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Establishing the prevalence of healthcare associated infections in Australian hospitals: Protocol for the Comprehensive Healthcare Associated Infection National Surveillance (CHAINS) study

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ESTABLISHING THE PREVALENCE OF HEALTHCARE ASSOCIATED INFECTIONS IN AUSTRALIAN HOSPITALS: PROTOCOL FOR THE COMPREHENSIVE HEALTHCARE ASSOCIATED INFECTION NATIONAL SURVEILLANCE (CHAINS) STUDY

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ABSTRACT

Introduction

A healthcare associated infection data (HAI) point prevalence study (PPS) conducted in 1984 in Australian hospitals estimated the prevalence of HAI to be 6.3%. Since this time, there have been no further national estimates undertaken. In the absence of a coordinated national surveillance program or regular PPS, there is a dearth of national HAI data to inform policy and practice priorities.

Methods and Analysis

A national HAI PPS study will be undertaken based on the European Centres for Disease Control method. Nineteen public acute hospitals will participate. A standardised algorithm will be used to detect HAIs in a two stage cluster design, random sample of adult inpatients in acute wards and all ICU patients. Data from each hospital will be collected by two trained members of the research team. We will estimate the prevalence of HAIs, invasive device use, single room placement and deployment of transmission based precautions.

Ethics and Dissemination

Ethics approval was obtained from the Alfred Health Human Research Ethics Committee (HREC/17/Alfred/203) via the National Mutual Assessment and the Tasmanian Health and Medical Human Research Committee (H0016978). Findings will be disseminated in individualised participating hospital reports, peer review publications and conference presentations.

Keywords

Healthcare associated infection, point prevalence surveillance, infection prevention, infection control.

Article Summary: Strengths and limitations of this study

- The study is based on validated methods within the European Centres for Disease Control (ECDC) PPS surveillance protocol, with the addition of device use prevalence estimates
- Data from all sites will be collected by two trained data collectors minimising variation between sites
- Restriction to adult acute inpatients in public facilities limits representativeness
- Some infections may be missed due to sampling process

INTRODUCTION

Surveillance of healthcare associated infections (HAI) is a fundamental component of any infection prevention program.[1] National HAI point prevalence studies (PPS) provide a 'snapshot' of all HAI types and are used to identify priority areas for action and inform infection prevention recommendations and policy direction.[2] Many European countries regularly contribute HAI data to the European Centres for Disease Control (ECDC) PPS surveillance, and this is often in addition to existing, well established national HAI surveillance programs.[3 4]

Australia's first and only HAI PPS was conducted in 1984 and estimated the prevalence of "nosocomial" infections to be 6.5%.[5] Subsequently, many local HAI surveillance programs have evolved separately, resulting in broad variation in activity and methodology to the extent that data cannot be reliably collated to generate national Australian HAI data, with the exception of *Staphylococcus aureus* bacteraemia.[6-8]

Despite strong support for a national surveillance program,[9] there has been no funding identified to achieve this goal. This means that Australian national infection prevention policy is not informed by sound national data, nor can national interventions be effectively evaluated. Further, where existence of HAI surveillance occurs at local hospital or State level, variations in methodologies means that it is not possible to meaningfully aggregate data.

We will undertake the first Australian HAI PPS in over 30 years, the Comprehensive Healthcare Associated Infection National Surveillance (CHAINS) study. The European

protocol provides a standardised methodology to European Member States and hospitals. The current version 5.3 provides a framework to develop a PPS in Australia.[3] Whilst based on the protocol developed by the ECDC, the CHAINS protocol differs in a number of areas including participation and recruitment criteria, and does not include patient level risk factors or antimicrobial prescribing data.

The purpose of this study is to update our knowledge on the prevalence of HAIs and multi-drug resistant organisms in Australia and provide stakeholders with national benchmarks that can be used to identify areas for improvement, measure effectiveness of interventions, and importantly use as a model for future national surveillance activities**.** We will also determine the prevalence of device use, informing future research projects and providing useful data for industry.

Whilst guidelines for describing point prevalence study protocols have not been published, this paper describes the study protocol, and focuses on areas that vary from the ECDC protocol.

