Feasibility and acceptability of a virtual clinical pharmacy service (VCPS) in a tertiary metropolitan hospital

Research Study Protocol

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HOST ORGANISATION | Western NSW Local Health District

COLLABORATORS | Sydney Local Health District, Clinical Excellence Commission, Agency for Clinical Innovation, Hunter Medical Research Institute, Central Queensland University, University of Sydney

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2 STUDY PROTOCOL HISTORY

2.1 Study Title

Feasibility and acceptability of a virtual clinical pharmacy service (VCPS) in a tertiary metropolitan hospital

2.2 Version

Version 0.2. Last updated 20 January 2021

2.3 Amendments

Version	Date	Author	Comments
0.1	06/01/2020	Brett Chambers	First draft
0.2	20/01/2020	Brett Chambers	Incorporation of feedback from research team
0.3	03/03/21	Brett Chambers	Updated with feedback from GWHREC 11.2- updated to specify WNSWLHD virtual pharmacists will conduct the intervention 12.2, 12.6- clarified that patients will be given an opportunity to opt out of the PREM 12.7- Removed reference to Aboriginality 13.7- updated data retention period to 5 years 18.2.2- deleted aboriginality from demographics of PREM

3 INTRODUCTION

Medication-related incidents are the fourth most frequently reported incidents in NSW public hospitals after clinical management, pressure Injuries and falls [1]. Globally, medication errors are a leading cause of avoidable morbidity and mortality with an estimated cost of $42 billion annually [2]. There has also been an increasing focus on medication safety in National Safety & Quality Health Service Standards (NSQHS) [3]. Alongside this focus and acknowledging evidence that indicates between 60-80% of patients have a discrepancy with their medication history [4], clinical pharmacists play a vital role in ensuring best practice medication management however are not deployed in all hospital settings. Australian evidence reinforces this, acknowledging that clinical pharmacists in acute hospitals improve medication management, reduce medication harm, support patients in managing their medications, and decrease unwarranted clinical variation [5].

A Virtual Clinical Pharmacy Service (VCPS) offers a potential solution to improve compliance with Standard 4 and more importantly improve the delivery of safe and high-quality healthcare in hospitals or wards of hospitals without existing face-to-face clinical pharmacy coverage. Such a service has been created in Western NSW Local Health District (WNSWLHD) and Far West Local Health Districts (FWLHD) and is currently undergoing evaluation [6]. The WNSWLHD VCPS currently provides a range of clinical pharmacy services including patient education, medication reviews and medication reconciliation (Med Rec). Med Rec is a crucial overarching strategy that has been reliably found to improve medication safety [7-12]. Med Rec has been flagged as an international priority by the World Health Organization [7, 13, 14], and is well recognised that pharmacists are the most effective in performing Med Recs [14-17].

4 RATIONALE AND RESEARCH BACKGROUND

The roll out of electronic medical records (eMR) and electronic medication management (eMeds) in NSW Health facilities has provided the digital infrastructure for a VCPS to effectively support patient care. WNSWLHD has been operating a virtual pharmacy service since 2016 and more recently implemented a comprehensive inpatient virtual clinical pharmacy service to eight rural and remote hospitals in NSW [6].

Historically virtual models of care have focused on providing clinical services to patients in rural and remote communities to overcome workforce shortages, the need to travel vast distances and provide care closer to home. In response to the COVID-19 pandemic there has been a rapid expansion of virtual health delivery in both cities and rural communities [18-20]. As a result evidence is emerging of patient acceptability for various virtual healthcare models [21-23].

Current evidence indicates that telepharmacy has been implemented across parts of rural and remote Australia, particularly Queensland, however much of the literature is largely focussed on outpatient medication reviews (similar to Home Medication Reviews) as opposed to providing inpatient services [24-27]. A feasibility study evaluating a service developed to provide clinical pharmacy reviews for inpatients in rural and remote regions was found to be acceptable [26]. We are unaware of any such feasibility studies being conducted in Australian major metropolitan hospitals nor does the literature address acceptability in such environments.

A trial in a metropolitan site has the potential to generate new evidence for the feasibility and acceptability of virtual clinical pharmacy in a tertiary teaching hospital. This trial has the potential to influence the provision of future virtual pharmacy services in metropolitan hospitals, particularly in Australia and may be relevant to infection prevention and control for both staff and patients in an ensuing COVID-19 environment. This study also has the opportunity to increase collaboration and further enhance virtual care delivery across the NSW health system.

5 WHAT IS VIRTUAL CLINICAL PHARMACY?

5.1 Summary

The virtual clinical pharmacists will provide a telehealth service which is consistent with conventional face to face hospital pharmacy services. Depending on the patients' medical history and reason for admission they may receive one or more of the pharmacy activities summarised below:

- Patient prioritisation and recognition of high-risk patients
- Medication reconciliation particularly during transitions of care
- Patient education
- Medication review and addressing polypharmacy
- Antimicrobial stewardship

Virtual pharmacists can assist clinical staff through:

- Engagement them in medicine management
- Education
- Documentation of recommendations

The virtual pharmacists will utilise the eMR, eMeds and a teleconferencing cart with two–way audio and visual to provide clinical pharmacy services to the study site. The Pharmacists will work business hours Monday to Friday of each week over the study period.

5.2 Patient referral and prioritisation

It is not always possible to see all patients with face to face clinical pharmacy services and the same may occur with the VCPS. Patients who are at the highest risk of medication related harm will be prioritised for review. Prioritisation is based on the definition from the NSQHS Standard 4- medication safety (see Fig. 1 below) and the Society of Hospital Pharmacists of Australia (SHPA) Standards of Practice [12, 28].

