**Research Study Protocol**

**Title: Physiotherapy Defined Scope of Practice (Prescribing)**

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## 1. Background

Health practitioner prescribing has been in existence in the United Kingdom since 1989. The aims of health practitioner prescribing were to potentially benefit patient care without compromising safety, make better use of the skills of health professionals, and improve efficient medicine access [3]. Extensions to physiotherapy practice internationally have included prescribing medication, joint and soft tissue injections and/or aspiration of joints [3, 4]. In the UK where extended scope of practice roles for physiotherapy include prescribing medication and where such roles have been promoted by the UK Department of Health, the most recent reports available (2005 to 2006) indicate that there were no medication incidents related to health practitioner prescription [3].

New models of care have been implemented for physiotherapy in Queensland. These include musculoskeletal (Neurosurgical/Orthopaedic) Physiotherapy Screening Clinics (N/OPSCs), and primary contact emergency physiotherapy services. There is emerging evidence that these emergency and screening roles have been found to provide equal or better care than that provided by physicians for these discrete musculoskeletal patient groups in terms of diagnostic accuracy, treatment effectiveness, use of healthcare resources, economic costs and patient satisfaction [3-6].

In late 2013 the federal state and territory health ministers approved the non-medical health professional prescribing pathway [1]. This pathway also describes competency training and testing, registration, endorsement, and safe practice considerations. Currently, physiotherapists are authorised to administer S2 poisons, but other medicines that physiotherapists believe may assist in a patient's treatment are required to be referred back to their medical practitioner or to a pharmacist [2].

In addition to the current authorisation of physiotherapists to administer S2 poisons in the course of the care of their patient, and in order to optimise management of patients, it is proposed that credentialed physiotherapists will initiate (or cease), obtain, administer (via oral, topical, injection or inhalation routes), create a written instruction for and prescribe from a formulary of Schedule 2, 3, 4 and 8 medications (Appendix A – Formulary). Physiotherapists in this trial will use and refer to the LAM, MIMS and Australian Medicines Handbook (AMH) in relation to determining if there are any contra-indications, precautions, adverse reactions, and /or drug interactions for the limited formulary proposed.

If any further information is required the physiotherapist will contact their pharmacy department for clarification. Each facility will use the formulary (Appendix A) to develop a local drug protocol that is supported by the local Drug and Therapeutics or Medication Advisory Committee, the local reference or governance group and the allied health credentialing committee.

Terminology used to describe ***prescribing*** varies across the literature and legislation. In the Health Workforce Australia (HWA) Health Professional's Prescribing Pathway (HPPP), prescribing is defined as "*an iterative process involving the steps of information gathering, clinical decision making, communication and evaluation which results the initiation, continuation or cessation of a medicine*".[1] This process results in the creation of a prescription or written instruction, that directs a medication to be administered or ceased. Further to this definition, the HPPP defines the prescriber as "a health practitioner authorised to undertake prescribing within their scope of practice'. These definitions will be used for the purposes of this research protocol.

The aims of the Physiotherapy Defined Scope of Practice (Prescribing) study are:
A1: To investigate the safety of prescribing by physiotherapists credentialed for defined scope of practice (prescribing).
A2: To investigate the patient experience with physiotherapists credentialed for defined scope of practice (prescribing).

The hypotheses of the Prescribing by Physiotherapists study are:
H1: That prescribing by physiotherapists credentialed for defined scope of practice (prescribing) is safe.
H2: That the experience of patients receiving treatment by physiotherapists credentialed for defined scope of practice (prescribing) is acceptable.

**Methods**

This is a descriptive study using quantitative and qualitative analysis. It will be conducted in hospitals, outpatient, and emergency department settings of participating health services including: QEII Jubilee Hospital, Princess Alexandra Hospital (PAH), Royal Brisbane and Women's Hospital (RBWH), The Prince Charles Hospital (TPCH), Gold Coast University Hospital (GCUH), Robina Hospital, and Cairns Hospital. Institutional ethics committee approval will be sought by submitting a National Ethics Application Form (NEAF) - Multisite through Princess Alexandra HREC. Site Specific Application will also be submitted for the study to be carried out at the aforementioned hospitals. Only physiotherapists credentialed

for defined scope of practice (prescribing) will be permitted to prescribe approved medications during the study.

Individual physiotherapists who propose to obtain, prescribe and administer medicines as part of this study and who have completed the appropriate education and training will apply to the Chief Health Officer for authorisation to obtain, prescribe and administer specified medicines under the Health (Drugs and Poisons) Regulation 1996 for the period of the research.