Study Objectives

The primary objectives of the CHAINS study are:

1. To estimate the total prevalence of HAIs among inpatients aged ≥16 in public acute care hospitals in Australia
2. To describe the HAIs by site, type of patient, specialty, type of facility and geographical location

The secondary objectives are:

1. To determine the prevalence of patients:
    a. managed under transmission based precautions isolation in a single room
    b. with an indwelling urinary catheter device
    c. with vascular access device(s)
    d. with a multidrug resistant organism (infection or colonisation)

METHODS AND ANALYSIS

Study Design

A rolling PPS across a sample of Australian public hospitals will be undertaken over a three month period. The PPS protocol is based on the ECDC standardised methodology for PPSs on HAIs,[10] with some modifications to the Standard Protocol option (see below and Table 1). The ECDC protocol was developed and tested extensively with reliable outcomes. It has been utilised across 29 European countries for national PPS, and has also been applied in several non-European countries [11-13]

Table 1 *– Summary of major differences in protocol*

ECDC protocol	Deviations	Rationale
Patient Inclusion and Exclusion		
– All patients admitted to the ward before or at 8 a.m. and not discharged from the ward at the time	– 50% patients in acute wards and all ICU patients – Only adults ≥18-year-olds admitted to the ward	– Insufficient resources to sample every patient

of survey, including neonates on maternity and paediatric wards, will be included	before or at 8 a.m. and not discharged from the ward at the time of survey will be included	
Data Collection Processes		
– Composition of the team responsible for data collection varied from one hospital to another	– The same data collectors will be collecting data for all hospitals in the PPS	– To minimise variation and maximise consistency in classifying infections – Minimise the burden of data collection on participating hospitals
– Total time frame for data collection for all wards of a single hospital did not exceed two to three weeks	– Data to be collected during a one off hospital visit (1-3 days)	– Same data collectors used across all facilities – Smaller sample size
Patient Data Fields (see supplementary table for all data fields)		
– McCabe score was employed to classify the severity of underlying medical conditions	– No risk factor data will be collected	– Insufficient resources to collect risk factor data
– Antimicrobial use	– No antimicrobial use data will be collected	– Antimicrobial data already collected in

		annual point prevalence survey
Data Validation		
– Recommended sample size at the national level was 750 patients in 25 hospitals	– Records of 100% of patients identified as having an infection at the first hospital (up to a maximum of 40), and a random sample of 5% of those identified as not having an infection will be reviewed	– Same data collectors used across all facilities – Pragmatic validation within existing resources
– Validation team consisted was separate from the original data collection team	– Validation team members will consist of the chief investigators who cross-check the data	– Same data collectors used across all facilities
– Blinded data validation recommended	– Validation team will not be blinded	– Not practical for this study

Hospital Selection

Public acute care hospitals categorised as a Principal Referral hospital or a Group A hospital as per the Australian Institute for Health and Welfare peer groupings will be eligible to participate.[14] These two peer groups are characterised by providing a broad range of services, include emergency and intensive care units, and have larger patient volumes than

other peer groups.[14] Because of anticipated heterogeneity and to maximise representation of large acute care public facilities, specialist hospitals (e.g. maternity, cancer and paediatric hospitals) and private hospitals will be excluded.

Limited resources for this PPS restricts the number of participating hospitals to a sample of public acute care facilities. We will launch a call for expressions of interest for hospitals to participate in the study to measure the appetite for participation. To best meet the objectives of the study, 19 hospitals will be purposively selected to participate from those who meet the selection criteria. Hospital selection numbers will be approximately proportional to the size of the six States and one of Territories in Australia (the other Territory will not be included due to logistical reasons)

Ward Selection

In each participating hospital, all acute care inpatient wards will be included with the exception of:

- paediatric wards
- psychiatric wards (acute and non-acute)
- neonatal ICUs
- rehabilitation, palliative, sub-acute and long-term care wards in acute care facilities (e.g. nursing homes, spinal rehabilitation wards);
- accident and emergency (A&E) departments (except for wards attached to A&E departments where patients are monitored for more than 24 hours).