Consumers at risk of medication related harm: Examples of risk factors known to predispose people to medication related adverse events are:

- age 65 years and older;
- currently taking five or more regular medications;
- taking more than 12 doses of medication per day;
- significant changes made to medication treatment regimen in the last three months;
- medication with a narrow therapeutic index or medications requiring therapeutic monitoring;
- sub-optimal response to treatment with medicines;
- suspected non-compliance or inability to manage medication related therapeutic devices;
- patients having difficulty managing their own medicines because of literacy or language difficulties, dexterity problems or impaired sight, confusion/dementia or other cognitive difficulties;
- patients attending a number of different doctors, both general practitioners and specialists; and
- recent discharge from a facility/hospital (in the last four weeks).

Figure 1: NSQHS definition of a patient at high risk of medication harm

Pharmacists will take direct phone referrals from the study site. Referring staff should include if the patient has visual, hearing or cognitive impairment and if the patient consents to the pharmacist contacting their community pharmacy or GP for medication information.

The pharmacist will self-refer patients based on medication chart review or by utilising the available eMR summary pages such as the Pharmacy Care Organiser (see Fig. 2 below), which can assist in the identification of patients requiring pharmacy services.

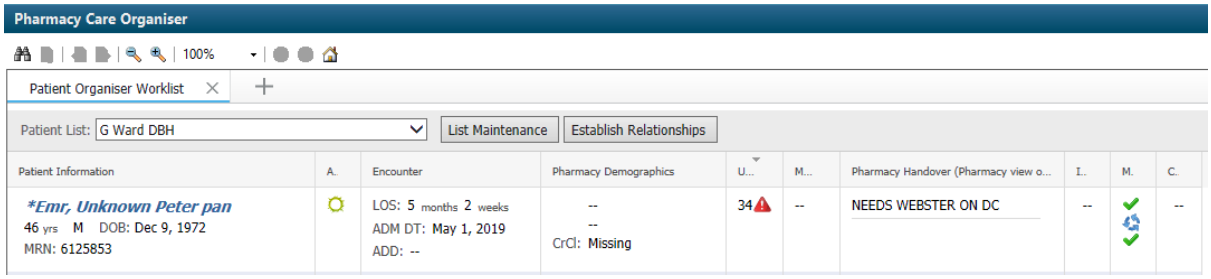

Figure 2: Pharmacy Care Organiser summary page

5.3 Medication Reconciliation

Med Rec is a formal process intended to prevent medication errors and medication related problems at transition points in patient care [12]. Virtual clinical pharmacists will conduct Med Rec on admission, discharge or transfer and document the best possible medication history in eMeds. A summary of the Med Rec and any identified issues will be documented in the patient medical record. Interventions will be raised for issues that require prescriber or nursing management. Interventions of immediate clinical concern will be followed up with direct communication between pharmacist and site doctor or nurse. To ensure continuity of medication management on discharge back to the community, the pharmacist will provide an updated medication list on discharge.

5.4 Patient education

Providing medication information to patients is a core element of patient centred care [12]. It engages patients with their healthcare, improves patient capacity for involvement and encourages safe and appropriate use of medications [12]. Where appropriate, the virtual clinical pharmacist will provide comprehensive information to the patient or carer to enable safe and effective use of the medications. This will be tailored to suit the patient's individual circumstances and may be in the form of verbal instructions, demonstration, education, a medication list (see Fig. 3 below), written advice or a consumer medicines information sheet.

Health
Western NSW
Local Health District

Discharge Medication List

Name: John Smith			**Allergies/ Adverse Drug Reactions:** Penicillin		**Pharmacy:** Orange Health Service
Regular Medications	**Dosage Directions**				
Name/ strength	**B'fast**	**Lunch**	**Dinner**	**Bedtime**	**Comments**
Amlodipine 5mg tablet	ONE				To help reduce blood pressure
Perindopril 2.5mg tablet	ONE				To help reduce blood pressure
Bisoprolol 5mg tablet	ONE				To help the heart
Atorvastatin 40mg tablet			ONE		To help reduce cholesterol
When Required Medications					
Glyceryl Trinitrate SL Tablet	Place HALF a tablet under the tongue until pain subsides. Repeat every 4 minutes up to a maximum of 3 tablets.				To help treat angina
Medication Changes This Admission Bisoprolol dosage has been increased from 2.5mg to 5mg. Please see your GP for a new prescription. Aspirin has been stopped for the next TWO weeks. See your GP before restarting aspirin					
Compiled By: A. Pharmacist			**Date: 16/10/2019**		

Figure 3: An example of a patient medication list

5.5 Staff education

Virtual pharmacists can influence the use of medicines through information provision to health professionals on the safe prescribing, administration, monitoring and use of medicines for individual patients [12]. The virtual clinical pharmacists may respond directly to a request for information from another health professional. This may be in the form of verbal instructions, demonstration, provision of specific drug protocols or product information and advice on medication availability and formulary restriction.

5.6 Medication Review

Medication order review involves assessing all current and recent medication orders with the aim of optimising quality use of medicines, patient outcomes and minimise medication related problems [9]. The virtual clinical pharmacist will take into account patient specific factors and provide advice on the most appropriate dose, dosage form, timing and duration of therapy so that risk of medication related problems are minimised [12]. The virtual clinical pharmacist will do this by:

- Reviewing all prescribed medication orders
- Optimising chronic disease pharmacotherapy
- Identifying drug related causes of admission
- Detecting medication interactions
- Reviewing medications that may contribute to falls risk
- Optimising venous thromboembolism (VTE) prophylaxis
- Providing antimicrobial stewardship review
- Providing monitoring for narrow therapeutic drugs

5.7 Documentation and intervention recording

The virtual clinical pharmacists will document identified actual and potential medication related problems, clinical decisions and suggested changes to medication therapy in the patient's eMR.

5.8 Communication, engagement and change management

The virtual clinical pharmacists, project lead or other investigators will work on coordinated communication, engagement and change management processes with the study site to ensure the

new model of care is embedded into practice. This will involve providing education and training on the service with the aim of building rapport and ensuring a successful implementation. This engagement may occur face to face or virtually using videoconferencing.

