to legislation to enable nurses and midwives to prescribe exempt (unauthorised) medicinal products within their scope of practice. This group submitted a report to the Clinical Lead for the HSE Medicines Management Programme, who subsequently submitted it to the Department of Health. At the commencement of the *Review of Nurse Midwife Prescribing Systems and Processes*, the DoH requested that this be included as one of the Terms of Reference.

7.2 Methodology

In discussion with the Advisory Group for the *Nurse Midwife Prescribing Review*, and following a stakeholder meeting with the DoH Medicines Unit and the HPRA, a survey was conducted to elicit the current views of candidate and Registered Nurse Prescribers on this specific issue.

Invitations to participate in the survey were sent by email which contained a link to the online survey. A purposive sample (n = 960) was selected using the NMBI candidate and Registered Nurse Prescriber register. A total of 111 responses were received. The participants were informed that all information collected would be reported anonymously and confidentially, and the purpose of the data collection was to inform the writing of a report for the Advisory Group. The link to the NMBI/ONMSD project was provided in the introduction of the email.

7.3 Key Findings

This section reports on the key findings from the survey. Full survey results are available on request.

(Clinical Area of Practice)

Respondents were from diverse areas of clinical practice, ranging from Emergency/Minor Injuries (n = 18), Diabetes (n = 5), neonatology (n = 3) and midwifery (n = 4).

Do you have any current or anticipated requirement to prescribe exempt (unauthorised) medicines?

A total of 49 (44%) if respondents answered Yes to this question; 52 (46%) answered No and 10 (9%) responded that they did not know.

If "Yes", list the medicines you would include if you had authority to prescribe exempt (unauthorised) medicines

Respondents identified a number of exempt (unauthorised) medicines that they would include in their CPA if they had authority to do so.

Respondents also identified some off label medicines (authorised medicinal product prescribed for an unauthorised indication) that they would include. The list has not been included in this report as RNPs have had authority to prescribe these medicines since 2011. A significant survey finding is that there appears to be a misinterpretation regarding the difference between exempt (unauthorised) and off label medicines. The reasons for this may include:

- Widespread use of British National Formulary (BNF) rather than Irish resources, eg HPRA website.
- Candidates are allowed to use the BNF as a resource when undertaking the nurse midwife prescribing education programmes.
- Misinterpretation at individual health service provider level; for example anecdotal feedback of off label products being stamped as "Unlicensed" by pharmacy departments.

Respondents also included some controlled drugs in this section. Most of these items are included in Schedule 8, the list of controlled drugs RNPs are authorised to prescribe.

The majority of respondents (67) agreed or strongly agreed with the following statement with 39 having no opinion/undecided and the remaining 5 disagreeing.

My ability as a RNP to prescribe the medicinal products listed above would enhance patient/service user care

Please comment on your choice of answer to the above question/Any further comments

When asked to provide comment in support of the above statement the majority of respondents represented a broad spectrum of views, including timeliness, continuity of care, autonomy and independence and avoiding delays in treatment to the patient. In some instances these medicines are frequently used in the area of practice, for example neonatology.

7.4 Recommendations

Recommendation 9: The Department of Health to amend the legislative authority for RNPs to prescribe exempt (unauthorised) medicines and draft regulations to enable this. The health service provider should utilise the existing HSE and NMBI guidance frameworks for the use of medicines for unauthorised indication for managing the implementation of exempt (unauthorised) medicine prescribing by RNPs.

Rationale: The issue of enabling RNPs to prescribe exempt (unauthorised) medicines was identified in 2009 in the *Report of the National Independent Evaluation of the Nurse and Midwife Prescribing Initiative*. Current medicines legislation prohibits RNPs prescribing these medicines. This lack of authority has contributed to delays and inefficiencies for patients requiring exempt (unauthorised) medicine prescriptions as the RNP must refer them to a medical practitioner for their prescriptions. Additionally there are increasing shortages of authorised medicines requiring health services to source and supply exempt (unauthorised) medicines across the health care sectors. RNP authority to prescribe these medicines will help to ensure more timely and efficient care for patients. It will also contribute to increasing the autonomy and expansion of prescribing practices for RNPs, particularly in neo-natal and palliative care settings. There have been previous representations to the Department of Health from the ONMSD HSE and Medicines Management Programme and the NMBI on this issue.