Patient sampling

Patients will be sampled in a two-stage cluster design, with a sample of patients in a sample of Principal Referral and Group A Hospitals. Patients will be systematically sampled on each eligible ward at participating hospitals by randomly selecting either odd or even numbered beds (50% sample). Randomisation will be achieved by the toss of a coin by the Lead Investigator (PLR) prior to the RAs visiting each site. If the bed is empty due to it not being used, then this is not counted in the denominator, and the next bed occupied within the random sample with be surveyed. As a high-risk group of interest, all patients in adult intensive care units (ICUs) will be surveyed.

We estimate that we will survey 50% of patients at 19 hospitals (estimated up to 5000 patients total). Assuming an intracluster correlation coefficient of 3% and a prevalence of hospital acquired infection of 7.5-10%, we will be able to estimate prevalence with a precision of +/- 2.2-2.5% (based on the 95% CI). Estimates of prevalence will account for the clustered design and oversampling in ICU (using inverse probability weighting).

Patient Selection

Consistent with the ECDC protocol, in each ward meeting the above inclusion criteria, all patients admitted to the ward before or at 0800 on the first survey day, and not discharged from the ward at the time of the survey will be eligible. In practice, this means that patients transferred in or out after 0800 of the first survey day from or to another ward, or location outside the hospital, will not be included.

Patients who meet the following criteria on the eligible wards will be excluded:

- patients under 18 years of age (in any hospital ward or unit)
- patients undergoing same day treatment or surgery
- patients seen at outpatient department
- patients in the emergency room;
- dialysis patients (outpatients)

Data collection and management

Data collection from 19 sites across Australia will occur over a 3-month period from August to October 2018. A specific date for each hospital visit will be coordinated with the hospital. The location and size of the facility will be considered when planning visits to maximise efficiency of data collection.

All data will be collected by two trained Research Assistants (RAs). As a condition of enrolment in the study, hospitals will be required to provide a hospital-based clinician, preferably a member of the infection prevention team, on the survey days. The role of the hospital clinician will be to accompany the RAs and to facilitate access to all wards and data.

The two RA's will be trained by the research team in data collection methodology, and use of data collection tools. The RA's will also undergo competency based assessment prior to data collection. A secure online web-based survey tool will be accessed for data entry.

We will collect four levels of data; hospital, ward, patient and HAI.

Hospital data

General hospital demographic data will be collected based on the ECDC protocol. However the only indicator data similar to ECDC protocol is data on hand hygiene compliance, and the number of infection control FTE nurses. Further indicator data to be included are *Staphylococcus aureus* bacteraemia rates (routinely reported to the Australian Health and Institute of Welfare) and intensive care unit central line-associated bloodstream infection rates if available. This data will be collected prior to the visit.

Ward Data

Ward demographic data will be collected on the day of the survey. Data on the ward specialty, total number of beds and number of single rooms is the same as for ECDC. Different to ECDC protocol will be data collected on the number of patients placed in single room isolation and the type of isolation. No other ward level data will be collected.

Patient data

Patient-level data is a modified version of the ECDC Standard Protocol. Two main differences are the omission of both risk factor data (McCabe) score and antimicrobial use data. The omission of risk factor data is to ensure patient data can be collected in a timely manner. Detailed antimicrobial data was omitted given that Australia has an annual national antimicrobial prescribing PPS which allows more thorough analysis of antimicrobial use in Australia than what was possible in this PPS. [15] As a screen to determine the presence of a HAI, data on the presence of fever and current antimicrobial therapy will be collected.

HAI data

For each patient with a fever or currently receiving antimicrobial therapy, the RA's will work through an algorithm applying the HAI definitions in the ECDC protocol. Data on each HAI identified will be consistent with the ECDC protocol.

Data validation

Data will be assessed for completeness and accuracy at the first hospital to undergo the survey. Records of 100% of patients identified as having an infection (up to a maximum of 40), and a random sample of 5% of those identified as not having an infection will be reviewed by two chief investigators. Findings will be discussed with the research team prior to the survey proceeding.