Activities may include:

- Initial site visits to meet staff, engage clinicians and education on the service
- Monthly report on pharmacy activities to provide evidence for NSQHS Standard 4 accreditation
- Service rounding using a structured feedback template
- Short monthly newsletters
- Project update emails
- Monthly staff education

6 RESEARCH TEAM, GOVERNANCE AND FUNDING

6.1 Investigators

Name	Position and Institution	Responsibilities	Contact Details
CHIEF INVESITGATOR			
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ASSOCIATE INVESTIGATORS			
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Dr Chris Oldmeadow	Senior Statistician, Hunter Medical Research Institute	Research design. Assist ethics approval process, data analysis and preparation of publication	christopher.oldmeadow@hmri.org.au
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Lesa Towers	Manager Aboriginal Workforce Capability Development and Culture, WNSWLHD	Leadership in the design and implementation of the project for Aboriginal peoples	lesa.towers@health.nsw.gov.au
Dr Alice Munro	Director of Research, WNSWLHD	Research design, implementation and preparation of publications	alice.munro@health.nsw.gov.au
A/Prof Georgina Luscombe	Associate Professor, Rural Heath, School of Rural Health, University of Sydney	Research design, and preparation of publications	georgina.luscombe@sydney.edu.au
Dr Emma Webster	Senior Lecturer Rural Research School of Rural Health, University of Sydney	Research design and preparation of publications	emma.webster@sydney.edu.au

6.2 Research Governance and Partners

The study will be overseen by a steering committee comprising of representatives from the following services and organisations:

- Sydney Local Health District
- Western NSW Local Health District
- Far West Local Health District
- eHealth NSW
- Centre for Aboriginal Health, NSW Health
- Clinical Excellence Commission
- Agency for Clinical Innovation

Throughout the duration of the study, the Advisory Group will be responsible for the oversight of strategic aspects of the project including operational and strategic management of project; advise on design, clinical implementation and translation of project within the setting of the larger eHealth agenda for NSW; ensure knowledge translation to assist with NSW health policy; ensuring the cultural appropriateness of the service for the Aboriginal community; and assessing the overall impact on patient outcomes or health and wellbeing of the rural and remote population. The group will meet at strategic milestones during the research period and maintain regular contact between meetings to facilitate feedback on specific issues via project updates.

6.3 Funding

Funding for the project had been provided by the NSW Ministry of Health Translational Research Grant Scheme for the 2019-20 and 2020-21 financial years.

7 PROJECT DURATION AND TIME LINE

The VCPS project activities are planned for a total of 8 months from January 2021 to August 2021. Subsequently research papers or conference presentations may occur depending on the outcome of the study. See each intervention of the study for more specific information.

The VCPS high level projected timeline is listed below.

Key Milestone	Achievement Date
Commence recruitment of key resources	January 2021
Ethics application submitted	January 2021
Commence site engagement and change management	January 2021
Project Implementation, change management and communication. Staff credentialing and orientation	February 2021
Commence intervention	March 2021
Data analysis and interpretation	July 2021
Draft reports	July 2021
Final reports	August 2021
Submission of papers to journals and/or conference presentations	August to December 2021

8 AIMS OF PROJECT

The VCPS will evaluate the feasibility of virtual clinical pharmacy support to an elective orthopaedic ward in a tertiary metropolitan hospital where there is no existing clinical pharmacy services. The aim of the project is not to evaluate the effectiveness of clinical pharmacy services which is well defined in the literature.

9 RESEARCH QUESTIONS

The VCPS aims to answer the following research question:

- Is a Virtual Clinical Pharmacy Service feasible in a metropolitan hospital setting?

To assess feasibility the study will:

1. Assess the utilisation of a virtual pharmacy service (routine data)
2. Demonstrate the detection of preventable medication harms and uptake of recommendations (routine data)
3. Assess if the VCPS is perceived to be an acceptable service by patients in a metropolitan setting (Patient Reported Experience Measures Survey)
4. Assess if the VCPS is perceived to be an acceptable service by clinicians in a metropolitan setting (staff focus group)

10 PROJECT SETTINGS AND LOCATIONS

10.1 Site eligibility and selection

For facilities to participate in the study they must meet the following criteria:

- Utilising the eMR and eMeds for medication management
- Not have an existing comprehensive on site clinical pharmacy services
- Agree to participate in the study

Sydney Local Health District (SLHD) was approached due to existing strong relationships with WNSWLHD as a tertiary referral centre. Study site selection was based on a gap analysis of existing on-site clinical pharmacy services within SLHD. Support from SLHD executive, medical, pharmacy, nursing and information technology teams were sought during the study site selection.

10.2 Study site

Pending ethical approval, the feasibility site is a 33-bed elective orthopaedics ward known as Q6E and Q7E located in the Institute of Rheumatology and Orthopaedics at Royal Prince Alfred Hospital (RPA), SLHD, Sydney Australia

11 EVALUATION OF VIRTUAL PHARMACY

11.1 Duration

The virtual pharmacy service and collection of routine health data will begin March 2021 and continue for three months.

11.2 Research design and methodology

Virtual clinical pharmacy services will be provided to the study site as outlined in *What is Virtual Clinical Pharmacy?* (section 5). Virtual pharmacists employed by WNSWLHD and credentialed to work at SLHD will act as an extension of the RPA Hospital pharmacy department and where possible, follow existing workflows and processes as on site pharmacists for delivering pharmacy services. Existing SLHD policies, procedures and guidelines will be followed where relevant. At the end of the three

month period, routinely collected health data will be used to evaluate the feasibility of a virtual clinical pharmacy service.