Governance

*Registration*

The physiotherapists participating in this study are to be registered with the Physiotherapy Board of Australia.

*Education and Training*

The prescribing competency framework developed by NPS Medicinewise is the only nationally available standard for health professional prescribing education. In the absence of an accredited program for physiotherapist prescribing the education and training undertaken by physiotherapists participating in this study will be aligned to this Framework (http://www.nps.org.au/health-professionals/professional-development/prescribing-competencies-framework).

Physiotherapists will complete a tertiary level study program, through a higher education institution, that will enable them to complete the required education to undertake prescribing consistent with their scope of practice. The study program will be aligned to the NPS Medicinewise Prescribing Competencies Framework and include assessment of the essential competencies of clinical therapeutics, safe prescribing and quality use of medicines. This will provide the underpinning knowledge and skill required to safely prescribe within their scope of practice.

A period of supervised practice is a component of the study program and the physiotherapist prescriber will be supervised by an authorised prescriber in their workplace for this element. The workplace based supervision is also required to meet governance arrangements necessary for local credentialing. In addition, development and assessment of competencies in the administration of medicines will be through supervised practice within the local work environment.

*Local Health Service Credentialing*

Individual physiotherapist/s will be credentialed by their local Hospital Health Service Allied Health Credentialing Committee which will include authorisation from the local Drugs and Therapeutics Committees or equivalent (e.g. Executive Director of Medical Services) at their facility.

*Reference Group:* A reference group will be formed at the local facility level to support the trial and act as a clinical advisory team. This group will be tasked with oversight of the local trial, reviewing clinical decisions, reviewing near-misses and incidents as required, acting as an advisory team should issues arise and initiating clinical audits. Regular meetings of this group will ensure that any issues identified (e.g. near-miss, adverse events) are reported and addressed promptly. The group will also be responsible for overseeing the clinical auditing of prescribing events by physiotherapists. This auditing will involve reviewing the discharge prescriptions, medical records and National Inpatient Medication Charts (NIMCs) of participants recruited to the study.

Membership of the reference group will include:

- Project sponsor

  The project will have a facility level project sponsor who will take overall responsibility for the research project delivery.
- Medical supervisor

  Local credentialing via competency assessment will be provided by a designated medical supervisor prior to commencing practice. The physiotherapist will be required to practice under the supervision of the designated medical supervisor until declared competent.
- Key members from the clinical team involved in the new model of care as nominated by the Sponsor
- Pharmacist

  To provide oversight of the local procedures that will ensure safety of prescribing practice, including oversight of the development of the local drug protocols for physiotherapists, involvement in the credentialing of the physiotherapist for defined scope of practice (prescribing) and review and report on local medication errors, near-misses and adverse drug events pertaining to the credentialed physiotherapist(s) for defined scope of practice (prescribing)

- Physiotherapy Director (Associate Investigator)

  To ensure appropriate clinical expertise and experience is demonstrated by the prescribing physiotherapist and that ongoing clinical supervision, peer support and opportunities for updating knowledge is undertaken. To ensure local credentialing for the physiotherapists credentialed for defined scope of practice (prescribing) and oversight of the local procedures that will ensure safety of practice
- Physiotherapist credentialed for defined scope of practice (prescribing). (once available)

Participants for Aims A1 and A2

Eligible participants will be recruited from acute hospital outpatient and emergency department environments in participating health services by physiotherapists credentialed for defined scope of practice (prescribing). Participants will be issued a participant information sheet and asked to sign a consent form after which time their details will be added to a password protected Microsoft Excel spreadsheet stored on a secure QLD Government server.

Assuming a 70% recruitment rate in the Emergency Department and a 50% recruitment rate in the N/OPSC, it is expected that the total number of participants recruited to the study across all sites will be approximately 2781. This estimation is based on the following information:

In the two participating *Outpatient N/OPSCs* (PAH & GCUH) there were approximately 894 new case presentations in the 2015/2016 financial year. It is estimated that 70% (n= 626) of new case presentations would be eligible for inclusion in the study.

In the *Emergency Department* there were approximately 5036 primary contact patients seen by the participating emergency department physiotherapists in the 2015/2016 financial year. Of these primary contact presentations, 70% (n=3526) are estimated to be patients with a musculoskeletal injury/condition who would meet the eligibility criteria for inclusion in the study.