Responsibility Recommendation 9: Department of Health

Recommendation 10: Based upon findings of consultation activities regarding exempt (unauthorised) and off label products, communication should be circulated to stakeholders regarding:

- **a.** The provision of information updates about exempt (unauthorised) medicines and unauthorised indication medicine usage (off label).
- **b.** RNP use of Irish medicine references such as HPRA and the Irish Medicines Formulary vs reliance on UK sources (British National Formulary BNF).

Rationale: The RNP and candidate survey findings revealed a general misunderstanding amongst responders regarding the difference between exempt (unauthorised) medicines and medicines prescribed for unauthorised indication (off-label). This misunderstanding was also noted during the discussions at the DON/M/PHN/Services workshop.

The candidate nurse prescribers have been directed in their education programmes to use the BNF as a main resource for medicine referencing. There are distinct differences in the data provided in the UK vs Irish context based on the available, authorised medicines in the two markets.

Responsibility Recommendation 10: NMBI and ONMSD, HSE

SECTION 8 ADDITIONAL RECOMMENDATIONS

The consultation process involved in this review resulted in additional recommendations which evolved from the various stakeholder meetings and are outside of the Terms of Reference of the Review. These are presented below.

Recommendation 11(a): NMBI to examine a process for competency assurance for addressing the current issue of long term candidate nurse prescribers (i.e. candidates who have successfully completed the education programmes but not yet registered as RNP).

Recommendation 11(b): NMBI to examine a process for competency assurance for addressing the current issue of RNPs who have not utilised their prescriptive authority, i.e. those returning from long term leave /maternity leave/career break etc.

Rationale: There are noted time delays of 2 years or more post education completion for candidates applying for registration with NMBI. The NMBI and the ONMSD have previously communicated individually with these candidates and DON/M/PHN/Services.

These significant delays may contribute to competence and safety concerns from the regulator, health service provider and the candidate nurse or midwife prescriber. Consideration should be given to developing a process for competency assurance, for example through liaising with HEIs to develop a refresher programme for this group.

Responsibility Recommendation 11: NMBI, ONMSD HSE

Recommendation 12: The Director of Nursing/Midwifery/Public Health Nursing/Services must have overall responsibility and authority for the governance of nurse midwife prescribing to ensure due diligence in their health service provider. This should be in collaboration with the Chief Executive Officer (group hospitals) Chief Officer (Community Health Organisations) or equivalent, Superintendent Pharmacist and Clinical Directors as appropriate.

Rationale: Across the continuum of health services there is some evidence of limited support for the implementation and monitoring of the nurse and midwife prescribing initiative. This contributes towards the diminished numbers of applications to the education programmes and the delays and non-progression of registration as RNPs with NMBI as captured by the ONMSD and NMBI databases. The DON/M/PHN/Services role is critical and underpins the future success and expansion of the initiative. DON/M/PHN/Services must be a champion and motivator within their health service provider and be empowered by senior management to support this. This ensures that nurse midwife prescribing is firmly supported by senior management throughout the complete cycle of recruitment for the education programme including medical mentorship, CPA development and signoff, registration with NMBI and the commencement of and subsequent audit of prescribing by the RNP. Senior management must collaborate on the initiative to address emerging concerns such as:

- bilocation and integrated services
- locum medical practitioners working with RNPs
- Multiple collaborating medical practitioners

Responsibility Recommendation 12: Directors of Nursing/Midwifery/Public Health Nursing/Services

SECTION 9 CONCLUSION

A number of trends both in Ireland and internationally supports the continued advancement of nurse midwife prescribing within the Irish healthcare system. These trends encompass the following:

- social and demographic change, for example, the aging population in Ireland
- changing health service provision and reconfiguration, for example the development of group hospitals and community healthcare organisations.
- increased specialisation of services, such as chronic disease management, nurse and midwifery led services, integrated nursing and midwifery roles etc.
- value for money including a return on investment in the education of health care professionals
- implementation of the European working time directive
- greater focus on community based services.