11.3 Process Measures

The following routinely collected health data will be evaluated post the virtual clinical service feasibility trial:

Process Measure	Data Source	Level of Data
Detection of preventable medication errors	Incident Management System	Patient
Number of pharmacist clinical interventions	eMR DA2 Clinical Pharmacy Interventions	Patient
Number of medication reconciliations completed	eMR report EM002	Facility
Uptake of pharmacy recommendations	eMR DA2 Clinical Pharmacy Interventions	Patient
Number of medication histories completed	eMR report EM007	Facility
Total number of patients receiving a pharmacy service	eMR Report PC039	Patient
Number of Medication Management Plans	eMR Report PC039	Patient
Number of medication lists on discharge	eMR Report PC039	Patient
Number of pharmacist medication reviews	eMR Report PC039	Patient
Number of pharmacist discharge reviews	eMR Report PC039	Patient
Number of pharmacist AMS reviews	eMR Report PC039	Patient
Time spent on Videoconference	Pexip report	Patient
Number of medication verifications for supply	eMR Report EM006/ iPharmacy dispensing data	Patient

11.4 Patient Population

The VCPS aims to provide access to virtual pharmacy services for all patients admitted to the study site.

11.4.1 Inclusion criteria

All orthopaedic inpatients admitted to Q6E and Q7E (Institute of Rheumatology & Orthopaedics) will be eligible for virtual clinical pharmacy services. Patients admitted for major surgeries such as elective knee and hip replacements will be prioritised for pharmacy review in line with standards of practice for hospital pharmacy.

11.4.2 Exclusion criteria

All other wards and services at RPA and across SLHD

11.5 Potential for risk, burden and benefits

11.5.1 Risks

The following risks are anticipated

Risk	Description	Mitigation
Privacy	As with face to face clinical services there is a risk of	• Pharmacists will utilise secure NSW health systems including the eMR, end-to-end

	breach of participant privacy.	telehealth system which fulfils NSW data and privacy guidelines. • All pharmacists will be credentialed within SLHD facilities • All pharmacists and will abide by NSW Health Policies including the code of conduct and privacy policies (such as PD2015_049 NSW Ministry of Health Code of Conduct).
Technology failure	• Telehealth Downtime • eMR downtime	• Utilise a range of technology modalities (eMR, videoconference, telephone call, fax) • Dedicated telehealth devices • Technology testing prior to implementation
Processes, systems and technology	Local policies, procedures, processes and technology solutions may differ between WNSWLHD and SLHD	• Careful workflow analysis conducted prior to implementation • Orientation, training and credentialing of staff prior to implementation • Engaging ICT subject matter experts for systems support • Dedicated referral pathways • Ongoing engagement with the local pharmacy department servicing other departments in the hospital
Staff acceptability	metropolitan site as staff may have limited past exposure to telehealth	• Effective engagement, communication, change management and training • Extensive on boarding highlighting the benefits of clinical pharmacy
Language barriers	Due to the multicultural nature of the study site, there may be more patients with limited understanding of English or use English as a second language.	• Utilise existing interpreter services • Explore options for additional telehealth interpreter service available to NSW Health

11.5.2 Burdens

- Patients may not wish to have reviews over telehealth. Patients, as with face-to-face services, may decline medication interviews and/or education sessions.
- There may be an increased workload for staff at the study site setting up telehealth equipment and assisting when needed
- Increased time for clinicians to manage pharmacist identified interventions

- Increased one off administrative workload to process recruitment, system accesses and orientation for WNSWLHD pharmacists and SLHD pharmacy, ICT and recruitment.
- Increased utilisation of interpreter services to assist pharmacists providing clinical services to patients of non-English speaking backgrounds.

11.5.3 Benefits

It is expected the intervention may:

- Improve medication management for inpatients who otherwise would not have access to on site clinical pharmacy services
- Provide access to a clinical pharmacy service which will improve medication safety and reduce medication related harm
- Engage patients, increase involvement and understanding of medication regimen and encourage safe use of medicines
- Reduce the workload of inpatient pharmacy services by assisting with inpatient medication supply and for nursing and medical staff by performing medication reconciliation
- Improve facility compliance with NSQHS Standard 4- medication safety
- Opportunity to network, collaborate and share knowledge and experience in virtual pharmacy and other relevant areas between health districts
- Demonstrate the feasibility and scalability of virtual pharmacy across health districts
- Influence planning and development of future virtual pharmacy services at SLHD
- Increase staff exposure to virtual service delivery

11.6 Consent

The Investigators are seeking a Waiver of Consent for the use of routinely collected health data (listed in section 11.3) for patient participants due to the high number of patients admitted over the study period. The Investigators believe a Waiver of Consent is suitable as set out in the national statement [29].

- The data collected will be de-identified, therefore there is sufficient protection of the participant's privacy
- There is minimal foreseeable risk, including distress, to participants. Care provided will be as per established standards of pharmacy practice that are currently provided to patients with onsite pharmacy services.
- It is considered impractical to collect consent due to the large cohort of patients over the study period and the virtual nature of the project. The research is likely to be compromised if the participation rate is low, as results may not be indicative of the whole patient population, nor able to be translated to other areas.
- The data will be managed in accordance with relevant security standards to ensure protection of the confidentiality of the data. All computerised data will be kept on a limited access drive on a secure NSW Health server.
- There is a governance process and steering committee in place that has responsibility for appropriate data management.
- This study is of public interest with potential significance in furthering public knowledge in virtual pharmacy services and addressing the current inequity of access to healthcare for patients. The findings will be communicated in scientific congresses and journal publications. This study also aims to address identified health priorities, of improving access to the right care at the right time.

- The possibility of commercial use of derivatives of the data will not deprive the participants of any financial benefits. Regardless of consent procedure, participants would not be offered financial gain for participation in the study
- The Waiver is not prohibited by State, Federal or International Law.

11.7 Data management

A large portion of the measures are routinely collected data that poses minimal risk of patient identification. There are however still a number of process measures that will be collected at a patient level. These measures will be de-identified and pooled for analysis.

