Perceptions, impact and scope of medication errors with opioids in Australian specialist palliative care inpatient services: A mixed methods study (the PERISCOPE project)

Nicole Heneka
Appendix 1: Publications, permissions and associated media

Study 1


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Appendix 1: Publications, permissions and associated media

Study 3


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On Wed, 27 Feb 2019 at 10:57, Nicole Heneka <nicole.heneka1@mynd.edu.au> wrote:

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Thank you very much.

Nicole

Kind Regards
Nicole Heneka

PhD Candidate
The University of Notre Dame Australia
School of Nursing
160 Oxford St, Darlinghurst, NSW
Postal address: PO Box 110, Broadway NSW 2007, Australia

Email: nicole.heneka1@mynd.edu.au
Phone: 0400 674 378
A review of reported medication errors involving opioids in palliative care has found that the majority of errors involve misunderstanding and may be contributing to the burden of palliative patients’ pain. Australian researchers looked at opioid errors in three inpatient palliative care services in NSW and found that the rate of errors involving opioids was almost three times higher than in other healthcare settings. The most common types of errors were missed doses and wrong doses, with 17 per cent of patients receiving a lower dose of opioid than ordered.

Journal/Conference: BMJ Supportive & Palliative Care

Organisation/s: The University of Wollongong Australia, The University of Sydney, University of South Australia, University of Technology Sydney (UTS)

Funders: This work was supported by an Australian government, Collaborative Research Networks (CRN) program scholarship (NH).

Media Release

From University of South Australia

Palliative care study highlights need for more vigilance

An Australian review of palliative care services has revealed the impact of opioid medication errors on patients in the final weeks of their lives.

In a paper published in BMJ Supportive & Palliative Care today, researchers from NSW and the University of South Australia reveal that errors involving opioids are almost three times higher than previously reported in other healthcare settings.

Researchers looked at opioid errors in three inpatient palliative care services in metropolitan NSW over a two-year period, from 2013-2015. More than half of the errors (57 per cent) involved patients receiving a lower dose of pain-relief than ordered, requiring clinical intervention in a third of cases. The majority of patients had cancer and were aged in their 70s.

Professor Deltra Rowett, from UniSA’s School of Pharmacy and Medical Sciences, says the study highlights the importance of understanding why opioid errors occur — particularly when timing — which may contribute to patients’ pain.

“Palliative care clinicians have identified that such use of opioids is a patient safety priority and this study is an important first step in quantifying and identifying opioid errors,” Professor Rowett says.

“The high rate of errors in palliative care environments compared to other healthcare services most likely reflects the higher-volume of opioids such as morphine being used for patients to manage their pain in the last stages of their lives.”

Of 55 opioid errors identified, most involved morphine dosage (53 per cent) and two-thirds related to administration errors. Researchers say better understanding the factors that contribute to or mitigate opioid errors is a priority in this clinical setting.

Medication errors pose one of the greatest risks to patient safety, researchers say, particularly those involving opioids, which are high-risk medicines. The risk is amplified in patients who are older, have multiple health issues and are taking numerous medications.

To the editors

Opioid errors in inpatient palliative care services: a retrospective review is published in the British Medical Journal for a copy of the paper please email cancer.glow@health.sa.gov.au.

The study was undertaken by Nicole Himmels and Professor Jane Phillips from the University of Technology, NSW; Professor Tim Shaw, University of Sydney; Professor Deltra Rowett; UniSA; and Dr. Samuel Lapitis, St George Hospital, Sydney.
Opioid errors add to patient suffering, study finds

Melissa Cunningham

A review of medication errors involving opioids in palliative care has found under-dosing may be contributing to the burden of the pain of terminally ill patients in the last weeks of their lives.

In a paper published in British Medical Journal Supportive and Palliative Care today, researchers from NSW and the University of South Australia found errors involving opioids are almost three times higher than previously reported in other healthcare settings.

The most common types of errors were missed doses and wrong doses, with the study finding 37 per cent of patients in palliative care received a lower dose of opioid than ordered.

The researchers looked at opioid errors in three independent palliative care services in metropolitan NSW.

The study found the errors adversely impacted on pain and symptom management in 42 per cent of patients, with more than half of them requiring additional treatment as a direct consequence of the opioid error.

The majority of patients examined had terminal cancer and were aged in their 70s.

Opioids are a high-risk medicine frequently used to manage palliative patients' cancer-related pain and other symptoms. But researchers found that, despite the high volume of use in inpatient palliative care services, few studies have focused on opioid errors in this population.

Professor Debra Rowett of the University of South Australia's school of pharmacy and medical sciences said the study highlighted the importance of understanding why opioid errors occur – particularly lower dosing, which can contribute to the pain of terminally ill patients.

"Palliative care clinicians have identified that safe use of opioids is a patient safety priority and this study is an important first step in quantifying and identifying opioid errors," Professor Rowett said.

"The high rate of errors in palliative care environments compared to other healthcare services most likely reflects the higher volume of opioids such as morphine being used for patients to manage their pain in the last stages of their lives."

'Safe use of opioids is a patient safety priority.'

Of the 85 opioid errors identified, most involved morphine dosages (35 per cent) while two-thirds related to administration errors.

The researchers argued better understanding the factors that contribute to or mitigate opioid errors must be a priority in palliative care.

The researchers added medication errors posed one of the greatest risks to patient safety, particularly those involving opioids, which are high-risk medicines.

The risk is amplified in patients who are older, have multiple health issues and are taking numerous medications, the study said. It also found medication errors are consistently under-reported.
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Subject: The best article to read this month

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BMJ Supportive & Palliative Care

Dear Philippa,

It can be difficult to stay on top of the latest research and discussion in your field, so we've highlighted an interesting article recently published that we hope you enjoy!

Opioid errors in inpatient palliative care services: a retrospective review

Best wishes,
The BMJ Supportive & Palliative Care team
Study 4


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Nicole Heneka, Tim Shaw, Debra Rowett, Samuel Lapkin, and Jane L. Phillips

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Study 5


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Appendix 2: Severity Assessment Code (SAC) tables

### Severity Assessment Code (SAC)

**STEP 1**  Consequences Table: Use this table as a guide; the examples listed here are not exhaustive

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Death of patient due to natural causes (e.g., heart attack)</td>
<td>Patient with heart attack due to natural causes.</td>
</tr>
<tr>
<td>Staff</td>
<td>Death of a staff member</td>
<td>Permanent injury to a staff member.</td>
</tr>
<tr>
<td>Visitor</td>
<td>Death of a visitor</td>
<td>Permanent injury to a visitor.</td>
</tr>
<tr>
<td>Service</td>
<td>Complete loss of service or output</td>
<td>Major loss of agency service to users.</td>
</tr>
<tr>
<td>Financial</td>
<td>Loss of assets</td>
<td>Loss of assets due to fire, theft, or fraud.</td>
</tr>
<tr>
<td>Environmental</td>
<td>Environmental damage</td>
<td>Loss of assets due to environmental damage.</td>
</tr>
</tbody>
</table>

**STEP 2**  Likelihood Table

<table>
<thead>
<tr>
<th>Probability</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent</td>
<td>Likely</td>
</tr>
<tr>
<td></td>
<td>Will probably occur in most circumstances (several times a year)</td>
</tr>
</tbody>
</table>

**STEP 3**  SAC Matrix

<table>
<thead>
<tr>
<th>Consequence</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious</td>
<td>Major</td>
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<tr>
<td>Frequent</td>
<td>1</td>
</tr>
<tr>
<td>Likely</td>
<td>1</td>
</tr>
<tr>
<td>Possible</td>
<td>1</td>
</tr>
<tr>
<td>Unlikely</td>
<td>2</td>
</tr>
<tr>
<td>Rare</td>
<td>3</td>
</tr>
</tbody>
</table>

**STEP 4**  Action Required Table

<table>
<thead>
<tr>
<th>Action Required</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extreme risk</td>
<td>Immediate action required – Notify Organization Director. Summation report for all SAC 1 incidents must be forwarded to Organization Director and QBAD within 48 hours. Confidential Root cause analysis (RCA) investigation must be undertaken.</td>
</tr>
<tr>
<td>High risk</td>
<td>Notify Organization Director – Detailed investigation required. Ongoing monitoring of trended aggregated incident data may also identify and prioritize issues requiring a practice improvement project.</td>
</tr>
<tr>
<td>Medium risk</td>
<td>Concise analysis must be undertaken – Aggregate data analysis may also be done for practice improvement purposes.</td>
</tr>
<tr>
<td>Low risk</td>
<td>Concise analysis must be undertaken – Aggregate data analysis may also be done for practice improvement purposes.</td>
</tr>
</tbody>
</table>

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![Image of the SAC tables](image-url)
**Appendix 3: Permission to reproduce Yorkshire Contributory Factors Framework**

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</tr>
<tr>
<td>Description of figure/table/extracts</td>
<td>Figure 2: The Yorkshire Contributory Factors Framework</td>
</tr>
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<td>Clinicians’ perceptions of opioid error contributing factors in inpatient palliative care services: A qualitative study.</td>
</tr>
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<td>Dissertation/Thesis</td>
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<td>Author of new article</td>
<td>Nicole Heneka</td>
</tr>
<tr>
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</tr>
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<td>Estimated size of new article (pages)</td>
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<td>Invoice</td>
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</table>
Appendix 4: Study 3a - snapshot audit data extraction tool

Variables:

1. Study ID
2. Date of admission
3. Date of discharge
4. Number of days on ward in snapshot audit period
5. Opioid regular order 1-5 (opioid, route, dose, timing)
   a. date ordered
   b. time commenced
   c. number of times administered in audit period (n)
   d. ceased (if applicable)
6. PRN opioid order 1-5 (opioid, route, dose, timing)
   a. date ordered
   b. time commenced
   c. number of times administered in audit period (n)
   d. ceased (if applicable)
7. STAT opioid order 1-5 (opioid, route, dose, timing)
   a. date/time ordered
   b. time administered
   c. number of times administered in audit period (n)
### Appendix 5: Study 3b data collection tool (retrospective audit)

<table>
<thead>
<tr>
<th>1. Patient data sheet</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Demographics</strong></td>
</tr>
<tr>
<td><strong>RiskMan/IIMS Incident #</strong></td>
</tr>
<tr>
<td>Age in years</td>
</tr>
<tr>
<td>Reason for admission</td>
</tr>
<tr>
<td>Length of stay (days)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Opioid Error Data</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of incident</td>
</tr>
<tr>
<td>Route</td>
</tr>
<tr>
<td>Timing</td>
</tr>
<tr>
<td>Site ID</td>
</tr>
<tr>
<td>Error made by</td>
</tr>
</tbody>
</table>

**Details of patient outcome following incident:**

**Action by service following incident:**

**Other notes:**

1. Incident as recorded in patient chart:

2: Incident notes from RiskMan/IIMS:

3. Contributing factors per RiskMan/IIMS:
Appendix 6: Audit summary exemplar for qualitative study (Study 5)

Opioid Error Audit - Main Messages

- Over a three year audit period (2013-2015), opioid incidents were the major medication related clinical incident reported at [site] accounting for two thirds of all reported medication incidents.