Data Analysis

The prevalence of HAI will be estimated from the proportion with infection in the sample (correcting for oversampling of ICU patients) with confidence intervals corrected for the clustered design. This will be performed using the svy module in Stata 14.2 (College Station, Texas 2017). The analysis will consider each hospital as a cluster, and adjust for oversampling in ICU using inverse probability weights. Logistic regression will be used to examine factors associated with infection. These factors will include:

- Location of hospital: metro, remote etc.
- Age
- Gender
- Ward type

- Intubation
- Presence of peripheral vascular access device
- Presence of central vascular access device
- Indwelling urinary catheter

Outcome measures

The outcomes for each objective of the study are outlined in Table 2.

Table 2 *Key outcome measures*

	Objective	**Outcome measure**
Primary objectives	To estimate the total prevalence of HAIs among inpatients aged ≥18 in public acute care hospitals in Australia	Total number of patients classified as having a HAI divided by the total number of patients surveyed, weighted by the probability of sampling
	To describe the HAIs by site, type of patient, specialty, type of facility and geographical location	Of the patients with a HAI, the proportion by • infection site • elective or emergency • gender • age • ward specialty • facility type
Secondary	Prevalence of patients	Total number of patients cared for under

objectives	managed under transmission based precautions isolation in a single room	transmission-based precautions divided by the total number of patients surveyed, overall (weighted by the probability of sampling), by hospital, by ward specialty
	Prevalence of patients with an indwelling urinary catheter device	Total number of patients with a urinary catheter divided by the total number of patients surveyed, overall, by hospital, by ward specialty
	Prevalence of patients with vascular access device(s)	Total number of patients with a vascular access device divided by the total number of patients surveyed Of those with a vascular device, the proportion by type of device, overall, by hospital, by ward specialty
	Prevalence of patients with a multi drug resistance organism (infection or colonisation)	Total number of patients infected or colonised with a multi drug resistance organism divided by the total number of patients surveyed Of those with a multi drug resistance organism, the proportion by organism, overall, by hospital, by ward specialty

Ethical Considerations

This study has been approved by the Alfred Health Human Research Ethics Committee (HREC) (HREC/17/Alfred/203) through the National Mutual Assessment (NMA) process. The

NMA is a system of single scientific and ethical review of multicentre human research projects in public health organisations in, Australian Capital Territory, New South Wales, Queensland, South Australia, Victoria and Western Australia. A separate approval was obtained from the Tasmanian Health and Medical Human Research Committee (H0016978) for participating Tasmanian hospitals.

Any risks or harms identified and associated with the study will be reported to the HRECs. Reporting of the study and progress, including audits, will be conducted consistent with the requests of the HRECs. Any modification to the study that have ethical implications will be forwarded to the HRECs for approval. In the main results paper for the study, we will also aim to estimate the resources required to obtain ethics approval and site specific authorisations.

Informed consent

A waiver of individual patient consent has been obtained for this study from the HRECs based on a number of considerations. These considerations are: there are no interventions and no harm or discomfort to the patient as a result of the project; the benefits of the research justify any risk of harm associated with not obtaining consent; results of the research are not individualised or indeed patient identifiable; the study requires no direct involvement of patients, rather it collates existing information obtained during their hospitalisation; and no new information will be obtained about individual patients, therefore results will have no significance for the individual welfare of patients.

Dissemination

Dissemination of knowledge gained from this study will be facilitated using a variety of modes. Each participating hospital will be provided with an individualised report highlighting their outcomes in comparison to other hospitals (deidentified) and aggregated data. Overall study findings will be presented through peer reviewed publications, presentations to jurisdictional policy representatives and relevant conferences.

Discussion

There is a dearth of national HAI data in Australia. Data from a multicentre PPS on urinary tract infections in Australia estimated the HAI rate of UTI was 1.4%, and the catheter associated UTI prevalence to be 0.9%.[16] Recently an estimate of the burden of HAI in Australia was generated from a systematic review of studies published between 2010 and 2016 and suggested the incidence of HAIs in Australia may be up to 165,000 per year.[17]

Although the Australian Commission for Safety and Quality in Health Care has a number of national initiatives to prevent HAI, it can be argued that these initiatives may be misdirected given the lack of national HAI data to inform and evaluate interventions. While administrative data will soon be used to measure HAIs in Australia[18], we contend that HAI surveillance cannot be adequately performed with this approach.[19 20]

The importance of reliable national HAI data in Australia cannot be underestimated. The CHAINS study is a small first step towards an improved understanding of the prevalence of HAIs in Australia. To identify, develop, implement and evaluate national HAI initiatives, reliable data based on validated methods must be used.