All data will be managed in accordance with relevant security standards to ensure protection and confidentiality of the data. All computerised data will be kept on a limited access drive on a secure NSW Health server and maintained for 5 years as per the NHMRC requirements. Paper records will be securely stored in a locked filing cabinet with access restricted to VCPS research team.

Patient level data created by the virtual clinical pharmacy interventions will be recorded in the patient's clinical record on the eMR (PowerChart) as per standard face to face clinical pharmacy. This includes information relating to patient prioritisation, medication history and reconciliation, patient education, medication review and documentation and intervention recording. The electronic health record has sufficient security measures and policies in place to protect patient privacy. These include restricted access, password protection, privacy auditing and access levels set by position. Any eMR reporting will have patient names removed by the person generating the report, but will maintain demographic data such as sex and date of birth for analytical purposes.

11.8 Sample size and data analysis

11.8.1 Quantitative analysis

Descriptive statistical analysis will summarise the process measures.

Sample size: The Institute of Rheumatology and Orthopaedics is a 33 bed mixed orthopaedic with historical average admissions of 50 patients per week. Historically, half of admissions are elective knee and hip replacement and will be prioritised for a pharmacist review. Therefore we estimate a referral rate of 300 patients over the trial period.

12 PATIENT REPORTED EXPERIENCE MEASURES

12.1 Duration

The Patient Reported Experience Measures Survey (PREMS) data collection will start in March 2021 and continue for three months.

12.2 Research design and methodology

Participants who have seen the virtual pharmacist will be invited to complete a PREMS. The PREM survey consists of 12 questions which will be delivered via SMS test message. On opening the survey link participants will be taken to the Customer Feedback Solutions electronic system to complete the survey.

The PREMS will be used to quantitatively assess improvements in patients' knowledge and perceived acceptability of virtual pharmacy. The VCPS questions address patient communication of medication management during hospital admission, patient's confidence managing medications and overall satisfaction with the VCPS (see Appendix 18.2).

12.3 Process and outcome measures

The following outcome and process measures will be used to assess the PREM surveys.

Outcome Measure	Data Source	Level of Data
% overall score	Customer Feedback Systems	Facility
% Score per question	Customer Feedback Systems	Facility
Process Measure	**Data Source**	**Level of Data**
Total number of PREM surveys completed	Customer Feedback Systems	Facility
PREMs results by question	Customer Feedback Systems	Facility
Month on Month PREMS scores by question	Customer Feedback Systems	Facility

12.4 Patient Population

12.4.1 Inclusion criteria

All orthopaedic inpatients admitted to Q6E and Q7E (Institute of Rheumatology & Orthopaedics) who have been seen by the virtual pharmacist be invited to complete the PREMS

12.4.2 Exclusion criteria

The following patient populations will not be asked to complete PREMS surveys:

- Less than 18 years of age
- Do not speak English
- Communication problems that require specialist skills e.g. severe intellectual disabilities, brain injuries or dementia

12.5 Potential for risk, burden and benefits

12.5.1 Risks

- Participant does not have a device to complete survey

12.5.2 Burdens

- Patients may not wish to complete a short survey

12.5.3 Benefits

- The survey is expected to provide evidence the study sites meets NSQHS standard 4.3 which is involving patients in care, meeting patient information needs and shared decision making
- The study is expected to demonstrate that virtual pharmacy is an acceptable mode of delivery for patients
- By demonstrating acceptability, the study has the capacity to develop a model of care that could easily be scaled and implemented in other local health districts across the state and country.

12.6 Consent

Participants will be given an opportunity to decline to participate in the survey when they see the virtual pharmacist. The PREMS will use implied consent as an alternative to consent as outlined in the National Statement [29]. The investigators believe this meets the criteria for implied consent due to:

- Consent is implied by the participant choosing to complete the survey
- Participation is voluntary
- Completion of the PREMS survey carries a low risk to participants, including distress.

- Participant information sheets (see Appendix 18.4) will be provided to participants providing a reasonable time to decline the survey. The participant information sheet provides a contact number to seek more information.
- The data collected will be de-identified, therefore there is sufficient protection of the participant's privacy.
- The data will be managed in accordance with relevant security standards to ensure protection of the confidentiality of the data. All computerised data will be kept on a limited access drive on a secure NSW Health server.
- There is a governance process and steering committee in place that has responsibility for appropriate data management.
- This study is of public interest with potential significance in furthering public knowledge in virtual pharmacy services and addressing the current inequity of access to healthcare for patients. The findings will be communicated in scientific congresses and journal publications
- The implied consent approach is not prohibited by state, federal, or international law.

12.7 Data management

All data will be managed in accordance with relevant security standards to ensure protection and confidentiality of the data. All computerised data will be kept on a limited access drive on a secure NSW Health server and maintained for 5 years as per the NHMRC requirements. Any paper records will be securely stored in a locked filing cabinet in WNSWLHD with access restricted to VCPS research team.

The PREMS data will be collected electronically using the Customer Feedback Systems (CFS) platform. This platform is used by WNSWLHD for the collection, secure storage and reporting of patient reported measures. The survey responses are anonymous but does collect age and sex for demographic analysis of the results.

12.8 Sample size and data analysis

All patients receiving the VCPS will be invited to complete the PREMS (estimated n = 300). Descriptive statistical analysis will summarise patient answers, and linear regression models will be used to explore characteristics associated with the overall score (using age, sex and Aboriginality as independent variables).

13 STAFF FOCUS GROUPS

13.1 Duration

Staff focus groups will be held in June 2021 at the conclusion of the three month feasibility trial.