- Three quarters of reported opioid incidents reached the patient at [site] with almost 40% of these patients requiring clinical intervention to manage symptoms directly related to the incident.

- Opioid administration and prescribing problems were the most frequently reported incident category at [site].

- Omitted opioid doses were the major reported administration incident type reported at [site].

- Nurses were instrumental in identifying and rectifying potential prescribing incidents, or alerting medical staff to other incidents that had already reached the patient.

- Patients were more likely to receive an under-dose of opioid as a result of opioid prescribing or administration incidents than an over-dose.

- Whereas administration incidents were more likely to result in an opioid under-dose, all reported prescribing incidents that reached the patient resulted in an opioid over-dose at [site].

Figure 1: [site] - Percentage of reported opioid incidents by problem type
Table 1: Reported opioid incidents by problem and incident type

<table>
<thead>
<tr>
<th>Problem type % (n)</th>
<th>Incident type</th>
<th>(N=45) (100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Administration 51.1% (n=23)</strong></td>
<td>Omitted dose</td>
<td>10 (43.5)</td>
</tr>
<tr>
<td></td>
<td>Wrong dose</td>
<td>4 (17.4)</td>
</tr>
<tr>
<td></td>
<td>Wrong drug</td>
<td>4 (17.4)</td>
</tr>
<tr>
<td></td>
<td>Wrong patient</td>
<td>3 (13.0)</td>
</tr>
<tr>
<td></td>
<td>Wrong route</td>
<td>1 (4.3)</td>
</tr>
<tr>
<td></td>
<td>Device – wrong rate</td>
<td>1 (4.3)</td>
</tr>
<tr>
<td><strong>Prescribing 24.4% (n=11)</strong></td>
<td>Medication charting</td>
<td>4 (36.4)</td>
</tr>
<tr>
<td></td>
<td>Opioid conversion error</td>
<td>3 (27.3)</td>
</tr>
<tr>
<td></td>
<td>Wrong dose</td>
<td>2 (18.2)</td>
</tr>
<tr>
<td></td>
<td>Wrong drug</td>
<td>2 (18.2)</td>
</tr>
<tr>
<td><strong>Patient factors 8.9% (n=4)</strong></td>
<td>Patient self-administered opioid</td>
<td>2 (50.0)</td>
</tr>
<tr>
<td></td>
<td>Drug discrepancy</td>
<td>2 (50.0)</td>
</tr>
<tr>
<td><strong>Documentation 6.7% (n=3)</strong></td>
<td>Withheld drug not documented</td>
<td>1 (33.3)</td>
</tr>
<tr>
<td></td>
<td>Administered dose not signed in med chart</td>
<td>1 (33.3)</td>
</tr>
<tr>
<td></td>
<td>Medication entry error in drug register</td>
<td>1 (33.3)</td>
</tr>
<tr>
<td><strong>Near miss 4.4% (n=2)</strong></td>
<td>Wrong patient</td>
<td>2 (100)</td>
</tr>
<tr>
<td><strong>Controlled drug discrepancy 2.2% (n=1)</strong></td>
<td>Medication entry error in drug register</td>
<td>1 (100)</td>
</tr>
<tr>
<td><strong>Drug storage/wastage/security 2.2% (n=1)</strong></td>
<td>Patient S8 drug storage</td>
<td>1 (100)</td>
</tr>
</tbody>
</table>
Appendix 7: Participant information sheet and consent form (master) Study 5

Part 1  What does my participation involve?

1  Introduction

You are invited to take part in this research project, which is called: Specialist palliative care clinicians’ and health service managers’ perceptions and experiences of opioid errors within their service: a mixed methods study.

You have been invited because you are a clinician involved in the prescribing, dispensing or administration of opioids in a specialist palliative care service and/or you are a manager involved with the opioid medication process/patient quality and safety.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or colleague.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read
• Consent to take part in the research project
• Consent to be involved in the research described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.
2 What is the purpose of this research?

Aim of the project
The aim of this project is to explore clinician (registered nurses, doctors, pharmacists) and health service managers (managers) perceptions of and attitudes towards opioid errors in specialist palliative care services. This includes: error type and incidence; reporting practices; patient and clinician impact; barriers and facilitators to safe opioid medication processes, e.g., ordering, dispensing, administration; and identification of priority areas for strategies to address local opioid errors.

Project background
Specialist palliative care services oversee a higher volume of opioid orders and administrations compared to other acute care services, with a corresponding increased potential for error. Addressing opioid errors in palliative care services has been identified as a quality improvement priority by senior clinicians, however, there is very little research on opioid error types and strategies to reduce opioid errors in specialist palliative care services. This project is an opportunity to gain an in-depth understanding of the contributing and mitigating factors to opioid errors so that tailored intervention and implementation strategies that address these errors in adult specialist palliative care services can be developed.

The results of this research will be used by the researcher, Nicole Heneka, to obtain a Doctor of Philosophy.

3 What does participation in this research involve?

This project is being conducted as a series of focus groups and semi-structured interviews conducted at [Insert site name]. Focus groups and semi-structured interviews will run for approximately 30-60 minutes. If you consent to participate, you will be asked to provide your preferred email address so the focus group and/or interview details can be sent to you. You will also be asked complete a short demographic survey (approximately 5 minutes to complete). No study activities (e.g, survey completion, provision of contact details), will occur before you have signed the consent form.

During the focus groups and semi-structured interviews, a facilitator will guide the discussion to explore the groups’ perceptions of opioid error type and incidence; reporting practices; patient and clinician impact; barriers and facilitators to safe opioid medication processes, e.g., ordering, dispensing, administration; and identification of priority areas for strategies to address opioid errors in your service. Focus group discussions and semi-structured interviews will be audio recorded.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no costs associated with participating in this research project, nor will you be paid.

4 Other relevant information about the research project

This project follows on from a quality audit of opioid errors in your service. The results of this audit will be presented at the start of the focus groups. There are three specialist palliative care services taking part in this research project, with approximately 30 participants in total.

Focus groups will be structured by roles in the opioid medication process, i.e., opioid ordering, opioid administration, opioid dispensing and/or quality and safety. For example, participants involved primarily in opioid administration (nurses) will be grouped together.

Semi-structured interviews can be conducted: face to face at [Insert site name]; by phone; or via Skype, at a time that suits you and the researcher(s).
5  Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with professional staff or your relationship with [Institution].

6  What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include: a better understanding of why opioid errors occur in this service and how they could be prevented; recommendations for future quality improvement projects to support and re-enforce safe opioid medication processes; an opportunity to reflect on your role in the medication process and identify strategies that support you in safe opioid medication processes; an opportunity to explore the impact of opioid errors on patients and identify practices which support patient safety.

7  What are the possible risks and disadvantages of taking part?

The risks associated with this study are perceived to be low. In the focus groups and semi-structured interviews we will be exploring opioid medication practices. You may feel that some of the questions we ask make you feel uncomfortable due to previous exposure to or awareness of medication errors. If you do not wish to answer a question, you do not need to answer. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge.

Whilst all care will be taken to maintain privacy and confidentiality in the focus groups, you may experience embarrassment if one of the group members were to repeat things said in a confidential group meeting.

8  What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do withdraw, you will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

9  Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include unforseen events that affect the researchers capacity to complete the project.
10 What happens when the research project ends?

If you give us your permission by providing your consent, we plan to publish the results in a peer reviewed journal. In any publication, information will be provided in such a way that you and your place of work cannot be identified. The purpose of the published information is to inform the development of strategies to reduced opioid errors for health services in Australia and overseas. Results of the study will be provided to you, if you wish. Additionally, a report summarising the study findings will be prepared and/or presented in your service within 12 months of project completion.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

By signing the consent form you consent to the research team collecting and using personal information about you for the research project. The personal information that the research team collect and use is limited to the questions found in the demographic survey. Any information obtained in connection with this research project that can identify you, e.g., as disclosed in the focus groups, will remain confidential. Any identifiable information that is collected form you in the demographic survey will also remain confidential.

Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Only the researchers named above will have access to your identifiable details. Information you provide will be non-identifiable prior to data analysis and held securely at the University of Technology Sydney under password protection.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your express permission. Any reports or publications resulting from this study will not identify your place of work.

In accordance with relevant Australian and/or New South Wales privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

12 Complaints and compensation

If you suffer any distress as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

13 Who is organising and funding the research?

This research project is being conducted by Prof Jane Phillips and Ms Nicole Heneka (University of Notre Dame Australia). No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

14 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of St Vincent’s Hospital (Darlinghurst). The HREC reference for this study is: LNR/16/SVH/321: This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been
developed to protect the interests of people who agree to participate in human research studies.

15 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the following people:

Research contact person
Name Nicole Heneka
Position Co-ordinating investigator
Telephone 0400 674 378
Email nicole.heneka1@my.nd.edu.au

Name
Position Site Principal Investigator
Telephone
Email

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person
Name [Name]
Position [Position]
Telephone [Phone number]
Email [Email address]

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC name: St Vincent's Hospital HREC
HREC Executive Officer HREC Executive Officer
Telephone 02 8382 4960
Email SVHS.Research@svha.org.au

Reviewing HREC approving this research and HREC Executive Officer details

Local HREC Office contact
Name [Name]
Position [Position]
Telephone [Phone number]
Email [Email address]

University HREC Office contact
Name Dr. Natalie Giles
Position Research Ethics Officer
Telephone 08 9433 0964
Email Natalie.Giles@nd.edu.au
Demographic questions accompanying participant information and consent forms

This study has been approved by the St Vincent’s Hospital Human Research Ethics Committee (LNR/16/SVH/321). Please ensure you have read and signed the consent form before completing this survey and providing your contact information. The following questions assist the research team in data analysis and interpretation of the focus groups/interviews. All responses to these questions will be non-identifiable. Only global data will be reported in the publishing of the results, individuals and the service they work at will not be identified. The last section asks you to select whether you would like to participate in a focus group, a semi-structured interview, or both; and to provide contact details so the research team can set up a time that suits you. Thank you for taking part in this study.