*Participant Inclusion criteria (all sites)*

1. Male or female aged 18 years and over
2. Identified through existing triage processes as being a suitable patient for the primary contact Emergency Physiotherapy Practitioner (EPP) in the Emergency Department or triaged from the Orthopaedic or Neurosurgery Outpatient waiting list as being suitable for the N/OPSC service.
3. There may be a requirement to write a written instruction and/or prescribe medication to the extent necessary for the physiotherapist to practice physiotherapy
4. Peripheral and/or spinal musculoskeletal injuries / conditions / symptoms
5. Able to provide informed consent
6. Able to understand written and spoken instructions

*Participant Exclusion criteria*

1. Male or female less than 18 years of age
2. Primary presenting complaint is a non-musculoskeletal injury or pain from a non-musculoskeletal source requiring management by a medical practitioner
3. Women who are pregnant
4. Unable to provide informed consent
5. Unable to follow written and spoken instructions

<u>Interventions</u>

Physiotherapists credentialed for defined scope of practice (prescribing) will ask patients under their therapeutic management who meet the inclusion criteria to participate in the trial. Participants will be issued a participant information sheet and a consent form.

Following consent, the physiotherapists credentialed for defined scope of practice (prescribing) in ED or OPSC will assess and manage the participant as per usual clinical guidelines and processes. In addition to this usual care, the physiotherapist credentialed for defined scope of practice (prescribing) may obtain, administer, write a written instruction for and /or prescribe medications to the extent that it is necessary in order to practice physiotherapy as required for the care of the patient and as per agreed local credentialing processes and local drug protocol. All other requirements for medication will be referred to the medical officer for review. Patients will be discharged or referred for further management as per usual processes.

Risk management

The local reference group will review PRIME/RiskMan and iPharmacy reports to check for incidents related to prescribing by physiotherapists in their facility, at a frequency recommended by local credentialing committee. The ED Data Collection systems (EDIS & FirstNet) will be searched for study participants who present to ED for medication related events up to 28 days post physiotherapist prescribing. Local reference group audits of discharge prescriptions, medical records and/or National Inpatient Medication Charts (NIMCs) will also be used to identify any prescriber errors. The prescribing physiotherapists will be required to report all medication errors, near misses and adverse drug events that occur during the prescribing trial to the local reference group for appropriate action.

Outcomes

The primary outcome for this study is the medication error related adverse event count attributed to prescribing by physiotherapists. This data will be sourced from several systems including incident reporting systems such as PRIME/RiskMan, iPharmacy, ED data collection systems (EDIS & FirstNet) and reports from the local reference group prescribing audits.

The secondary outcomes are:

1. Participant satisfaction and experience questionnaires that will take place following care and will not impact on the clinician's / researcher's relationship with the patient.
2. Prescribing events by physiotherapists credentialed for defined scope of practice (count)

Data collection

Data collected at the point of intervention will include participant information and the prescribing activity performed by the physiotherapist. A satisfaction and experience survey will be provided to the patient following the physiotherapy assessment/treatment. The patient will be given the opportunity to choose between an electronic or paper version of the survey. Re-presentation information from EDIS/FirstNet will be collected and reviewed for re-presentations related to physiotherapy prescribing. PRIME/RiskMan,and local reference group audit reports will be requested and reviewed for incidents related to physiotherapy prescribing. All data collected during the trial will be added to a secure, online, password protected database and may be used in the completion of a research higher degree by the Chief Investigator.

Data analysis

Descriptive statistics including frequencies, percentages, means, standard deviations and ranges will be produced for all data. No parametric or inferential analyses will be conducted.

Data management

All data will be kept for a period of 5 years and after that electronic data will be deleted and paper data will be shredded.

Budget

This project will be completed within the existing resources of the Departments of physiotherapy. Education of physiotherapists in prescribing will be provided through the Queensland University of Technology and will be part-funded through scholarship programs administered by the Allied Health Professions Office of Queensland.

Time line

It is anticipated that this study will commence in July 2016, after the physiotherapists have completed relevant training and have been credentialed to undertake these activities.

Eighteen months of subsequent data collection and a period of time for data analysis and report writing will see the Project completed by July 2018.

**Definitions**

*Prescribe*

To make a written direction (other than a purchase order or written instruction) authorising a dispenser to dispense a stated controlled or restricted drug or a stated poison.(Health Drugs Poisons Regulation (HDPR)1996). Under this definition, the prescriber is creating a prescription that is taken to a pharmacy for dispensing.

*Prescriber*

A person who, under this regulation, is endorsed to prescribe a controlled or restricted drug or a poison (Health (Drugs & Poisons) Regulation 1996).