13.2 Research design and methodology

The focus group will aim to address the perceived acceptability of the service for staff (research question 4) who have worked with the virtual pharmacy. The focus group will be held at the end of the trial to provide adequate time for staff to be exposed to the service and go through the stages of change. The focus group discussion will be qualitative and aim to explore the issues, benefits, barriers and overall acceptability of the VCPS (see Appendix 18.3). Two focus groups will be held. One for doctors, senior staff and managers' and one separate focus group for all other staff to take into account potential power relationships that may inhibit the responses of junior staff. The focus group may be held either face to face or virtually utilising videoconferencing technologies.

13.3 Process and outcome measures

The following measures will be used to evaluate staff acceptability of the VCPS:

Outcome Measure	Data Source	Level of Data
Thematic analysis	Transcripts	Facility
Process Measure	**Data Source**	**Level of Data**
Total number of staff participants	Manual	Facility
Staff role	Manual	Facility

13.4 Participant Population

13.4.1 Inclusion criteria

- All health professionals such as nurses, doctors, allied health and managers who work in clinical areas where the VCPS operates will be invited to participate in the focus group
- Staff must be employed by the Local Health District
- Aged 18 years or over

13.4.2 Exclusion criteria

- Students on placements will be excluded from the focus group

13.5 Potential for risk, burden and benefits

13.5.1 Risks

- Not enough staff will be available to participate in focus groups. The research team will work with sites to enable rostering and holding the focus group at a time to enable staff participation.
- Too many staff wish to participate in focus groups. If too many staff are willing to participate in focus groups then a random selection of participants within each specialty will be selected.
- There is a risk to staff member confidentiality as it is a group session. It will be explained at the beginning of the focus groups that the contents of the session are confidential and not to be discussed outside of the focus group. While the research team will not disclose any information, due to the nature of focus groups confidentiality cannot be guaranteed.
- Participation in the focus group is not anticipated to cause any distress and no personal experiences with medication errors are required to be disclosed. However, should a participant become distressed they will be supported outside the group meeting, until their distress subsides. They will be provided with details of Employee Assistance Program to access further support if required.
- Non-verbal communication cues and responses may be less apparent over videoconferencing technologies. This may include early identification of potential participant distress.

13.5.2 Burdens

- Disruption to clinical duties for staff attending focus groups

13.5.3 Benefits

- The study is expected to demonstrate that virtual pharmacy is an acceptable mode of delivery for staff including doctors and nurses and allied health.

- By demonstrating staff acceptability to virtual pharmacy, the study has the potential to develop a model of care that could easily be scaled and implemented in other local health districts.

13.6 Consent

The staff focus group will require verbal consent from participants. Each participant will be emailed a Participant Information Sheet at least one week prior to the scheduled date of the focus groups. Participants will be given an opportunity to ask any questions at the beginning of the session and then asked for verbal consent to participate before any data collection commences. Consent will be audio recorded.

13.7 Data management

All focus group participants will remain anonymous and responses not linked to individuals. Any publication will omit statements that may identify an individual. Transcripts and recordings will be kept on a secure NSW Health servers only accessible by the research team. Data will be destroyed after 5 years by the chief investigator.

13.8 Sample size and data analysis

A strengths-based approach called 'appreciative enquiry' (an organisations change based methodology) will be used to undertake focus groups with participating staff (n=10 approximately). The focus groups will be audio-recorded, transcribed verbatim and entered into QSR NVivo. Thematic analysis will be utilised to deductively and inductively identify barriers and facilitators, but open to unexpected findings that may contribute to these in each of the study sites.

14 OUTCOMES AND SIGNIFICANCE

14.1 Tangible benefits to patients and staff

This project is expected to improve medication-related communication on transfer of care to primary care providers, empowering patients with a better understanding of their medications, improve concordance with medication management and improving evidence-based prescribing (including antimicrobial stewardship).

This trial has the potential to increase staff exposure and understanding of virtual healthcare delivery. The project has the potential to foster relationships, increase collaboration and knowledge transfer between health districts.

14.2 Potential scalability of the VCPS

A number of small-scale studies have assessed the feasibility and acceptability of telepharmacy services in rural and remote locations [20-23]. This study has the potential to add to existing literature to provide evidence of the feasibility and acceptability of virtual pharmacy in a metropolitan setting. If this trial is successful the VCPS will be operating simultaneously over three LHD's demonstrating the scalability of virtual pharmacy across the NSW health system.

15 ETHICAL APPROVAL

Greater Western Human Research Ethics Committee will provide ethical approval before the study commences.

16 DISSEMINATION OF RESULTS AND PUBLICATIONS

- The results will be prepared and submitted to Journals for publication. Where possible open access publication will be sought to ensure equitable dissemination of information.

- Results will also be published in a report for conferences (e.g. SHPA and NRHA), network meetings and to relevant stakeholders (e.g. Western PHN, ACI, CEC, other LHDs).

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18 APPENDICES

18.1 Glossary of abbreviations

ACI	Agency for Clinical Innovation
AMS	Antimicrobial stewardship review
CEC	Clinical Excellence Commission
CFS	Customer Feedback Systems
DA2	eMR Discern Analytics 2 reporting tool
eMeds	Electronic medication management (part of the Cerner eMR)
eMR	Electronic medical record (including Cerner Millennium PowerChart and FirstNet)
FWLHD	Far West NSW Local Health District
IRO	Institute of Rheumatology and Orthopaedics
LHDs	Local Health Districts
Med Rec	Medication reconciliation
MMP or eMMP	Medication Management Plan/ electronic Medication Management Plan
NRHA	National Rural Health Alliance
NSQHS	National Safety & Quality Health Service Standards
PFML	Patient friendly medication list
PREMS	Patient Reported Experience Measures Survey
RPA	Royal Prince Alfred Hospital
SHPA	Society of Hospital Pharmacists of Australia
SLHD	Sydney Local Health District
VCPS	Virtual Clinical Pharmacy Service
VTE	Venous thromboembolism
WNSWLHD	Western NSW Local Health District

18.2 Patient reported experience measures survey

18.2.1 PREMS survey invitation

We are interested in your experience with the pharmacy service. Your feedback will help to improve services in the hospital.