1. What is your age in years? _________

2. What is your gender? (Tick one answer only)
   - Male
   - Female

3. What is your discipline? (Tick one answer only)
   - Nursing
   - Medical
   - Pharmacy
   - Quality and Safety - Please specify your role: __________________________
   - Service Management - Please specify your role: ________________________
   - Other (please specify): ____________________________________________

4. What is your classification (clinicians)? (Tick one answer only)

<table>
<thead>
<tr>
<th>Nursing</th>
<th>Medical</th>
<th>Pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolled Nurse</td>
<td>Intern</td>
<td>Pharmacy Assistant</td>
</tr>
<tr>
<td>Endorsed Enrolled Nurse</td>
<td>Resident Medical Officer</td>
<td>Pharmacy Technician</td>
</tr>
<tr>
<td>Registered Nurse</td>
<td>Senior Resident Medical Officer</td>
<td>Senior Pharmacist</td>
</tr>
<tr>
<td>Clinical Nurse Educator</td>
<td>Registrar – Basic Trainee</td>
<td>Deputy Director of Pharmacy</td>
</tr>
<tr>
<td>Clinical Nurse Consultant</td>
<td>Registrar – Advanced Trainee</td>
<td>Director of Pharmacy</td>
</tr>
<tr>
<td>Clinical Nurse Specialist</td>
<td>Consultant</td>
<td></td>
</tr>
<tr>
<td>Nurse Practitioner</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurse Unit Manager</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OTHER (Please specify):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A63
5. What is highest level of education you have attained (nurses and pharmacists only)?
   (Tick one answer only)
   - Certificate IV
   - Diploma
   - Advanced Diploma
   - Bachelor Degree
   - Graduate Certificate
   - Post Graduate Diploma
   - Masters Degree
   - Other (please specify): ______________________________

6. How many years have you been a nurse/doctor/pharmacist? (question tailored to discipline) (Tick one answer only)
   - < 1 year
   - 1-2 years
   - 3-5 years
   - 6-10 years
   - 11-15 years
   - 16-20 years
   - 21 years or more

7. How many years of experience do you have specifically caring for patients in palliative care? (Tick one answer only)
   - < 1 year
   - 1-2 years
   - 3-5 years
   - 6-10 years
   - 11-15 years
   - 16-20 years
   - 21 years or more

8. How many years have you worked in this unit? (Tick one answer only)
   - < 1 year
   - 1-2 years
   - 3-5 years
   - 6-10 years
   - 11-15 years
   - 16-20 years
   - 21 years or more

9. What is your primary role in the opioid medication process?
   - Prescribing
   - Dispensing
   - Administration
   - Quality and Safety
   - Other: Please specify:
10. How often do you prescribe/administer/dispense opioid medications (question tailored to discipline)?
   - frequently (daily)
   - occasionally (several times per week)
   - rarely (several times per month)
   - never

11. What is your employment status:
   - Full-time
   - Part-time
   - Causal
   - Agency
   - Rotation
   - Other - please specify:

12. Which shift(s) do you usually work?
   - Day
   - Afternoon
   - Night
   - Combination – please specify:
   - Other - please specify:

[This section starts on new page which will be removed from the demographic data above].

- Preference for participation (can select both):
  - Semi-structured interview
  - Focus Group

- Format:
  - face to face
  - telephone
  - Skype

Please provide your email address so an interview can be scheduled and/or details of the focus groups can be sent to you:

Name:

Email:
Appendix 8: Exemplar data report provided to each participating service
## Appendix 9: Ethics and site specific approvals

### Table A9: Ethical and site specific approval overview

<table>
<thead>
<tr>
<th>Study</th>
<th>Ethical approval reference</th>
<th>Site specific approval reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study 1</td>
<td>Not applicable – systematic review</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Study 2</td>
<td>NSW Population and Health Services Research Ethics Committee: AU/RED Reference: LNR/16/CIPHS/8&lt;br&gt;Cancer Institute NSW reference number: LNR 2016/02/041&lt;br&gt;University of Notre Dame Australia: 017390S</td>
<td>Not applicable, included in ethical approval</td>
</tr>
<tr>
<td>Study 3 and Study 4</td>
<td>St Vincent’s Hospital HREC: SVH File Number: 15/033; HREC Reference LNR/15/SVH/51&lt;br&gt;University of Notre Dame Australia: 015115S</td>
<td>St Vincent’s Hospital HREC: LNRSSA/15/SVH/60&lt;br&gt;Hunter New England Local Health District HREC: LNRSSA/15/HNE/536&lt;br&gt;Calvary Health Care Kogarah Research and Ethics Committee: 2015.10.01</td>
</tr>
<tr>
<td>Study 5</td>
<td>St Vincent’s Hospital HREC: SVH File Number: 16/230; HREC Reference LNR/16/SVH/321&lt;br&gt;University of Notre Dame Australia: 017042S</td>
<td>St Vincent’s Hospital HREC: LNRSSA/17/SVH/243&lt;br&gt;Hunter New England Local Health District HREC: LNRSSA/17/HNE/188&lt;br&gt;Calvary Health Care Kogarah Research and Ethics Committee: Reciprocal approval for Catholic Ethical requirements met and acknowledged via correspondence; no separate approval number</td>
</tr>
</tbody>
</table>
14 April 2016

Prof Jane Phillips
Director
Centre for Cardiovascular and Chronic Care
University of Technology Sydney
PO Box 123
Ultimo NSW 2007

Dear Prof Phillips,

NSW Population & Health Services Research Ethics Committee

AU RED Reference: LNR/16/CIPHS/8

Cancer Institute NSW reference number: LNR 2016/02/041

Project Title: "Opioid errors in adult oncology and palliative care services Analysis of statewide data (CEC NSW)."

Thank you for your Low and Negligible Risk application submitted to the NSW Population & Health Services Research Ethics Committee. The Executive Committee has reviewed your documentation and has agreed that the aforementioned application meets the requirements of the National Statement on Ethical Conduct in Human Research (2007). This approval is for a maximum of five years from the date of this letter, after which time a renewal application will be required if the protocol has not been completed.

The Committee reviewed and approved the following documents:

- Submission Checklist
- Protocol Version 1.1, dated 17 November 2015
- IIMS Data Request form, dated 23 December 2015
- Letter of Support from CEC, dated 8 September 2015
- NSW Health Privacy Form
- CV, Jane Phillips

Approval is now valid for the following sites:

- Centre for Cardiovascular and Chronic Care, University of Technology Sydney
- University of Notre Dame Australia, Sydney

The NSW Population & Health Services Research Ethics Committee has been accredited by the NSW Ministry of Health to provide single ethical and scientific review of research proposals conducted within the NSW public health system.
The Committee is a joint initiative of the Cancer Institute NSW and NSW Ministry of Health. The Committee has been constituted and operates in accordance with the National Health and Medical Research Council’s National Statement on Ethical Conduct in Human Research (2007) and relevant legislation and guidelines.

Please note that ethical approval is valid for 5 years, conditional on the following:

- Principal investigators will immediately report anything which might warrant a review of ethical approval of the research, including unforeseen events that might affect continued ethical acceptability.
- Proposed amendments to the research proposal or conduct of the research which may affect the ethical acceptability of the research are to be provided to the NSW Population & Health Services Research Ethics Committee for review.
- The NSW Population & Health Services Research Ethics Committee will be notified giving reasons, if the research is discontinued before the expected date of completion.
- The Principal Investigator will provide a progress report to the NSW Population & Health Services Research Ethics Committee annually and at the completion of the study.

Your first progress report will be due on 14/04/2017 and the duration of approval is until 14/04/2021, after which time a new submission to the Ethics Committee will be required.

You are reminded that this letter constitutes 'ethical approval' only. This research project must not commence at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained. It is your responsibility to forward a copy of this letter together with any approved documents as enumerated above, to all site investigators for submission to the site’s Research Governance Officer. Where relevant, copies will also need to be provided to the CHeRReL and the data custodian.

For further information about the NSW Population & Health Services Research Ethics Committee, please refer to our website www.cancerinstitute.org.au/research.

Should you have any queries about the ethical review of your research proposal, please contact me on 02 8374 3562 or email ethics@cancerinstitute.org.au.

The NSW Population & Health Services Research Ethics Committee wishes you well in your research endeavours.

Yours sincerely,

Dr Eric Turner
Ethics and Research Governance Manager
Cancer Institute NSW
8 September 2015

TRIM Ref: D15/11077-5

Ms Nicole Heneka
PhD Candidate
University of Notre Dame Australia
School of Nursing
PO Box 944
BROADWAY NSW 2007

Dear Ms Heneka,

Re: Request for IIMS Data relating to opioid medication errors in adult oncology and palliative care services.

In regard to our letter dated 21 July 2015, the CEC has now received a response from the Cancer Institute NSW, confirming the study would be of value to the NSW Health system.

In light of this information, we are pleased to offer in-principle support for this request, subject to the CEC receiving a copy of the full ethics approval for the study.

In granting in-principle support, we also advise that the greatest benefit of IIMS analysis is the narrative, which helps highlight issues and system-related opportunities for improvement. Given the wide variation between services and facilities, accurate comparisons based on notification numbers alone cannot be made.

Caution is advised if using IIMS reporting counts or rates as the single source of benchmarking data for a project or program, as many variables influence incident reporting. Lower rates of reporting are not a reliable indicator of safer care. Qualitative, rather than quantitative, interpretation of the data is recommended.

CEC’s Patient Safety Program Manager, Ms Cate Malone, will contact you to discuss the data you are seeking, to ensure the details of the IIMS data request search criteria are consistent with your study protocol and ethics application. Alternatively, please feel free to contact Cate directly via email cate.malone@health.nsw.gov.au.

Please note that all publications relating to the study and citing IIMS data require the following statement:
The incident review is based only on information contained in the 'incident description' and 'review of incident' section in IIIMS notifications. If the information was not documented in these sections, or the selected search terms were not used or were spelt differently, the incidents will not have been captured during this review. It should be noted that all reviews of incident data are retrospective and can reflect both hindsight and outcome bias.