Strengths

This study has a number of strengths. First, it is based on established and validated methodology from the ECDC. Second, rather than rely on each hospital to collect and submit data, which is the common process in large PPS studies, this study will use the same trained and competent data collectors at each hospital. This greatly increases the likelihood of consistency in data collection and application of HAI definitions and prevents any subjective influences that may occur at a hospital level. Third, the two stage cluster design, randomised sampling of patients at each facility, and the inclusion of facilities in six of the seven Australian jurisdictions will provide confident estimates of the prevalence of HAI. Fourth, data on the prevalence of device use, single room placement and transmission based precautions has never before been estimated in Australia and will generate new knowledge.

Limitations

Data collecting is limited to adult acute inpatients, no data is being collected from hospitals within the private sector, and to ensure timely collection of data at each site, patient level risk factor data (i.e. McCabe index data) is not being collected. Some HAIs may be missed due to randomisation and the use of fever or current antimicrobial therapy as a screen to explore the presence of HAI.

Study status

Data collection is due to commence in August 2018.

Footnotes

Author contributions

Five authors (PLR, AS, AC, TB, BGM) are chief investigators and are involved in the design and implementation of the study. KM has provided expert advice on national point prevalence surveys and provided access to data collection tools and educational materials. PLR prepared the manuscript, all other authors contributed sections, critiqued and revised and approved the manuscript

Competing interests

None declared

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Patient and Public Involvement statement

There was no patient or public involvement in the development of this study however the study was reviewed by patient and consumer representatives on the Human Research Ethics Committee. Whilst results will not be provided directly to the

patients surveyed in the study, data will be provided back to each participating facility, policy representatives and disseminated through peer review publications and conferences.

Data sharing statement

Any available unpublished data can be requested on contacting the authors.

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The authors acknowledge the work of the CHAINS Project Manager, Bridey Saultry, and the key stakeholders at potential sites. The Centre for Quality and Patient Safety, Deakin University for supporting and administering the project. We also acknowledge Professor Jacqui Reilly and Professor Jennie Wilson for expert advice and guidance in the planning stages of this project.

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We will undertake the first Australian HAI PPS in over 30 years, the Comprehensive Healthcare Associated Infection National Surveillance (CHAINS) study. The European

protocol provides a standardised methodology to European Member States and hospitals. The current version 5.3 provides a framework to develop a PPS in Australia.[3] Whilst based on the protocol developed by the ECDC, the CHAINS protocol differs in a number of areas including participation and recruitment criteria, and does not include patient level risk factors or antimicrobial prescribing data.

The purpose of this study is to update our knowledge on the prevalence of HAIs and multi-drug resistant organisms in Australia and provide stakeholders with national benchmarks that can be used to identify areas for improvement, measure effectiveness of interventions, and importantly use as a model for future national surveillance activities**.** We will also determine the prevalence of device use, informing future research projects and providing useful data for industry.

Whilst guidelines for describing point prevalence study protocols have not been published, this paper describes the study protocol, and focuses on areas that vary from the ECDC protocol.

Study Objectives

The primary objectives of the CHAINS study are:

1. To estimate the total prevalence of HAIs among inpatients aged ≥18 in public acute care hospitals in Australia
2. To describe the HAIs by site, type of patient, specialty, type of facility and geographical location

The secondary objectives are:

1. To determine the prevalence of patients:
    a. managed under transmission based precautions isolation in a single room
    b. with an indwelling urinary catheter device
    c. with vascular access device(s)
    d. with a multidrug resistant organism (infection or colonisation)

METHODS AND ANALYSIS

Study Design

A rolling PPS across a sample of Australian public hospitals will be undertaken over a three month period. The PPS protocol is based on the ECDC standardised methodology for PPSs on HAIs,[10] with some modifications to the Standard Protocol option (see below and Table 1). The ECDC protocol was developed and tested extensively with reliable outcomes. It has been utilised across 29 European countries for national PPS, and has also been applied in several non-European countries [11-13]