*Prescription*

A prescriber's direction (other than a purchase order or written instruction) to dispense a stated controlled or restricted drug or a stated poison, and includes, for sections 79, 80, 81, 190, 191 and 192 of the Health (Drugs and Poisons) Regulation 1996 a duplicate of a prescription attached to a repeat authorisation, under the National Health Act, issued by a dispenser. [2]

*Dispensing*

Performed by a Pharmacist in QLD is the process of reviewing, clinically and legally assessing a prescription or written order, then preparing, (either compounding or packaging) recording and providing counselling and education to a patient.

Written Instruction

A written direction '*other than a prescription'* which may be a standing order, or a written entry on a patient's medical records (ie: medication chart), which is signed and dated.

## Appendix A Formulary

Queensland Physiotherapy Scheduled Medicines Formulary

Within the scope of practice for physiotherapists in advanced musculoskeletal physiotherapy roles in Emergency and N/OPSC, prescribing the attached formulary may involve the following actions:

1. Commence: - a patient attending Emergency or N/OPSC may be prescribed to commence this medication (via prescription or written instruction) or advised to obtain this medication over the counter (where relevant) in the community

2. Optimise use of a medicine already prescribed for the patient which may involve advice to:
   Cease: a patient attending emergency or N/OPSC may be advised to cease this medication
   Modify: a patient attending emergency or N/OPSC may be advised to modify their use/dose of this medication. Note: If modification of the use of a medicine includes the need to obtain a different stock of the medicine (eg. different dose tablet), then a written instruction or prescription will be required
   Inform: a patient attending emergency or N/OPSC may be advised about this specific medication eg. Adherence, times of day taken, titration

3. Obtain, possess, and administer: An extended scope ED physiotherapist or N/OPSC Clinical Leader would need to obtain, possess and administer this medicine in the emergency department or N/OPSC clinic

None: none of the above actions will occur for a patient attending emergency or N/OPSC – any advice provided would be within current physiotherapy scope of practice (general advice only to discuss this medication with a doctor or pharmacist)

| *Class* | *Drug* | *Route* | *Durations/ Restrictions* | Indicator | ESP – ED Scope | ESP-ED Method of access | N/OPSC Scope | N/OPSC Method of access |
|---|---|---|---|---|---|---|---|---|
| *Analgesic* | | | | | | | | |
| *Non opioids* | Paracetamol | Oral | Max 8 tablets/24 hours | Pain | 1,2,3, | -Provide a written instruction on National Inpatient Medication Chart (NIMC)<br>-Refer patient to purchase medicine in community/community pharmacy | 1,2 | Refer patient to purchase medicine in community/ community pharmacy |

| *Class* | *Drug* | *Route* | *Durations/ Restrictions* | Indicator | ESP – ED Scope | ESP-ED Method of access | N/OPSC Scope | N/OPSC Method of access |
|---|---|---|---|---|---|---|---|---|
| *Opioids* | | | | | | | | |
| | Paracetamol +Codeine | Oral | Max 8 tablets/24 hours | Moderate pain | 1,2, | Provide a written instruction on NIMC<br><br>Provide a written instruction or prescription for patient to take to hospital pharmacy | 1,2 | Provide a written instruction or prescription for patient to take to hospital pharmacy |
| | Codeine | Oral | Restrictions apply – controlled drug | | 1,2 | Provide a written instruction on NIMC Provide a written instruction or prescription for patient to take to hospital pharmacy | 2 | Recommendation provided to patient; communication to GP for follow up |
| | Tramadol | Oral | | | None | | 2 | Recommendation provided to patient; communication to GP for follow up |
| | Oxycodone | Oral | Restrictions apply – controlled drug | | 1,2 | Provide a written instruction on NIMC | 2 | Recommendation provided to patient; communication to GP for follow up |
| | Fentanyl | Intra-nasal | Restrictions apply – controlled drug | Severe pain | 1 | Provide a written instruction on NIMC in the once only section | None | |