If you would like to discuss any elements of this letter, please feel free to contact to Murray Stone, Corporate Governance & Reporting Officer on 02 9269 5520 or via email murray.stone@health.nsw.gov.au. Please also forward a copy of the full ethics approval to the CEC via Murray, once obtained.

Yours sincerely

[Signature]

Dr Karen Luxford
Acting Chief Executive Officer

cc: Prof Jane Phillips (Principal Investigator)
    Prof Tim Shaw
    Adjunct A/Prof Debra Rowett
    Dr Sam Lapkin
11 May 2017

Professor Jane Phillips & Ms Nicole Heneka
School of Nursing
The University of Notre Dame Australia
PO Box 944
Broadway NSW 2007

Dear Jane & Nicole,

Reference Number: 0176395

Project Title: “Opioid Medication Errors in Adult Oncology and Palliative Care Service in New South Wales: Retrospective Analysis of Incidents Reported to the NSW Clinical Excellence Commission.”

Thank you for submitting the above project for Low Risk ethical review. Your application has been reviewed by a sub-committee of the university’s Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Human Research (2007, updated May 2015). I advise that approval has been granted conditional on the following issues being addressed:

- Researchers indicate that this project is for a PhD but name only one supervisor. Please include all researchers involved in this project in Section 1.5 of the application.
- Researchers to provide copies of other HREC approvals as stated in Section 1.8.
- Researchers to ensure that a copy of the data is stored in the School of Nursing, Sydney campus, as per university policy Code of Conduct for Research.

Please send your response addressing each of the issues as listed above, including supporting information where applicable, to me at Natalie.Giles@nd.edu.au by 13th June. Failure to respond and/or communicate by this time could result in a suspension of the ethical review of the project.

Yours sincerely,

[Signature]

Dr Natalie Giles
Research Ethics Officer
Research Office

cc: A/Prof Joanna Patching, SRC Chair, School of Nursing Sydney
16 February 2015

Ms Nicole Heneka
University of Notre Dame Australia
PO Box 944
Broadway NSW 2007

Dear Nicole

SVH File Number: 15/633

Project Title: Exploring the incidence and types of opioid medication errors in the adult specialist palliative care and inpatient cancer setting: a quality audit.

HREC Reference Number: LNR/15/SVM/51

Thank you for submitting the above project for ethical and scientific review.

Based on the information you have provided and in accordance with the NHMRC National Statement 2007 and NSW Health Policy Directive PD2010_055 'Ethical and Scientific Review of Human Research in NSW Public Health Organisations', this project has been assessed as low/negligible risk and is therefore exempt from full HREC review.

This HREC has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and certified by the NHMRC under the National model for Harmonisation of Multicentre Ethical Review (MoMEER). This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council’s National Statement on Ethical Conduct in Human Research and the CPMP/ICH Note for Guidance on Good Clinical Practice. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the HREC Executive at a meeting on 9 February 2015 has granted ethical and scientific approval of the above multi-centre project.

You are reminded that this letter constitutes ETHICAL and SCIENTIFIC approval only. You must not commence this research project at a site until a completed Site Specific Assessment Form and associated documentation have been submitted to the site Research Governance Officer and Authorised. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The project is approved to be conducted at the following sites:

- St Vincent’s Hospital, Sydney
- Prince of Wales Hospital (NSW)
- Westmead Hospital (NSW)

If a new site(s) is to be added please inform the HREC in writing and submit a Site Specific Assessment Form (SSA) to the Research Governance Officer at the new site.

The following documents have been approved:

- Data Collection Form Version 1.1 dated 10/02/2015
The Low and Negligible Risk Research Form (LNRF) reviewed by the HREC was LNRF AU/6/E13C120

Please note the following conditions of approval:

- HREC approval is valid for 5 years from the date of the HREC Executive Committee meeting and expires on 9 February 2020. The Co-ordinating Investigator is required to notify the HREC 6 months prior to this date if the project is expected to extend beyond the original approval date at which time the HREC will advise of the requirements for ongoing approval of the study.

- The Co-ordinating Investigator will provide an Annual Progress Report beginning in February 2016, to the HREC as well as a Final Study Report at the completion of the project in the specified format.

- The Co-ordinating Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project and any complaints made by participants regarding the conduct of the project.

- Proposed changes to the research protocol, conduct of the research, or length of approval will be provided to the HREC Executive for review, in the specified format.

- The HREC Executive will be notified, giving reasons, if the project is discontinued before the expected date of completion.

- Investigators holding an academic appointment (including conjoint appointments) and students undertaking a project as part of a University course may also be required to notify the relevant University HREC of the project. Investigators and students are advised to contact the relevant HREC to seek advice regarding their requirements.

Please note that only an electronic copy of this letter will be provided, if you require the original signed letter please contact the Research Office and we will be happy to provide this.

Should you have any queries about your project please contact the Research Office, Ph: (02) 8382-2075 or by E-mail: SVHR.Research@svha.org.au. The HREC Terms of Reference, Standard Operating Procedures, National Statement on Ethical Conduct in Human Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice and standard forms are available on the Research Office web-site to be found externally at: www.svha.org.au/researchoffice or at http://wwwsvh.svha.org.au/researchoffice (internally).

Please quote SVH File Number 15/033 in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely,

Sarah Charlton
HREC Executive Officer
St Vincent’s Hospital Research Office
Level 6, de Lacy Building

TRIM REF: D/2015/3428
28 August 2015

Ms Nicole Heneka
University of Notre Dame Australia
PO BOX 584
Broadway NSW 2007

Dear Nicole,

SVH File Number: 15/933
Project Title: Exploring the incidence and types of opioid medication errors in the adult specialist palliative care and inpatient cancer setting: a quality audit.
Short Title: Opioid medication errors in adult palliative care and oncology: a quality audit
HREC Reference Number: LUR/15/SVH/51

Thank you for your request, dated 17 August 2015, to extend HREC approval to additional sites. This HREC has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National model for Harmonisation of Multicentre Ethical Review (NMHEM). This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research and the CPMP/ICH Note for Guidance on Good Clinical Practice. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the HREC Executive at a meeting on 21 August 2015 approved this request. After receipt of outstanding documentation on 26 August 2015, HREC approval has been extended to the following additional sites:

• Calvary Mater Newcastle, Edith St, Waratah NSW 2298 - Principal Investigator: Prof. Katherine Clark
• Calvary Health Care Sydney, 91-103 Rocky Point Road, Kogarah NSW 2217 – Principal Investigator: Ms Nicole Heneka
• St George Hospital, Gray Street Kogarah NSW 2217 – Principal Investigator: Ms Nicole Heneka

You are reminded that this letter constitutes ETHICAL and SCIENTIFIC approval only. You must not commence this research project at a site until a completed Site Specific Assessment Form/Access Request and associated documentation have been submitted to the site Research Governance Officer and Authorised. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Please note that only an electronic copy of this letter will be provided; if you require the original signed letter, please contact the Research Office and we will be happy to provide it.

Should you have any queries about your project please contact the Research Office, Tel: (02) 8382-2075, or by E-mail SVHR.Research@wha.org.au. The HREC Terms of Reference, Standard Operating Procedures, National Statement on Ethical Conduct in Human Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice and standard forms are available on the Research Office website that can be found at www.stvincents.com.au/researchoffice or at http://www.wha.stvincents.com.au/researchoffice (internally).

Yours sincerely,

[Signature]

Dr Pamela Blakie
Research Office Manager
Research Office
St Vincent's Hospital
Level 6, de Lucy Building

TRIM REF: D/2015/43876
3 August 2015

Professor Jane Phillips
School of Nursing
The University of Notre Dame Australia
P.O Box 944
Broadway NSW 2007

Dear Jane,

Reference Number: 015115S

Project title: “Exploring the incidence and types of opioid medication errors in the adult specialist palliative care and inpatient cancer setting: a quality audit.”

Thank you for submitting the above project for review. It is noted that you have ethics approval for this project from St. Vincent’s Hospital HREC, approval number LNR/15/SVH/51. Your application has been assessed as qualifying for a Cross-Institutional approval and is therefore exempt from HREC review. I am pleased to advise that ethical clearance has been granted for this proposed study.

The UNDA students and researchers identified as working on this project are:

<table>
<thead>
<tr>
<th>Name</th>
<th>School</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ms Nicole Heneka</td>
<td>School of Nursing, Sydney</td>
<td>PhD Student</td>
</tr>
</tbody>
</table>

All research projects are approved subject to standard conditions of approval. Please read the attached document for details of these conditions.

Should you have any queries about this project, please contact me at #2964 or Natalie.Giles@nd.edu.au.

Yours sincerely,

Dr Natalie Giles
Executive Officer, Human Research Ethics Committee
Research Office

cc: Alfred Tracey Moroney, Dean, School of Nursing, Sydney
Dear Jane,

SVN File Number: 16/230
Project Title: Specialist palliative care clinicians’ and health service managers’ perceptions and experiences of opioid errors within their service: a mixed methods study.
Short Title: Perceptions of opioid errors in specialist palliative care services
HREC Reference Number: LNR/16/SVN/321

Thank you for your email, dated 1 December 2016, responding to issues raised regarding the above project, which was first considered by the HREC Executive on 21 November 2016.

Based on the information you have provided and in accordance with the NHMRC National Statement 2007 and NSW Health Policy Directive PD02010_055 ‘Ethical and Scientific Review of Human Research in NSW Public Health Organisations’, this project has been assessed as low/negligible risk and is therefore exempt from full HREC review.

St Vincent’s Hospital HREC (EC004-09) has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National Certification Scheme. This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council’s National Statement on Ethical Conduct in Human Research and the EPMP/CH Note for Guidance on Good Clinical Practice. No HREC members with a conflict of interest were present for review of this project.

This project meets the requirements of the National Statement on Ethical Conduct in Human Research. I am pleased to advise that the Committee at an Executive meeting on 6 December 2016 has granted ethical and scientific approval of the above multi centre project.

You are reminded that this letter constitutes ETHICAL and SCIENTIFIC approval only. You must not commence this research project at a site until a completed Site Specific Assessment Form and associated documentation have been submitted to the site Research Governance Officer and Authorised. A copy of this letter must be forwarded to all site Investigators for submission to the relevant Research Governance Officer.

Please note that it is not considered best practice to store research data on personal hardware. No identifiable participant data can leave a site. There always needs to be data security measures in place and a clear plan for permanent destruction of data needs to be adhered to at completion of the project.