This survey takes about 5 minutes to complete. Participation is voluntary and all responses are confidential. This survey is being conducted by Customer Feedback Systems (CFS) on behalf of …… hospital. Reply 'No' to opt out.

18.2.2 PREMS survey questions

Virtual Clinical Pharmacy Service Patient Experience Survey Questions

1	Did a pharmacist discuss your medicines with you during your stay in hospital?	Yes	No [The selection of No ends the survey]				
2	If you talked to the pharmacist through videoconferencing, how would you rate the quality of the picture and sound?	very good	good	Neither Good or Poor	poor	very poor	Not Applicable
3	The pharmacist talked to me in a way I could understand?	Strongly agree	Agree	Neither Agree or Disagree	Disagree	Strongly disagree	
4	Following my discussion with the pharmacist, I feel confident in managing my medications at home?	Much more confident	A little more confident	about the same	Less confident	worse than before	
5	I was involved as much as I wanted in making decisions about my medications while in hospital?	Strongly agree	Agree	Neither Agree or Disagree	Disagree	Strongly disagree	
6	Overall, how would you rate your experience of care with the Pharmacist?	Very good	Good	Neither Good or Poor	Poor	Very Poor	
7	How likely are you to recommend the pharmacy service to your	Extremely likely	likely	neither likely or unlikely	unlikely	Extremely unlikely	

	friends or family if they were in hospital?						
8	Please select your gender	female	male	Indeterminate / Intersex / Unspecified	Other	prefer not to say	
9	What is your age?	18-54	55-64	65-74	75-84	85+	prefer not to say
10	Would you like to make a…	Compliment	Suggestion	Complaint	Nothing to add		
11	Please enter your feedback in the space provided	[Free text]					

18.3 Focus group questions

To be completed 3 months After Virtual Clinical Pharmacy Service has commenced at the site. Information sheets will be made available in the focus group room.

I am here as an independent person to conduct the focus group to find out how VCPS has been going and if you would recommend any changes. It is really important to get insight and feedback from people who have a good understanding of how the service works and not just count how many patients have been seen. Your contribution will be invaluable.

This group discussion will go for about 30 minutes, there are 8 questions about your experiences working with the pharmacists and supporting the pharmacy service. It will be recorded and transcribed into a word document to be compiled with the information collected from other sites. You will not be individually identified in any reports or publications arising from this discussion. It is confidential to the extent that your personal details are not required however, obviously other people in this group will know what you have said.

Have you read the information sheet about the research part of the project? Do you have any questions about the research or the focus group?

By continuing to participate in this group you are giving consent for the discussion to be recorded and your comments used as part of the research. Is that okay with everyone (get verbal consent)

1. The virtual pharmacy has been operating for 3 months at this site. What was the implementation like? (Prompt – how were you informed about it? How it would work? How to refer patients?) (service delivery)
2. What is your experience of the virtual clinical pharmacy service? (Prompt - has the virtual clinical pharmacy service changed the way you work? What tasks are you required to do that are different? Describe what you like or don't like about the service, how does it benefit clinicians, or does it cause any problems (Employee experience)
3. What was your experience of availability of a clinical pharmacist for medication review and medication advice prior to the virtual service? (Prompt- was the pharmacist approachable? (employee experience)
4. What benefits do patients and their cares experience as a result of the VCPS? (Prompt – Compliance with meds, understanding of meds, availability of pharmacist, ask for examples - Do you have any VCPS success stories you would like to share?) (Employee experience)
5. What about problems for patients? Can you give any examples? (Employee experience and service delivery)
6. How well do you think the structure and management of virtual pharmacy are working? Can you recommend any changes? (Prompt- What feedback have you received from the VCPS e.g. monthly data, in services, service rounding, one-on-one? How do you feel VCPS supports your work?) (service delivery)
7. What is your experience with the formal or informal education and advice provided by the Virtual Clinical Pharmacy Service? (service delivery/ experience – Are you happy with the level of support and education provided to develop skills in medication management)
8. What else would you like to add (do you experience challenges with medication information and advice when the pharmacist is not available? For example weekends, what are your thoughts regarding the level of service provided? E.g. ward coverage, ED, inpatient, HiTH,)

18.4 Participant information sheet

Dr Shannon Nott
Chief Investigator
T: +61 (2) 6378 6272
E: Shannon.Nott@health.nsw.gov.au

Participant Information Sheet

Invitation
You are invited to participate in a research study called *Feasibility and acceptability of a virtual clinical pharmacy service (VCPS) in a tertiary metropolitan hospital*

Who is doing this project?
Project team: Shannon Nott, Ged Hawthorn, Brett Chambers, Lesa Towers, Chris Doran, Chris Oldmeadow, Jo-Anne Brien, Julaine Allan, Alice Munro, Georgina Luscombe, Emma Webster, Clare Coleman
Organisations: Sydney Local Health District, Western NSW Health District, Far West Health District, Central QLD University, Hunter Medical Research Institute, University of Sydney

What is the purpose of this study?
We are conducting a research project to evaluate the provision of hospital pharmacy services (VCPS) via video link to patients in elective orthopaedics (Q6E and Q7E wards) at Royal Prince Alfred Hospital. The aim of the virtual pharmacy service is to improve medication use for patients in hospital where they do not have an onsite hospital pharmacist.

What does this study involve?
If you see a pharmacist via video link you will be asked to complete a short survey while you are in hospital to provide feedback on your experience. We will send the survey to your smart phone to complete via a secure electronic platform. Your feedback will help us review how care is delivered and improve it.

Why have I been invited to participate in this study?
You are eligible to participate in this study because you are a patient in elective orthopaedics (Q6E or Q7E) at Royal Prince Alfred Hospital where the virtual pharmacy service is operating.

Do I have to participate in this study?
Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you. You can withdraw consent and stop participation at any time without giving reasons.