| *Class* | *Drug* | *Route* | *Durations/ Restrictions* | Indicator | ESP – ED Scope | ESP-ED Method of access | N/OPSC Scope | N/OPSC Method of access |
|---|---|---|---|---|---|---|---|---|
| *Rheumatologic Drugs* | | | | | | | | |
| *NSAIDS- for Musculoskeletal conditions* | Ibuprofen | Oral | Max 1200mg in 24 hours | Mild to Moderate pain | 1,2,3 | -Provide a written instruction on NIMC<br>-Refer patient to purchase medicine in community/community pharmacy | 1,2 | Refer patient to purchase medicine in community/ community pharmacy |
| | Naproxen | Oral | 500 mg initially then 250 mg 6 – 8 hourly to maximum 1250 mg in 24 hours | Mild to Moderate pain | 1,2,3 | Provide a written instruction on NIMC<br>Refer patient to purchase medicine in community/community pharmacy | 2 | Recommendation provided to patient; communication to GP for follow up |
| | Diclofenac | Oral | | Mild to Moderate pain | 1,2,3 | Provide a written instruction on NIMC<br><br>Refer patient to purchase medicine in community/community pharmacy | 1,2 | Refer patient to purchase medicine in community/community pharmacy or Provide a written instruction or prescription for patient to take to hospital pharmacy |
| | Ketorolac | Intra-muscular | 30mg | Adjunct moderate severe pain | 1 | Provide a written instruction on NIMC | None | |
| | Indomethacin | Oral | | Mild to Moderate pain | 2 | Provide a written instruction on NIMC | 2 | Recommendation provided to patient; communication to GP for follow up |
| *Gout* | Allopurinol | Oral | | | 1,2 | Provide a written instruction on NIMC | 2 | Recommendation provided to patient; communication to GP for follow up |

| *Class* | *Drug* | *Route* | *Durations/ Restrictions* | Indicator | ESP – ED Scope | ESP-ED Method of access | N/OPSC Scope | N/OPSC Method of access |
|---|---|---|---|---|---|---|---|---|
| *Corticosteroids* | | | | | | | | |
| | Betamethasone | Injection | | Musculo-skeletal conditions such as arthritis and bursitis. | None | | 3 | Obtain in SOPD, administer and document in patient record |
| | | | | | | | | |
| | Methylprednisolone | Injection | | | None | | 3 | Obtain in SOPD, administer and document in patient record |
| | Triamcinolone | Injection | | | None | | 3 | Obtain in SOPD, administer and document in patient record |
| *Inhaled Anaesthetics* | | | | | | | | |
| | Nitrous Oxide 30-70% | Inhaled | Single dose | Analgesia for procedures in ED | 1,3 | Provide a written instruction on NIMC &/ or Document in patient notes | None | |
| *Anaesthetics* | | | | | | | | |
| | Lignocaine 1% or 2% | Injection | Single dose | 1. Analgesia for procedures in ED<br>2. Musculo-skeletal conditions – mixed in same syringe with corticosteroid | 1,3, | Provide a written instruction on NIMC &/or Document in patient notes | 3 | Obtain in SOPD, administer and document in patient record |

| *Class* | *Drug* | *Route* | *Durations/ Restrictions* | Indicator | ESP – ED Scope | ESP-ED Method of access | N/OPSC Scope | N/OPSC Method of access |
|---|---|---|---|---|---|---|---|---|
| *Gastro-intestinal drug* | | | | | | | | |
| | Metoclopramide | Oral | Single dose 10mg Max 30 mg in 24 hours | Relief of Nausea | 1,2,3, | Provide a written instruction on NIMC in once only section | None | |
| | Ondansetron | Oral | Single dose | Relief of opioid induced nausea | 1,2,3 | Provide a written instruction on NIMC in once only section | None | |
| | Proton Pump Inhibitors -Esomeprazole -Omeprazole -Pantoprazole | Oral | Single dose | Prevention and /or treatment of upper GI adverse effects of NSAIDS | 1,2,3, | Provide a written instruction on NIMC. Advise patient to purchase over the counter at community pharmacy | 1,2 | Provide a written instruction or prescription for patient to take to hospital pharmacy |
| *Neurological Drug* | | | | | | | | |
| *Anti-epileptics* | | | | | | | | |
| | Diazepam | Oral | | Adjunct in acute LBP Muscle relaxant | 1,2 | Provide a written instruction on NIMC in the once only section | 2 | Recommendation provided to patient; communication to GP for follow up |

| *Class* | *Drug* | *Route* | *Durations/ Restrictions* | Indicator | ESP – ED Scope | ESP-ED Method of access | N/OPSC Scope | N/OPSC Method of access |
|---|---|---|---|---|---|---|---|---|
| | Pregabalin | Oral | | Neuropathic pain | None | | 1,2 subject to establishing an approved protocol NB. Significant numbers of patients referred to N/OPSC with spinal pain have neuropathic pain | Provide a written instruction or prescription for patient to take to hospital pharmacy |
| *Anti-depressants* | | | | | | | | |
| | Amitriptyline TCA | Oral | Authority required | Neuropathic pain | None | | 1,2 subject to establishing an approved protocol | Provide a written instruction or prescription for patient to take to hospital pharmacy |

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