The project is approved to be conducted at the following sites:
- St Vincent’s Hospital, Sydney
- Calvary Mater Newcastle
- Calvary Health Care Kogarah

If a new site(s) is to be added please inform the HREC in writing and submit a Site Specific Assessment Form (SSA) to the Research Governance Officer at the new site.

The following documents have been approved:
• Study Protocol, Version 1.1 dated 16 September 2016
• Invitation to participate (clinician/health service manager), Version 1 dated 16 September 2016
• Appendix A_Survey, Version 1.1 dated 16 September 2016
• Appendix R_Participant Information Sheet and Consent Form including Demographic Survey, Version 1.1 dated 16 September 2016
• Appendix C_Question Routes, Version 1.1 dated 16 September 2016

The Low and Negligible Risk Research Form (LNRF) reviewed by the HREC was LNRF AU/6/6EB921B.

Please note the following conditions of approval:

• HREC approval is valid for 5 years from the date of the HREC Executive Committee meeting and expires on 6 December 2021. The Co-ordinating Investigator is required to notify the HREC 6 months prior to this date if the project is expected to extend beyond the original approval date at which time the HREC will advise of the requirements for ongoing approval of the study.
• The Co-ordinating Investigator will provide an Annual Progress Report beginning in December 2017, to the HREC as well as a Final Study Report at the completion of the project in the specified format.
• The Co-ordinating Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project and any complaints made by participants regarding the conduct of the project.
• Proposed changes to the research protocol, conduct of the research, or length of approval will be provided to the HREC Executive for review, in the specified format.
• The HREC Executive will be notified, giving reasons, if the project is discontinued before the expected date of completion.
• Investigators holding an academic appointment (including conjoint appointments) and students undertaking a project as part of a University course may also be required to notify the relevant University HREC of the project. Investigators and students are advised to contact the relevant HREC to seek advice regarding their requirements.

Please note that only an electronic copy of this letter will be provided, if you require the original signed letter please contact the Research Office and we will be happy to provide this.

Should you have any queries regarding this project please contact the Research Office, Ph: (02) 8382-4960 or by E-mail: SVHR.Research@svha.org.au. The HREC Terms of Reference, Standard Operating Procedures, National Statement on Ethical Conduct in Human Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice and standard forms are available on the Research Office web-site to be found at: https://svhs.org.au/home/research-education/research-office

Please quote SVH File Number: 16/230 in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely,

Sarah Charlton
HREC Executive Officer
St Vincent’s Hospital Research Office
Translational Research Centre, 97-105 Boundary Street

cc: Nicole Heneka
TRIM REF: D/2016/110332
13 March 2017

Professor Jane Phillips & Ms Nicole Heneka
School of Nursing
The University of Notre Dame Australia

Dear Jane and Nicole,

Reference Number: 0170425

Project title: “Specialist Palliative care clinicians’ and health service managers’ perceptions and experiences of Opioid errors within their service: A mixed methods study.”

Thank you for submitting the above project for review. It is noted that you have ethics approval for this project from St Vincent’s Hospital HREC, approval number LNR/16/SVH/321. Your application has been assessed as qualifying for a Cross-Institutional approval and is therefore exempt from HREC review. I am pleased to advise that ethical clearance has been granted for this proposed study.

Other researchers identified as working on this project are:

<table>
<thead>
<tr>
<th>Name</th>
<th>School/Centre</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Samuel Lapkin</td>
<td>St George Hospital</td>
<td>Co-Supervisor</td>
</tr>
<tr>
<td>Prof Tim Shaw</td>
<td>Sydney University</td>
<td>Co-Supervisor</td>
</tr>
</tbody>
</table>

All research projects are approved subject to standard conditions of approval. Please read the attached document for details of these conditions.

Should you have any queries about this project, please contact me at #2964 or Natalie.Giles@nd.edu.au.

Yours sincerely,

Dr Natalie Giles
Research Ethics Officer
Research Office

A/Prof Joanne Patshing, SRC Chair, School of Nursing Sydney
Appendix 10: PERISCOPE project alignment with national standards

The PERISCOPE project was developed to align with the following standards at the commencement of the project (2014):

(i) **Australian Commission on Safety and Quality in Health Care:**
   - Safety and Quality Improvement Guide Standard 4: Medication Safety - (Australian Commission on Safety and Quality in Health Care)
     particularly:
     - Standard 4.4.1 - Medication incidents are regularly monitored, reported and investigated
     - Standard 4.5.2 - Quality improvement activities are undertaken to reduce the risk of patient harm and increase the quality and effectiveness of medicines use
     - Standard 4.11.1 - The risks for storing, prescribing, dispensing and administration of high-risk medicines are regularly reviewed
     - Standard 4.11.2 - Action is taken to reduce the risks of storing, prescribing, dispensing and administering high-risk medicines
   - Guidelines for use of the National Inpatient Medication Chart
   - Recommendations for terminology, abbreviations and symbols used in medicines documentation

(ii) **Clinical Excellence Commission**
   - Medication Safety Self Assessment for Australian Hospitals ®

(iii) **Ministry of Health (NSW) Policy Directives and Safety Information:**
   - Patient Safety and Clinical Quality Program PD2005_608
   - Medication Handling in NSW Public Health Facilities PD2013_043 (ref)
   - Incident Management Policy PD2014_004
   - High-Risk Medicines Management Policy PD2015_029
   - Safety Information 003/11 - Safe Storage of Accountable Medicines

(iv) **Australian Adult Cancer Pain Management Guidelines**

(v) **Therapeutic Guidelines**
   - Palliative care

- Using medicines safely and effectively
- Providing facilities, systems, training opportunities and structures that support health practitioners and avoid medication errors

(vii) Palliative Care Australia’s National Standards Assessment Program (NSAP) (Palliative Care Australia, 2005):

- Standard 11 - The service is committed to quality improvement and research in clinical and management practices
Appendix 11: Joint display for Research Question 1

Joint display A11.1 representing quantitative data integration, convergence and inference for Research Question 1: What is the prevalence, patient impact, and characteristics of opioid errors in specialist palliative care inpatient services?

### RESEARCH QUESTION 1: What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?

<table>
<thead>
<tr>
<th>Domain</th>
<th>Quantitative data – State-wide data (Study 2)</th>
<th>Quantitative data – Local data (Study 3)</th>
<th>Data convergence</th>
<th>Mixed methods inference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence</td>
<td>Could not be identified in quantitative data</td>
<td>Opioid errors accounted for 32% of all reported medication errors</td>
<td>Could not determine – follow-up with qualitative data</td>
<td>The higher prevalence of reported opioid errors in specialist palliative care inpatient services, compared to other inpatient settings, may be related to the high volume of opioid delivery in inpatient palliative care.</td>
</tr>
<tr>
<td>Volume of opioid administration over 24 hours</td>
<td>Could not be identified in quantitative data</td>
<td>Snapshot audit findings:  - mean 82.5 (SD±44.8) opioid administrations per 24 hours/per unit  - equivalent one opioid administration every 5.8 minutes</td>
<td>Could not determine – follow-up with qualitative data</td>
<td></td>
</tr>
<tr>
<td>Patient Impact</td>
<td>Data set 1: Four year trend search of reported opioid incidents (N=467)  - SAC 1: n=0</td>
<td>Reported opioid errors over two years (N=55)  - SAC 1: n=0</td>
<td>Confirmed – follow-up with qualitative data</td>
<td>Serious patient harm due to opioid error is exceedingly rare in specialist palliative care inpatient services.</td>
</tr>
</tbody>
</table>
**RESEARCH QUESTION 1:** What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?

<table>
<thead>
<tr>
<th>Domain</th>
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<th>Mixed methods inference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- SAC 2: n=4 (0.9%)</td>
<td>- SAC 2: n=0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- SAC 3: n=133 (28.5%)</td>
<td>- SAC 3: n=21 (38.2%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- SAC 4: n=314 (67.2%)</td>
<td>- SAC 4: n=34 (61.8%)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>- SAC not allocated: n=16 (3.4%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data set 2: Analysis of case reports (N=241)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>- SAC 1: n=0</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>- SAC 2: n=2 (&lt;0.1%)</td>
<td></td>
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<td></td>
<td>- SAC 3: n=73 (30.3%)</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>- SAC 4: n=159 (66.0%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- SAC not allocated: n=16 (6.6%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NCC MERP Index</strong></td>
<td><strong>Data set 2: Case reports (N=241)</strong></td>
<td><strong>Reported opioid errors (N=55)</strong></td>
<td><strong>Confirmed</strong></td>
<td><strong>Approximately half of opioid errors that reach the palliative inpatient will require clinical intervention to preclude or manage harm.</strong></td>
</tr>
<tr>
<td></td>
<td>- Category B – error occurred, did not reach patient n=15 (6.2%)</td>
<td>- Category B – error occurred, did not reach patient n=6 (16.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Category C – error reached patient, no patient harm; n=11 (4.6%)</td>
<td>- Category C – error reached patient, no patient harm; n=11 (20.0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Category D - patient required monitoring and/or intervention to preclude harm: n=72 (29.9%)</td>
<td>- Category D - patient required monitoring and/or intervention to preclude harm: n=11 (20.0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Category E - error resulting in temporary patient harm which required intervention: n=37 (15.4%)</td>
<td>- Category E - error resulting in temporary patient harm which required intervention: n=18 (32.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Category F - error resulting in temporary patient harm which required initial or prolonged hospitalisation: n=2 (0.8%)</td>
<td>- Category F - error resulting in temporary patient harm which required initial or prolonged hospitalisation: n=0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### RESEARCH QUESTION 1: What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?

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<th>Data convergence</th>
<th>Mixed methods inference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Error reached patient - patient impact/outcome not documented:</td>
<td>n=104 (43.2%)</td>
<td>n=6 (10.9%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Dose outcome following error

<table>
<thead>
<tr>
<th>Problem type</th>
<th>Data set 2: Case reports – error that reached patient (N=223, 92.5%)</th>
<th>Reported opioid errors that reached patient (N=46, 83.6%)</th>
<th>Confirmed</th>
<th>Opioid errors in specialist palliative care inpatient services are more likely to result in opioid underdose than overdose. Opioid underdose due to error in specialist palliative care inpatient services is almost three times higher than in acute inpatient care (23%).</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Opioid underdose:</td>
<td>n=134 (60.1%)</td>
<td>n=26 (56.5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Opioid overdose:</td>
<td>n=66 (29.6%)</td>
<td>n=18 (39.1%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Could not determine:</td>
<td>n=23 (10.3%)</td>
<td>n=2 (4.3%)</td>
<td></td>
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</tr>
</tbody>
</table>

Palliative patients were significantly more likely to receive an opioid underdose due to error ($\chi^2=11, p=.001$), than an opioid overdose compared to patients in cancer services.