An example where nurse midwife prescribing can contribute to the DoH Strategy 2015-2017 relates to the strategic priorities for delivering improved patient outcomes. One of its priorities is to implement integrated care programmes through introducing clinically-led, multi-disciplinary integrated models of care in respect of patient flow, older persons, chronic disease prevention and management, children's health and maternal health. The role of the nurse and midwife is continually evolving and developing to meet the requirement to meet more efficient care delivery.

In consideration of the above strategies, future planning amongst stakeholders could incorporate more specific aspects of medicine management activities, for example limited scope of prescribing practice for entry level midwives.

This priority is also at the forefront of service development. The HSE Corporate Plan (2015-2017) refers to the requirement for the development of a national coordinated plan for the continued expansion of nurse and midwifery led services based on population need and taking account of service delivery efficiencies. With its emphasis on governance (clinical and corporate) the *HIQA National Standards for Safer Better Healthcare (2012) Theme 5 (Standard 5.2) Leadership, Governance and Management* also provides the future direction necessary to advance nursing and midwifery:

"Service providers have formalised governance arrangements for assuring the delivery of high quality, safe and reliable healthcare".

It is important to recognise the role of professional regulation in supporting nurses and midwives to provide safe quality care to patients across health and social care settings. Regulation and professional guidance concerning prescriptive authority should not be too prescriptive and cumbersome for registrants, by maintaining rigid professional criteria. Evidence demonstrates that this has contributed to registration delays and has been viewed as a barrier for attracting applicants to the education programmes. The "belt and braces" style used over the past 8 years needs to be replaced with systems and processes that are leaner and more user friendly. This reflects nursing and midwifery management accountability, responsibility and collaboration with other members of the healthcare team. The *NMBI Code of Professional Conduct* and *Ethics for Registered Nurses and Registered Midwives* (NMBI, 2014) and the updated Scope of Nursing and Midwifery Practice Framework (NMBI, 2015) provide enabling frameworks for clinical staff and managers to support their individual and collective professional roles for safe quality prescribing.

Cognisance should also be taken of the HIQA *National Standards for Safer Better Healthcare (2012), Chapter 5: Leadership Governance and Management*, as these are the current standards that healthcare organisations and their management teams are being measured against.

Standard 5.1 states "Service providers have clear accountability arrangements to achieve the delivery of high quality, safe and reliable healthcare". It explains that an "identified individual"

- "has overall executive accountability, responsibility and authority for the delivery of high quality, safe and reliable services
- leads a governance system that clearly specifies, delegates and integrates corporate and clinical governance.
- formally reporting on the quality and safety of the service through its relevant governance structures".

It goes on to state that: "A key function of governance is specifying the accountability and reporting structures in the service at individual, team and service level so that everyone working in the service is aware of their responsibility and accountability for the delivery of high quality, safe and reliable care".

Almost a decade has passed since a patient in the Irish healthcare system received a prescription written by a RNP. This report has drawn from the experiences of key informants on nurse midwife prescribing. It describes current practices and provides recommendations where new or revised systems and process should be implemented.

This Report was presented to the advisory group for review and consideration and subsequently approved by the NMBI Board and ONMS Director, HSE. The report will inform NMBI and ONMSD HSE regarding an implementation plan to action these recommendations. Cognisance must be given to resources, time frames and key stakeholder involvement.

ACKNOWLEDGEMENTS

Advisory Group members and their organisations

Participants in the Directors of Nursing/Midwifery/Public Health Nursing/Services Workshop

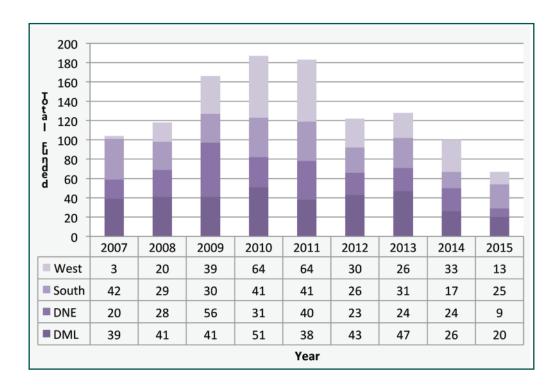
Candidate and Registered Nurse Prescribers who participated in all areas of the Review