How is this study being paid for?
This project is funded by the NSW Ministry of Health Translational Research Grants Scheme.

Are there any good things about being in the study?
This study aims to further our experience with pharmacy telehealth and may benefit the community by developing recommendations for best practice. The study will also help Sydney Local Health District and other health services evaluate and plan future virtual services including pharmacy telehealth.

Are there any bad things about being in the project?
This study will take up some of your time, but it won't cost you anything or it is not anticipated to cause any problems.

What will happen with the information collected during this project?
All of the information that we have from the project will be stored in a safe place and we will look after it carefully. We will not ask any information that may identify you and all responses will be anonymous and strictly confidential. We may also develop a report and submit it to an academic journal for publication; however information will be provided in such a way that you cannot be identified.

Will anyone else know I was in the study?
No identifiable information is collected about you in connection with this study, however the people treating you in hospital will know whether or not you are participating in this study. While all effort will be made to maintain confidentiality due to shared patient rooms, we cannot absolutely guarantee this.

What if I am not happy with the project or the people doing the project?

This ethical aspects of this research have been approved by the Greater Western Human Research Ethics Committee (HREC) of the Western NSW and Far West Local Health Districts. The conduct of this study at the Royal Prince Alfred Hospital has been authorised by the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer on 9515 7899 and quote protocol number X21-0117.

You can contact the project supervisor, Shannon Nott on (02) 6378 6272 or email Shannon.Nott@health.nsw.gov.au

This sheet is for you to keep.

18.5 Staff focus group participant information sheet

Dr Shannon Nott
Chief Investigator
T: +61 (2) 6378 6272
E: Shannon.nott@health.nsw.gov.au

Participant Information Sheet
Feasibility and acceptability of a virtual clinical pharmacy service (VCPS) in a tertiary metropolitan hospital

Project team: Shannon Nott, Ged Hawthorn, Brett Chambers, Lesa Towers, Chris Doran, Chris Oldmeadow, Jo-Anne Brien, Julaine Allan, Alice Munro, Georgina Luscombe, Emma Webster, Clare Coleman

Organisations: Sydney Local Health District, Western NSW Health District, Far West Health District, Central QLD University, Hunter Medical Research Institute, University of Sydney

Hello,

We are doing a research project to evaluate the Virtual Clinical Pharmacy Service (VCPS) that is being delivered to elective orthopaedics (Q6E or Q7E) at Royal Prince Alfred Hospital via a video link. The virtual pharmacy service aims to improve medication management, reduce medication harm, improve patient medication knowledge, and support staff with patients. Your workplace was selected to be involved in the project.

You are invited to participate in a focus group discussion to describe your experiences in using the virtual clinical pharmacy service. You are eligible to participate in this discussion because you work where the virtual clinical pharmacy service operates.

This sheet tells you what participating in this research project will involve. Please read it carefully and take time to decide whether or not you wish to take part.

- If you decide to take part in the research, you will be asked to participate in a focus group *discussion, lasting up to 30 minutes*, about your experience with virtual pharmacy services in your ward. There will be an opportunity at the beginning of the session to ask the researcher/s any question. We will then ask you to give verbal consent prior to starting.
- During the focus group, members of the research team will be present to facilitate the discussion and take notes of the key points.
- The focus group will take place in *a meeting room at your workplace*, however the project team may facilitate the session virtually using videoconferencing technologies.
- The discussion will be *recorded using an audio recording device* for data capture and analysis purposes. You will not be able to participate in this study if you do not agree to the information being recorded.
- You can leave the group at any time if you no longer wish to participate. Please note it will not be possible to exclude any responses you have made from the recording.

Who is doing this project?

The project team includes representatives from these organisations: Western NSW LHD, Far West NSW LHD, Central QLD University, Hunter Medical Research Institute and the University of Sydney. This project is funded by the NSW Ministry of Health Translational Research Grants Scheme.

What will happen with the information collected during this project?

The research team will record all focus group discussions and write them up word for word. Once all the recordings are transcribed, the transcripts will be analysed to identify key themes. These themes will be highlighted in an evaluation report that will not identify individuals.

We may also develop a report and submit it to an academic journal for publication or presented at conferences. No services or individuals will be identifiable in these reports or presentations.

Do I have to participate in this project?

No, participation is voluntary. If you decide you want to be in the project and then you change your mind later, that's ok. You can withdraw consent and stop participation in the focus group at any time without giving reasons and without any penalty. This will not affect your relationship with the project team or your employer. If you decide to withdraw consent to the focus group it will not be possible to exclude your contribution from the audio recording.

Will anyone else know what I say in the project?

We won't tell anyone else what you say to us but the other people in the focus group will know what you said. Although we will ask participants to respect the confidentiality of what is said, due to the nature of focus groups, we cannot absolutely guarantee this. All of the information that we have from the project will be stored in a safe place and we will look after it carefully. In our report about the project we won't say your name, or your worksite's name and no one will know that you were in the project.

How long will it take to be involved in this project?

It will take up to 30 minutes to complete the focus group discussions.

Are there any good things about being in the project?

You won't get anything for being in the project. We think this project will benefit the community by developing recommendations for best practice. This will help Sydney Local Health District and other health services to do their work better, by enhancing the care provided around medications.

Are there any bad things about being in the project?

This project will take up some of your time, but it won't cost you anything or cause any problems. You will not need to talk about personal experiences with medications or your own health.

What if I am not happy with the project or the people doing the project?

This ethical aspects of this research have been approved by the Greater Western Human Research Ethics Committee (HREC) of the Western NSW and Far West Local Health Districts. The conduct of this study at the Royal Prince Alfred Hospital has been authorised by the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer on 9515 7899 and quote protocol number X21-0117.

You can contact the project supervisor, Shannon Nott on (02) 6378 6272 or email Shannon.Nott@health.nsw.gov.au

This sheet is for you to keep.