#### Error characteristics

<table>
<thead>
<tr>
<th>Problem type</th>
<th>Data set 2: Case reports (N=241)</th>
<th>Reported opioid errors (N=55)</th>
<th>Confirmed</th>
<th>Approximately three-quarters of reported opioid errors in specialist palliative care inpatient services are administration errors. Prescribing errors account for approximately one-fifth of reported opioid errors. Dispensing errors and near miss incidents are rarely reported. The proportion of reported administration and prescribing errors in specialist palliative care inpatient services are more likely to result in opioid underdose than overdose. Opioid underdose due to error in specialist palliative care inpatient services is almost three times higher than in acute inpatient care (23%).</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Administration:</td>
<td>181 (75.1%)</td>
<td>42 (76.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Prescribing:</td>
<td>n= 45 (18.7%)</td>
<td>n= 8 (14.5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Dispensing:</td>
<td>n=7 (2.9%)</td>
<td>n=2 (3.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Near miss:</td>
<td>n=4 (1.7%)</td>
<td>n=3 (5.5%)</td>
<td></td>
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</tr>
</tbody>
</table>
**Research Question 1:** What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?

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</tr>
</thead>
</table>
| Administration error types | Data set 2: Case reports – administration errors (N=181)  
- Omitted dose: n=66 (36.5%)  
- Wrong dose: n=22 (12.2%)  
- Transdermal patch error: n=14 (7.7%)  
- Wrong drug: n=13 (7.1%)  
Data set 1: Four year trend search of reported opioid incidents  
- Omitted dose errors with opioids significantly higher in palliative care services compared to cancer services ($X^2=15, p<.001$) | Reported opioid administration errors (N=42)  
- Omitted dose: n=14 (33.3%)  
- Wrong dose: n=10 (23.8%)  
- Transdermal patch error: n=8 (19.1%)  
- Wrong drug: n=6 (14.3%) | Confirmed – follow-up with qualitative data | Omitted dose errors are the most frequently reported error type in specialist palliative care inpatient services, accounting for approximately one-quarter of all reported opioid errors.  
Omitted dose errors are also the leading administration error type in specialist palliative care inpatient services, accounting for one-third of reported administration errors.  
Specialist palliative care inpatient services report more omitted dose errors, but fewer wrong dose and wrong drug errors with opioids, compared to other healthcare settings.  
Omitted dose errors with opioids occur more frequently in specialist palliative care inpatient services than other healthcare settings, including settings where opioid use is similar (i.e., cancer services).  
Reported omitted dose errors in palliative care services are more than double the rate than identified internationally (14%). |
RESEARCH QUESTION 1: What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?

<table>
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<tr>
<th>Domain</th>
<th>Quantitative data – State-wide data (Study 2)</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Prescribing error types</strong></td>
<td>Data set 2: Case reports – prescribing errors (N=181) - Medication charting: n=20 (44.4%) - Conversion error: n=2 (4.4%) - Wrong drug: n=8 (17.8%) - Wrong dose: n=10 (22.2%)</td>
<td>Reported opioid prescribing errors (N=8) - Medication charting: n=4 (50.0%) - Conversion error: n=2 (25.0%) - Wrong drug: n=2 (25.0%)</td>
<td>Unclear due to small numbers at local sites – follow-up with qualitative data</td>
<td>Omitted dose errors are the primary contributors to opioid under-dosing due to error in palliative care patients.</td>
</tr>
<tr>
<td><strong>Opioid involved</strong></td>
<td>Data set 1: Four year trend search - Palliative care services State-wide significantly more likely to report hydromorphone ($\chi^2=787, p&lt;.001$) and morphine ($\chi^2=17, p&lt;.001$) errors compared to all other NSW Health services combined</td>
<td>Reported opioid errors (N=55) Two thirds of reported opioid errors involved morphine (n=19, 34.5%) or hydromorphone (n=16, 29.0%)</td>
<td>Confirmed</td>
<td>Morphine and hydromorphone errors are the most commonly reported in specialist palliative care inpatient services.</td>
</tr>
</tbody>
</table>
Joint display A11.2 representing data integration, convergence and inference for Research Question 1: What is the prevalence, patient impact, and characteristics of opioid errors in specialist palliative care inpatient services?

<table>
<thead>
<tr>
<th>RESEARCH QUESTION 1: What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Domain</strong></td>
</tr>
<tr>
<td><strong>Prevalence</strong></td>
</tr>
<tr>
<td><strong>Frequency of opioid administration in specialist palliative care inpatient services</strong></td>
</tr>
</tbody>
</table>
**RESEARCH QUESTION 1: What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?**

<table>
<thead>
<tr>
<th>Domain</th>
<th>Mixed methods inference from Study 2 (State-wide review) and Study 3 (local review)</th>
<th>Qualitative data (Study 5)</th>
<th>Data convergence</th>
<th>Mixed methods inference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Error reporting culture</td>
<td>Could not be determined from quantitative data</td>
<td><strong>Opioid error reporting – encouraged and expected</strong>&lt;br&gt;&quot;I've certainly seen that elsewhere…that it reflects badly on the unit, the more incidents you have. It doesn't look good, so you're not encouraged to (report) in other places, but they do encourage it here, to help highlight the issues so that we can rectify&quot; (ID29_Nurse).</td>
<td>Enhance</td>
<td>A non-punitive approach to error reporting was evident in the local specialist palliative care inpatient services in the PERISCOPE project. The higher prevalence of reported opioid errors in specialist palliative care inpatient services, compared to other inpatient settings, may also be due to a positive error reporting culture.</td>
</tr>
</tbody>
</table>

**Patient impact of opioid errors**

<table>
<thead>
<tr>
<th>Patient harm</th>
<th>Opioids pose a high risk for error, but serious errors are rare&lt;br&gt;&quot;I think serious opioid errors are uncommon, minor issues of all descriptions are relatively common&quot; (ID 1_Photician).</th>
<th>Confirm</th>
<th>Serious patient harm due to opioid error is exceedingly rare in specialist palliative care inpatient services.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioid errors in specialist palliative care inpatient services are more likely to result in opioid underdose than overdose.</td>
<td><strong>Opioid underdosing due to error</strong>&lt;br&gt;&quot;So we worry about the overdose, obviously, because that's a life threatening problem, but patients under-dosed is also a major problem&quot; (ID4_Physician).&lt;br&gt;&quot;They don't always choose too large (a dose), sometimes I think the dose is dangerously small…we had one case recently where sub-cut morphine was...&quot;</td>
<td>Confirm</td>
<td>Opioid errors in specialist palliative care inpatient services are more likely to result in opioid underdose than overdose.</td>
</tr>
<tr>
<td>Domain</td>
<td>Mixed methods inference from Study 2 (State-wide review) and Study 3 (local review)</td>
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</tbody>
</table>
|        | changed to sub-cut hydromorphone, but in my estimation they gave about a 1/3 of the dose needed’ (ID11_Psychician). | Mandated controlled drug management policy prompts error recognition and reporting
‘...with opioids, it's more serious, we have to do a report...I'm pretty sure that all opioid errors would be reported’ (ID18_Nurse). | Enhance | Opioid errors are perceived to be more accurately reported in specialist palliative care inpatient services than medication errors with non-high risk medicines. The mandated management policy for controlled drugs (opioids) appears effective in facilitating reporting of opioid errors. |
| Opioid error characteristics and error reporting practices | | | | |
| All opioid errors | Reported opioid errors in specialist palliative care inpatient services reflect opioid error prevalence in other healthcare settings. | | | |
| Opioid administration errors - general | Three-quarters of reported opioid errors in specialist palliative care inpatient services are administration errors. | Mandated controlled drug management policy prompts error recognition and reporting
‘If it's not the person making the mistake reporting it, someone else will; the next shift might pick up a mistake, they might see something in the drug book doesn’t correlate and they’ll report it...' (ID14_Nurse). | Enhance | The mandated management policy for controlled drugs (opioids) appears effective in facilitating recognition of opioid administration errors and prompts error reporting. Opioid administration errors in specialist palliative care inpatient services are perceived to be accurately reported. |
| Opioid administration errors - omitted dose errors | Omitted dose errors are the most frequently reported opioid error type in specialist palliative care inpatient services, accounting for...the missed dose is quite frequent...there is no doubt there’s an element of human error that we | Missed doses and miscalculations | Confirm | Omitted dose errors are the most prevalent opioid administration error in specialist palliative care inpatient services. |
### RESEARCH QUESTION 1: What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?

<table>
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<th>Data convergence</th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>approximately one-quarter of all reported opioid errors, and one-third of opioid administration errors.</td>
<td>haven't been able to eliminate entirely’ (ID5_Psychician).</td>
<td>Contradict</td>
<td>Opioid prescribing errors that are readily fixable are rarely reported. The prevalence of opioid prescribing errors is likely substantially higher than reported.</td>
</tr>
<tr>
<td><strong>Opioid prescribing errors</strong></td>
<td>One-fifth of reported opioid errors in specialist palliative care inpatient services are prescribing errors</td>
<td><strong>Rectify or report?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>'I think often you can rectify the problem quite simply…you go to the doctor to change it, so, rather than report it, it's quicker just to fix it; I think we don't report it because it's fixable…we report falls and pressure areas because we can't fix them on the spot but if it's a medication (prescribing) error we just go and get the chart fixed, and it's done’ (ID34_Nurse).</td>
<td></td>
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<tr>
<td><strong>Opioid prescribing errors - charting errors</strong></td>
<td>Opioid charting errors account for half of reported opioid prescribing errors in specialist palliative care inpatient services.</td>
<td><strong>Error contributory factors: Clinical communication</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Right now) there’s one (chart)...that has everything on that page ceased, and not a nice, neat, it's, you know, scribble-scribble-scribble...at first glance at that chart, you go, 'that's all ceased'...and right in the middle of it, there’s an oxycodone. That doesn't give us much of a chance, does it?’ (ID45_Nurse).</td>
<td>‘So I said to the doctor, are you sure this is what you want? I think the</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>‘So I said to the doctor, are you sure this is what you want? I think the</td>
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</tr>
</tbody>
</table>

Enhance Medication charting errors, including illegible or ambiguous written orders, are common in specialist palliative care inpatient services, however, they are usually promptly rectified.
RESEARCH QUESTION 1: What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?