Stakeholders met by the Collaborative Working Group

Prescribing Site Coordinators

APPENDIX 1: CANDIDATES FUNDED BY HSE

Candidates Funded by HSE 2007 - 2015



Source: Office of the Nursing and Midwifery Services Director, 30 June 2015



APPENDIX 2: GOVERNANCE STRUCTURES FOR REVIEW

Clinical Strategy and Programmes Directorate- Nursing and Midwifery Services Director/Nursing and Midwifery Board of Ireland

Dr Michael Shannon, Nursing and Midwifery Services Director, HSE

Dr Maura Pidgeon, CEO, NMBI



Advisory Group

A key stakeholder, multidisciplinary Advisory group to advise on the review. Chairperson: Professor Martin Bradley (see Appendix 5 for list).



Collaborative Working Group

Kathleen Walsh, Professional Officer, Standards of Practice and Guidance, NMBI

Gwen Byrne, A/Director of Registration, NMBI

Clare MacGabhann, Director of Nursing and Midwifery (Prescribing), ONMSD, HSE

Annette Cuddy, Assistant Director of Nursing and Midwifery (Prescribing), ONMSD, HSE

APPENDIX 3: CLINICAL GOVERNANCE GUIDING PRINCIPLES UTILISED TO TEST THE TERMS OF REFERENCE

To assist healthcare providers a suite of ten guiding principles for quality and safety, for the Irish health context, were developed with a title and descriptor (HSE, 2012). It is proposed that the principles (see Table 1) inform each action and provide the guide for managers and clinicians in choosing between options. Therefore the principles were used to inform this review (see Table 2).



Source: Quality and Patient Safety Directorate, HSE, February 2012

Table 1: Guiding principles descriptor

Principle	Descriptor
Patient First	Based on a partnership of care between patients, families, carers and healthcare providers in achieving safe, easily accessible, timely and high quality service across the continuum of care.
Safety	Identification and control of risks to achieve effective efficient and positive outcomes for patients and staff.
Personal responsibility	Where individuals as members of healthcare teams, patients and members of the population take personal responsibility for their own and others health needs. Where each employee has a current job-description setting out the purpose, responsibilities, accountabilities and standards required in their role.
Defined authority	The scope given to staff at each level of the organisation to carry out their responsibilities. The individual's authority to act, the resources available and the boundaries of the role are confirmed by their direct line manger.
Clear accountability	A system whereby individuals, functions or committees agree accountability to a single individual.
Leadership	Motivating people towards a common goal and driving sustainable change to ensure safe high quality delivery of clinical and social care.
Multi-disciplinary working	Work processes that respect and support the unique contribution of each individual member of a team in the provision of clinical and social care. Inter-disciplinary working focuses on the interdependence between individuals and groups in delivering services. This requires proactive collaboration between all members.
Supporting performance	Managing performance in a supportive way, in a continuous process, taking account of clinical professionalism and autonomy in the organisational setting. Supporting a director/manager in managing the service and employees thereby contributing to the capability and the capacity of the individual and organisation. Measurement of the patients experience being central in performance measurement (as set out in the National Charter, 2010).
Open culture	A culture of trust, openness, respect and caring where achievements are recognised. Open discussion of adverse events are embedded in everyday practice and communicated openly to patients. Staff willingly report adverse events and errors, so there can be a focus on learning, research and improvement, and appropriate action taken where there have been failings in the delivery of care.
Continuous quality improvement	A learning environment and system that seeks to improve the provision of services with an emphasis on maintaining quality in the future not just controlling processes. Once specific expectations and the means to measure them have been established, implementation aims at preventing future failures and involves the setting of goals, education, and the measurement of results so that the improvement is ongoing.