Table 1 *– Summary of major differences in protocol*

ECDC protocol	Deviations	Rationale
Patient Inclusion and Exclusion		
– All patients admitted to the ward before or at 8 a.m. and not discharged from the ward at the time	– 50% patients in acute wards and all ICU patients – Only adults ≥18-year-olds admitted to the ward	– Insufficient resources to sample every patient

of survey, including neonates on maternity and paediatric wards, will be included	before or at 8 a.m. and not discharged from the ward at the time of survey will be included	
Data Collection Processes		
– Composition of the team responsible for data collection varied from one hospital to another	– The same data collectors will be collecting data for all hospitals in the PPS	– To minimise variation and maximise consistency in classifying infections – Minimise the burden of data collection on participating hospitals
– Total time frame for data collection for all wards of a single hospital did not exceed two to three weeks	– Data to be collected during a one off hospital visit (1-3 days)	– Same data collectors used across all facilities – Smaller sample size
Patient Data Fields		
– McCabe score was employed to classify the severity of underlying medical conditions	– No risk factor data will be collected	– Insufficient resources to collect risk factor data
– Antimicrobial use	– No antimicrobial use data will be collected	– Antimicrobial data already collected in

		annual point prevalence survey
Data Validation		
– Recommended sample size at the national level was 750 patients in 25 hospitals	– Records of 100% of patients identified as having an infection at the first hospital (up to a maximum of 40), and a random sample of 5% of those identified as not having an infection will be reviewed	– Same data collectors used across all facilities – Pragmatic validation within existing resources
– Validation team consisted was separate from the original data collection team	– Validation team members will consist of the chief investigators who cross-check the data	– Same data collectors used across all facilities
– Blinded data validation recommended	– Validation team will not be blinded	– Not practical for this study

Hospital Selection

Public acute care hospitals categorised as a Principal Referral hospital or a Group A hospital as per the Australian Institute for Health and Welfare peer groupings will be eligible to participate.[14] These two peer groups are characterised by providing a broad range of services, include emergency and intensive care units, and have larger patient volumes than

other peer groups.[14] Because of anticipated heterogeneity and to maximise representation of large acute care public facilities, specialist hospitals (e.g. maternity, cancer and paediatric hospitals) and private hospitals will be excluded.

Limited resources for this PPS restricts the number of participating hospitals to a sample of public acute care facilities. We will launch a call for expressions of interest for hospitals to participate in the study to measure the appetite for participation. To best meet the objectives of the study, 19 hospitals will be purposively selected to participate from those who meet the selection criteria. Hospital selection numbers will be approximately proportional to the size of the six States and one of Territories in Australia (the other Territory will not be included due to logistical reasons)

Ward Selection

In each participating hospital, all acute care inpatient wards will be included with the exception of:

- paediatric wards
- psychiatric wards (acute and non-acute)
- neonatal ICUs
- rehabilitation, palliative, sub-acute and long-term care wards in acute care facilities (e.g. nursing homes, spinal rehabilitation wards);
- accident and emergency (A&E) departments (except for wards attached to A&E departments where patients are monitored for more than 24 hours).

Patient sampling

Patients will be sampled in a two-stage cluster design, with a sample of patients in a sample of Principal Referral and Group A Hospitals. Patients will be systematically sampled on each eligible ward at participating hospitals by randomly selecting either odd or even numbered beds (50% sample). Randomisation will be achieved by the toss of a coin by the Lead Investigator (PLR) prior to the RAs visiting each site. If the bed is empty due to it not being used, then this is not counted in the denominator, and the next bed occupied within the random sample with be surveyed. As a high-risk group of interest, all patients in adult intensive care units (ICUs) will be surveyed.

We estimate that we will survey 50% of patients at 19 hospitals (estimated up to 5000 patients total). Assuming an intracluster correlation coefficient of 3% and a prevalence of hospital acquired infection of 7.5-10%, we will be able to estimate prevalence with a precision of +/- 2.2-2.5% (based on the 95% CI). Estimates of prevalence will account for the clustered design and oversampling in ICU (using inverse probability weighting).