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<tr>
<td></td>
<td>intention was (for administration) today, but they re-charted it for tomorrow morning...they're human too...if we see something, we question it' (ID48_Nurse).</td>
<td>Missed doses and miscalculations ’...opioid conversions are the huge danger area...and that happens many times when you're trying to stabilise pain, we're changing routes and we're changing drugs’ (ID22_Physician).</td>
<td>Contradict</td>
<td>Opioid conversion errors are perceived to be the most commonly occurring opioid prescribing error type in specialist palliative care inpatient services. However, as with opioid prescribing errors generally, opioid conversion errors are often intercepted by palliative care nurses, rectified and not reported.</td>
</tr>
<tr>
<td>Opioid prescribing errors - opioid conversion errors</td>
<td>Less than 3% of reported opioid prescribing errors were attributed to conversion errors in NSW palliative care services.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Opioid dispensing errors</td>
<td>Dispensing errors were rarely reported (3%-4%).</td>
<td>Not identified in qualitative data</td>
<td>Could not determine</td>
<td>It is unclear why the rate of opioid dispensing errors is so low in specialist palliative care inpatient services than in other settings, and this warrants further exploration in the palliative care context.</td>
</tr>
<tr>
<td>Near miss incidents</td>
<td>Near miss incidents were rarely reported (2%-5%).</td>
<td>Rectify or report? If your double checking identifies something before you've drawn it all up and are going to give it then you've prevented it from being a problem, but</td>
<td>Enhance</td>
<td>Near miss incidents are generally only reported if the potential for patient harm was high, or if the incident resulted in a narcotic discrepancy.</td>
</tr>
</tbody>
</table>
### RESEARCH QUESTION 1: What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?

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<th>Mixed methods inference from Study 2 (State-wide review) and Study 3 (local review)</th>
<th>Qualitative data (Study 5)</th>
<th>Data convergence</th>
<th>Mixed methods inference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>I guess if someone’s actually willing to go and take it to the patient, and there’s the potential it would have been given without resistance, that would be reported (ID5_Nurse).</td>
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</tbody>
</table>

A128
Appendix 12: Joint display for Research Question 2

Joint display A12 representing data integration, convergence and inference for Research Question 2: What are the individual and systems factors that contribute to opioid errors in specialist palliative care inpatient services?

<table>
<thead>
<tr>
<th>Domain</th>
<th>Quantitative data (Studies 2 - 4)</th>
<th>Qualitative data theme and sample quote (Study 5)</th>
<th>Data convergence</th>
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</tr>
</thead>
<tbody>
<tr>
<td>[ALIGNMENT WITH YORKSHIRE CONTRIBUTORY FACTORS FRAMEWORK]</td>
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<tr>
<td>Active failures (human error)</td>
<td>Study 2 - State-wide data: - 59% (n=222) of reported opioid errors attributed to active failures Study 4 - Local review of error contributing factors: - 68% (n=53) of reported opioid errors attributed to active failures</td>
<td>Human error is inevitable 'We are aware that human error plays a part in medication administration, I don't think there's any way around that, completely; we can be as diligent as you want, but at times (errors will still happen)' (ID36_Nurse). 'I really do believe in improving systems rather than looking so much at people, because if systems are improved then people also improve automatically' (ID31_Nurse).</td>
<td>Enhance</td>
<td>Human error is an inevitable aspect of opioid errors, that cannot be completely eliminated. However, it is essential to also consider the systems factors that may facilitate human error.</td>
</tr>
<tr>
<td>[ACTIVE FAILURES]</td>
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<tr>
<td>Inexperience</td>
<td>Study 2 - State-wide data: - 8% (n=31) of reported opioid errors attributed to clinician inexperience Study 4 - Local review of error contributing factors: - 3% (n=3) of reported opioid errors attributed to clinician inexperience</td>
<td>Situational factors: clinician inexperience 'I think we've got to realise that we have a lot of new and young registrars that haven't seen, you know, someone on fentanyl and hydromorphone and methadone, and then being converted to a syringe driver…'(ID10_Nurse) When we have to make after hours calls…(the doctors) often they're going</td>
<td>Confirm Enhance</td>
<td>The nature of opioid delivery in specialist palliative care inpatient services (high frequency, high doses, unusual opioid combinations) poses considerable challenges for inexperienced clinicians such as: clinicians who are new to the palliative care unit; junior doctors; and non-specialist palliative care prescribers.</td>
</tr>
<tr>
<td>[SITUATIONAL FACTORS]</td>
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<tr>
<td>Domain</td>
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<td>[ALIGNMENT WITH YORKSHIRE CONTRIBUTORY FACTORS FRAMEWORK]</td>
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<tr>
<td>RESEARCH QUESTION 2: What are the individual and systems factors that contribute to opioid errors in specialist palliative care inpatient services?</td>
<td>by what we (nurses) see…if it’s a more junior doctor, or a doctor from (another service), there could be so much room for an error there (ID18_Nurse).</td>
<td>I think…when we have casual (staff)...or people who aren’t familiar (with opioids)...there just seem to be a number of errors if we use inexperienced staff (ID37_Nurse).</td>
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<tr>
<td>SYSTEMS FACTORS</td>
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<tr>
<td>Skill-mix and workload</td>
<td>Study 2 - State-wide data:</td>
<td>Nursing skill-mix and ratios</td>
<td>Enhance</td>
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<tr>
<td></td>
<td>- 2% (n=5) of reported opioid errors attributed to sub-optimal skill mix</td>
<td>‘If you are the only senior (nurse), you have to make the decisions. You have to help the new staff, the new grad, you have to guide them, help them to even (administer). You have to check not only twice, you have to check five times to make sure they’re all on the right track. That is time consuming, and takes away your energy as well, that’s how errors can come easily’ (ID57_Nurse).</td>
<td>Sub optimal skill mix and nurse ratios directly increases palliative care nurses’ workload and heightens the risk of opioid error.</td>
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<td></td>
<td>- 7% (n=17) of reported opioid errors attributed to workload Study 4 - Local review of error contributing factors:</td>
<td><strong>Interdisciplinary skill-mix</strong>&lt;br&gt;‘If an inexperienced doctor charts a wrong dose, an inexperienced nurse is far less likely to pick that up, and sometimes the safeguard is having experienced nurses, so if there’s a combination of inexperienced junior</td>
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<td>- nil reported opioid errors attributed to sub-optimal skill mix</td>
<td>10% (n=8) of reported opioid errors attributed to workload</td>
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</table>
Task characteristics of opioid delivery

Opioid delivery in palliative care is different

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RESEARCH QUESTION 2: What are the individual and systems factors that contribute to opioid errors in specialist palliative care inpatient services?

Doctors and inexperienced nursing staff, I think that is where the potential for error is high' (ID9_Philcian).

**Workload and errors**

'I think most of the prescribing errors happen at admission - they're understaffed for admissions and the complexity of our patients has increased, the constant turnover means complex patients are being admitted daily and their clinicians proportional workload to manage those admissions I think is too high' (ID21_Philcian).

'…of course, it’s workload that could be contributing to errors, time is a big contribution to errors' (ID61_Nurse).

**Time spent on opioid delivery**

Not identified in quantitative data

'We just said to each other the other day, ‘how's your day?’ she said, ‘I didn't get out of the (drug) cupboard the whole shift’ and I said, my shift was the same. And you’d hear it all the time...because...you can literally be standing in that (drug) room and not leave. Yesterday, we did five (infusion pumps) in a row...and then the time doing the drug check, and all the'

Enhance

Opioid delivery consumes a large part of each shift for specialist palliative care nurses.
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<tr>
<td><strong>Opioid doses</strong></td>
<td>Not identified in quantitative data</td>
<td>‘It’s different, totally different, in another hospital you wouldn’t use this dosage (of opioids)’ (ID1_Nurse).</td>
<td>Enhance</td>
<td>Opioid doses in specialist palliative care inpatient services are considerably higher than in other care settings.</td>
</tr>
<tr>
<td><strong>Complexity of opioid delivery</strong></td>
<td>Not identified in quantitative data</td>
<td>‘…when they’re doing complicated dose conversions, not only are they converting from one variety of opioid to another, but they’re converting the route or the formulation, so oral to subcutaneous, or long-acting to fourth hourly, or subcut morphine to hydromorphone, methadone rotations; the more the complexity of the dosing, the more chance there is for error, if there’s multiple steps, is my experience’ (ID1_Phyisician). ‘What’s expected of our nurses (is) …the concentration required with some of the medications (opioids)’ (ID41_Pharacist).</td>
<td>Enhance</td>
<td>Opioid delivery in specialist palliative care inpatient services routinely involves complex tasks, with error potential at each step.</td>
</tr>
<tr>
<td><strong>Interruptions</strong></td>
<td>Study 2 - State-wide data: - Nil reported Study 4 - Local review of error contributing factors: - 5% (n=4) of reported opioid errors attributed to interruptions and/or distractions</td>
<td>‘I think a point that’s critical is when you’re there at the drug cupboard and you’re drawing something up and people are talking to you and everything is busy…you know you’re trying to do your drug calculations, draw up the right dose…and it only takes that really quick thing for you to</td>
<td>Confirm</td>
<td>Preparing opioids for administration is a complex and time consuming task that requires concentration. Interruptions during the opioid preparation process are common, however, are seen as routine occurrences in the context of opioid</td>
</tr>
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</table>

breakthroughs…it’s hours, hours, hours’ (ID30_Nurse).
### Domain: [ALIGNMENT WITH YORKSHIRE CONTRIBUTORY FACTORS FRAMEWORK]

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<tr>
<td><strong>Research Question 2: What are the individual and systems factors that contribute to opioid errors in specialist palliative care inpatient services?</strong></td>
<td>pick the wrong thing, for something to happen' (ID2_Nurse). ‘Things happen and they can’t just wait half an hour for us to finish the drug round, we get interrupted all the time and we just have to deal with it, that’s what I think anyway, the reality of it' (ID15_Nurse).</td>
<td>delivery, that palliative care clinicians endeavour to actively manage.</td>
<td></td>
</tr>
<tr>
<td><strong>Patient factors</strong> [SITUATIONAL FACTORS]</td>
<td>Study 2 - State-wide data: - &gt;1% (n=2) of reported opioid errors attributed to patient factors Study 4 - Local review of error contributing factors: - Nil reported</td>
<td>‘...the patient that is being looked after in palliative care, is very complex with a lot of co-morbidities…and polypharmacy… It leaves the more junior staff in a very difficult situation because they have to provide care, and when they do that, often times this is where errors tend to happen’ (ID31_Nurse). ‘… there’s a lot of unstable patients, or deteriorating patients that need a lot of breakthroughs, the doctors are changing orders frequently, you have anxious families, that all adds up…and you could really do with extra staff numbers then’ (ID11_Nurse).</td>
<td>Enhance Although palliative inpatient care is increasingly complex, patient factors rarely contribute directly to opioid errors in specialist palliative care inpatient services. Rather, clinician inexperience and increased workload due to the fluctuating needs of palliative patients heightens the risk of error.</td>
</tr>
<tr>
<td><strong>Physical environment</strong> [LATENT ORGANISATIONAL FACTORS]</td>
<td>Not identified in quantitative data</td>
<td>Local working conditions ‘In our treatment room it gets super busy and super noisy, so when you’re trying to draw up a complicated (subcutaneous infusion pump), or</td>
<td>Enhance The physical environment of the drug preparation area contributes to opioid error.</td>
</tr>
</tbody>
</table>

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[Study references and data sources are not included in the table.]