Table 2: Review of processes for nurse and midwife medicinal product prescribing using the guiding principles for quality and safety

	СРА	D&T	Data Collection	Exempt medicines
Patient First	Patient first is supported by the description of the patient population & scope of practice for the RNP in the CPA. More accessible & timely if changed to once off requirement to register as RNP, remove annual and biannual review. New CPA to be developed if original is terminated, i.e. if RNP/medical practitioner leaves.	Role of D&T committee supports Patient First. However, many organisations have interpreted role locally & this has resulted in delays in registration, poor access, & cancellation/ deferral i.e. for 3/6 months/continuity of personnel/ restricturing of HSE services. Wording "authorise to prescribe" (NMBI) & "approval" (HSE) have resulted in some committees misinterpreting their role by overriding sign off & expertise of medical colleagues. View themselves as primary governance structure which does not take into account role of DON/M/PHN/ Services. Propose diagram to identify governance for D&Ts within services	Supports Patient First if outputs used appropriately, i.e. useful at national level. Not used to full potential at local level. Feedback from RNPs is that it is time consuming and takes them away from patient care.	Authority to prescribe exempt medicines supports Patient First approach
Safety	CPA identifies & seeks to minimise risk. Does not always achieve effective efficient &	This is the main function of D&T committee. Committee ensures proposed	Not an audit tool, data collection system is for monitoring only. Never intended as	Clear framework & guidance on governance (see off label) to supports this. Lack

	СРА	D&T	Data Collection	Exempt medicines
	positive outcomes for patients & staff due to individual & local interpretation of how to implement CPA. Can be delays.	medicinal product is authorised, generic, within scope of practice of RNP	a safety tool.	of authority may lead to delays for patient treatment.
Personal responsibility	CPA clearly sets out responsibilities etc. of RNP, signed by Collaborating Medical Practitioner, RNP & DON/M/PHN/ Services. Query how this has extended to other members of the healthcare team.	Each D&T committee has individual ToRs, clearly outlining their role, responsibilities, purpose, standards etc. Based on national guidance (NMBI & HSE), personal responsibility has been assumed for approving RNP within services. Culture of D&T committees is to apply rigorous, thorough standard to all aspects of role. This has been transferred to aspects of RNPs' practice	Individual accountability clearly outlined within policy relating to Data Collection System. DON/M/PHN/ Services signs up on Site Declaration Form. Average 50% of HSE employed RNPs are not currently using the System leaving a significant gap in monitoring	Issue of patient consent. Clear process in place to enable RNPs to prescribe off label, this can be transferred to exempt medications
Defined Authority	Not well met by CPA. DON/M/PHN/ Services & line managers not always clear re their role & authority.	Defined authority is weaved into D&T ToRs. Now requires revision of role &function for RNP.	Varies within services. Established in policy, however only some services use Data collection systems	As above. Legislation needs to be amended to support this.
Clear Accountability	Too intense, cumbersome. CPA does not foster clear accountability due to lack of standardisation of	D&Ts vary on who they are accountable to & what they are accountable for in terms of RNP, i.e. if	Role based, clear accountability within system. Only RNPs can input, specific to individual RNP.	As above

	СРА	D&T	Data Collection	Exempt medicines
	Attachments A, B, C. And challenges in obtaining support from multiple community based (GPs) collaborating multiple practitioners	no meeting for 6 months, creates delays. (lack of clarity in NMBI & HSE guidance)	Used nationally to support queries, for example parliamentary questions etc.	
Leadership	Dependent upon practice setting, e.g. multiple collaborating medical practitioners not motivating.	Varies across the continuum, some Committees function well & progress quickly. Where Committee is not functioning, results in poor motivation.	Varies depending on senior nursing buy in to the System.	Change in legislation would support this.
Inter-disciplinary working	CPA should support proactive collaboration. However it does not always support interdiscipli-nary working, delays in obtaining signatures, multiple reviews required in some services, trust element in some areas.	As above.	Not used for interdiscipli-nary working. Could be used to demonstrate trends nationally, e.g. to support national clinical programmes & their list of drugs. Has potential but this is not currently happening. Not always protected time for inputting data.	Supports this as there is connection with pharmacy/ medical colleagues. Very supportive of this.
Supporting Performance	CPA supports measurement of performance through clarity in documenting RNPs patient population & scope of parctice along with requirement for audit.	Some D&T committees support audit by reviewing RNP audit activity & monitoring. Deferral of meetings, lack of meetings,	Has potential to support performance/ business planning/trends etc. Huge potential but not used.	Provides a more efficient service, better outcomes for nurse/midwife prescribing.