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[Note: The table is a structured representation of the research findings, integrating quantitative and qualitative data to address the research question.]

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[Additional context or discussion about the research methods and implications for practice are not included in the table.]
<table>
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<tr>
<td><strong>RESEARCH QUESTION 2: What are the individual and systems factors that contribute to opioid errors in specialist palliative care inpatient services?</strong></td>
<td>even you're just trying to move because someone's got to get into the cupboard, you can (make an error)’ (ID45_Nurse).</td>
<td></td>
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<tr>
<td>Absence of pharmacist input</td>
<td>Study 3 - Local retrospective review: - palliative care services without a clinical pharmacist reported the highest number of opioid prescribing errors</td>
<td>Gaps in support from central functions ‘We don’t have enough clinical pharmacists on the ward so they don’t come to review the charts frequently, that is a concern...you know if the medication route is wrong but no-one checks, or the doctor charted for bd but only put down one time in the chart’ (ID01_Nurse)</td>
<td>Confirm</td>
<td>Absence of a clinical pharmacist in the specialist palliative care inpatient service increases opioid prescribing errors.</td>
</tr>
<tr>
<td>Clinical communication factors [OVERARCHING FACTOR]</td>
<td>Communication systems Not identified in quantitative data</td>
<td>Errors on admission ‘I think (there’s a risk) in the transition from community to inpatient, because there may be more than one prescriber of the opioid and what the actual patient has been taking may be different from what’s being prescribed...and that there’s not a uniform medication list between GP, the community team, and the inpatient team necessarily’ (ID48_Priest).</td>
<td>Enhance</td>
<td>A lack of centralised patient information increases the risk of error during palliative patient care transitions.</td>
</tr>
</tbody>
</table>
### RESEARCH QUESTION 2: What are the individual and systems factors that contribute to opioid errors in specialist palliative care inpatient services?

<table>
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<tr>
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</table>
| Interpersonal communication | Study 2 - State-wide data:  
- 15% (n=36) of reported opioid errors attributed to clinical communication deficits (written communication 70%, clinical handover 30%) | **Contemporaneous handover**  
'So if anything for a patient changes, as a nurse, our job is to then let the doctor know that this has just changed, the patient's in more pain, or whatever. It'd be really nice if that was reciprocated, in terms of, they've charted a new drug for a patient, especially an opioid, can you let us know that that has been charted? Just a quick tap on the shoulder and say "Hey, we've just charted this" (ID12_Nurse). | Confirm | Clinical communication deficits, particularly with clinical handover, result in opioid errors in specialist palliative care inpatient services. In local services, ambiguous or illegible written orders are promptly challenged and clarified. |
| | Study 4 - Local review of error contributing factors:  
- 17% (n=13) of reported opioid errors attributed to clinical communication deficits (written communication 39%, clinical handover 61%) | **Rectify or report?**  
'We're generally pretty good in going and saying: Can you rewrite this again? We can't read it!'(ID44_Nurse). | | |
Appendix 13: Joint display for Research Question 3

Joint display A13 representing data integration, convergence and inference for Research Question 3: What are the opioid error mitigating factors in specialist palliative care inpatient services?

### RESEARCH QUESTION 3: What are the opioid error mitigating factors in specialist palliative care inpatient services?

<table>
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<tr>
<th>Domain</th>
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</thead>
<tbody>
<tr>
<td>Safety culture</td>
<td></td>
<td>Clear expectations regarding safe opioid delivery</td>
<td></td>
<td>A positive, non-punitive, safety culture, underpins opioid safety in specialist palliative care inpatient services.</td>
</tr>
<tr>
<td>Supervision and leadership</td>
<td>Not identified in quantitative data</td>
<td>'For me [the safety culture] is from the top down, definitely management has a huge influence on the culture…' (ID36_Nurse).</td>
<td></td>
<td>A commitment to opioid safety from leadership is evident in specialist palliative care inpatient services.</td>
</tr>
<tr>
<td>Policies and procedures</td>
<td>Study 4 - Local review of error contributing factors: - 5% (n=4) of opioid error reports specifically identified adherence to</td>
<td>Empowering clinicians to practise safely</td>
<td>Confirm</td>
<td>Current opioid management/handling polices are effective in reducing opioid errors, and mitigating patient harm.</td>
</tr>
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</table>

We've said that because we do so many (opioids) instead of expecting that we would, as a result of that, have a high rate (of errors), we've said...we should be experts at it and we should be the best at it...we've continued to raise the profile in suggesting that it's a really pivotal part of what we do. I think it's that culture of, 'this is important' (ID33_Nurse Unit Manager).

'For me [the safety culture] is from the top down, definitely management has a huge influence on the culture…' (ID36_Nurse).
## RESEARCH QUESTION 3: What are the opioid error mitigating factors in specialist palliative care inpatient services?

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<tr>
<td>Opioid management/handling policy</td>
<td>opioid management/handling policy had prevented the error from reaching the patient, or mitigated patient harm following an error</td>
<td>start over the last year or two, and I think because they’ve come into that culture as existing, with all the strictness around doing things the right way (following policy)...that's the funny thing, we're just doing it the right way, it's not like we're re-inventing the wheel.</td>
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<td>harm from error, when they are consistently implemented.</td>
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<tr>
<td>Error reporting culture</td>
<td>Not identified in quantitative data</td>
<td>Promoting a non-punitive approach to error I don’t think we have a culture where we’re frightened to report anything. I don’t think we have a culture where we’re afraid to own up to any mistakes… I think we’re all accepting of each other, and if a mistake is made, you have to do something about it, and I don’t think there’s a culture of shielding that (mistake) from management (ID47_Nurse).</td>
<td>Enhance</td>
<td>A non-punitive error reporting culture is evident in specialist palliative care inpatient services, and promotes a systems approach to error management.</td>
</tr>
<tr>
<td>Palliative care nurses’ error interception practices</td>
<td>Study 4 - Local review of error contributing factors: - 10% (n=8) of identified opioid errors were intercepted by palliative care nurses and subsequently reported</td>
<td>Working as a team So I said to the doctor, are you sure this is what you want? I think the intention was (for administration) today, but they re-charted it for tomorrow morning…they’re human too…if we see something, we question it’ (ID48_Nurse).</td>
<td>Confirm</td>
<td>Palliative care nurses routinely identify and intercept opioid errors, particularly prescribing errors.</td>
</tr>
<tr>
<td>Palliative care pharmacists in the interdisciplinary team</td>
<td>Study 3 - Local retrospective review: - All bar one opioid prescribing error (88%, n=7) was reported in the</td>
<td>Working as a team We’re really fortunate that we have pharmacists on site, they’re very open to anybody spending time with them,</td>
<td>Confirm</td>
<td>A palliative care pharmacist in the interdisciplinary team appears to considerably reduce opioid</td>
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</table>
## Research Question 3: What are the opioid error mitigating factors in specialist palliative care inpatient services?

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<tr>
<td><strong>Service Without a Palliative Care Pharmacist</strong></td>
<td>service without a palliative care pharmacist.</td>
<td>clarifying anything, if the doctors are not here and the nurses are uncertain about why the breakthrough dose is such as it is (ID34_Clinical Nurse Educator).</td>
<td>prescribing errors, and is a valued team member.</td>
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</table>
| **Interdisciplinary Collaboration** | Not identified in quantitative data | Working as a team  
‘When I’m calculating something, if it’s particularly complex or warrants double checks I often ask one of the nurses, what do you think?’ (ID56_Physician).  
It’s that combination of alertness, awareness, everyone being aware of inexperience, and an open, blame-free culture (ID09_Physician). | Enhance | Effective interdisciplinary collaboration in specialist palliative care inpatient services is an additional error safeguard.  
Interdisciplinary collaboration is essential to mitigate the risk of opioid error by less experienced clinicians. |
| **Education and Training**     | Not identified in quantitative data | Education is empowering  
I think nurses are very happy to challenge orders…I think just learning about the opioid conversion, learning what that means and why it’s important (makes them confident to challenge), so being empowered by education (ID55_Clinical Nurse Educator). | Enhance | Targeted and ongoing opportunities for opioid education empowers clinicians to identify and intercept opioid errors. |
| **Electronic Medication Management System** | Study 3 - Local retrospective review:  
- Nil reported omitted dose errors in service using electronic medication management system  
- Omitted dose errors ranged from 29% to 69% of reported opioid administration errors in specialist | Quality process and risk management  
‘I worked in (other palliative care service) and the main issue there was we missed lots of drug. And that was because of the paper chart. Since I came here (electronic medication chart), I can’t think of going back to a | Confirm | Electronic medication management systems appear to substantially reduce omitted opioid dose errors in specialist palliative care inpatient services.  
Given that omitted dose errors are the most frequently reported opioid error type in specialist palliative care |
RESEARCH QUESTION 3: What are the opioid error mitigating factors in specialist palliative care inpatient services?

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<td></td>
<td>palliative care inpatient services using paper based medication charts</td>
<td>paper chart...because it (the electronic chart) alerts us all the time. We can't miss it' (ID57_Nurse)</td>
<td></td>
<td>inpatient services, and substantially contribute to iatrogenic patient harm, transitioning to electronic medication management systems for services currently using paper-based medication charts is warrants consideration.</td>
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