	СРА	D&T	Data Collection	Exempt medicines
		personnel leaving, & results in delay registering, therefore performance is not supported.		
Open culture	CPA supports & enables an open culture. Issue with culture of organisation rather than with CPA document.	There is little or no evidence of reporting of near misses/adverse events specific to nurse prescribing (feedback from D&T members). This may be because system does not differentiate between medical/nurse prescribing. May also be under reporting.	Has potential to identify/follow up adverse events/ inappropriate prescribing. Reports can be run at different levels in organisation. Reports can be exported & shared within organisations. Very good potential at national level i.e. reports can be run re antimicrobial prescribing/ out of hours/prefer-red medicines.	Lack of authority to prescribe has resulted in risk of adverse event, i.e. delay in treatment/ Initiation of prescription as the patient has to wait for medical practitioner to prescribe. Increasing numbers of exempt products coming on the market due to global shortages results in risk. Risk of products becoming exempt may result in inadvertent prescribing by RNP. Legal, regulatory and risk issue if authority not extended.
Continuous Quality Improvement	CPA does support CQI.	Improvement tends to be ad hoc rather than continuous. In some D& T committees there is monitoring of processes. Measurement of results ad hoc.	Very good resources section on System including access to specialist journals	Authority to prescribe exempt supports this. Findings from Survey identify a knowledge gap re: off label/exempt prescribing.

APPENDIX 4: CPA SWOT (STRENGTHS WEAKNESSES OPPORTUNITIES THREATS) ANALYSIS

SWOT Collaborative Practice Agreement

Strengths

- Ensures robust collaboration, i.e. with D&T and multidisciplinary team
- Good governance
- Lines of communication clearly outlined
- Protects scope of practice of RNP
- Avoids dispute locally
- Enhances awareness and understanding of nurse midwife prescribing and how it works within a system
- Provides assurance to RNPs re their list of medications
- Provides clarity regarding audit and ongoing evaluation and monitoring of nurse midwife prescribing
- Reassurance for employer that all regulatory and legislative requirements are adhered to.
- Enables RNP to reflect on enhancement of scope of practice
- Ensures safe practice within organisation
- Link to registration protects status of RNP
- Promotes communication and support from medical and pharmacy professions

Weaknesses

- Requirement for multiple signatures, very challenging particularly in community/cross sites/large geographical spreads/number of physicians.
- Requirement for developing new CPA every time renewal is due, including full form, attachments and signatures.
- Poor/lack of access to Drugs and Therapeutics Committees/review group causes delay in reviewing Att. B
- Requirement for annual/biannual renewal.
 Is this necessary and why? Not required in any other division. Should be local ownership and responsibility following initial registration. Confirm ongoing validation through annual retention.
 (Process for termination and subsequent renewal to be retained.)

Opportunities

- ? Obtain electronic agreement from collaborating medical practitioners (CMP) instead of individual signatures.
- Liaise with group hospital senior management regarding centralising D&T committees per group hospital (as Midwestern model) and per community area.
- Discuss issues with RNPs/PSCs/DON/M/PHN/SERVICESs through workshop (NMBI/HSE).

Threats

- Role of D&T/ lack of clarity of role re review and approval of Att. B in some areas.
- Difficult to build capacity as process too cumbersome in some areas.
- Renewal process and timeframe restrictive, e.g. where D&T committees may not meet.
 If renewal date passed, risk of CPA not being validated.
- No requirement to register as an RNP within a certain time frame following completion of education programme.



- HSE/NMBI develop revised FAQs information to include roles and responsibilities.
- Clarify requirement for every CMP to sign CPA form, this is challenging particularly in areas with large numbers of GPs/consultants. How could this be managed?



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Nurse and Midwife Medicinal Product Prescribing Review of Existing Systems and Processes

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