Patient Selection

Consistent with the ECDC protocol, in each ward meeting the above inclusion criteria, all patients admitted to the ward before or at 0800 on the first survey day, and not discharged from the ward at the time of the survey will be eligible. In practice, this means that patients transferred in or out after 0800 of the first survey day from or to another ward, or location outside the hospital, will not be included.

Patients who meet the following criteria on the eligible wards will be excluded:

- patients under 18 years of age (in any hospital ward or unit)
- patients undergoing same day treatment or surgery
- patients seen at outpatient department
- patients in the emergency room;
- dialysis patients (outpatients)

Data collection and management

Data collection from 19 sites across Australia will occur over a 3-month period from August to October 2018. A specific date for each hospital visit will be coordinated with the hospital. The location and size of the facility will be considered when planning visits to maximise efficiency of data collection.

All data will be collected by two trained Research Assistants (RAs). As a condition of enrolment in the study, hospitals will be required to provide a hospital-based clinician, preferably a member of the infection prevention team, on the survey days. The role of the hospital clinician will be to accompany the RAs and to facilitate access to all wards and data.

The two RA's will be trained by the research team in data collection methodology, and use of data collection tools. The RA's will also undergo competency based assessment prior to data collection. A secure online web-based survey tool will be accessed for data entry.

We will collect four levels of data; hospital, ward, patient and HAI.

Hospital data

General hospital demographic data will be collected based on the ECDC protocol. However the only indicator data similar to ECDC protocol is data on hand hygiene compliance, and the number of infection control FTE nurses. Further indicator data to be included are *Staphylococcus aureus* bacteraemia rates (routinely reported to the Australian Health and Institute of Welfare) and intensive care unit central line-associated bloodstream infection rates if available. This data will be collected prior to the visit.

Ward Data

Ward demographic data will be collected on the day of the survey. Data on the ward specialty, total number of beds and number of single rooms is the same as for ECDC. Different to ECDC protocol will be data collected on the number of patients placed in single room isolation and the type of isolation. No other ward level data will be collected.

Patient data

Patient-level data is a modified version of the ECDC Standard Protocol. Two main differences are the omission of both risk factor data (McCabe) score and antimicrobial use data. The omission of risk factor data is to ensure patient data can be collected in a timely manner. Detailed antimicrobial data was omitted given that Australia has an annual national antimicrobial prescribing PPS which allows more thorough analysis of antimicrobial use in Australia than what was possible in this PPS. [15] As a screen to determine the presence of a HAI, data on the presence of fever and current antimicrobial therapy will be collected. Data on the presence of a multidrug resistant organism will also be collected. These will include:

- MRSA: Methicillin Resistant *Staphylococcus aureus*,
- VRE: Vancomycin Resistant Enterococci
- ESBL: Extended-spectrum β-lactamase
- CPE: carbapenemase-producing *Enterobacteriaceae*
- *Clostridium difficile*
- Other drug resistant Gram negative organisms
- Other organisms that have been identified by the hospital as an MRO

Screening for colonisation will occur according to local protocols by participating hospitals. The prevalence of colonisation will therefore represent colonisation as detected according to current Australian infection prevention practices. We will report on the local screening practices to assist with interpretation of the prevalence of colonisation.

HAI data

For each patient with a fever or currently receiving antimicrobial therapy, the RA's will work through an algorithm applying the HAI definitions in the ECDC protocol. Data on each HAI identified will be consistent with the ECDC protocol.

Data validation

Data will be assessed for completeness and accuracy at the first hospital to undergo the survey. Records of 100% of patients identified as having an infection (up to a maximum of 40), and a random sample of 5% of those identified as not having an infection will be reviewed by two chief investigators. Findings will be discussed with the research team prior to the survey proceeding.

Data Analysis

The prevalence of HAI will be estimated from the proportion with infection in the sample (correcting for oversampling of ICU patients) with confidence intervals corrected for the clustered design. This will be performed using the svy module in Stata 14.2 (College Station, Texas 2017). The analysis will consider each hospital as a cluster, and adjust for oversampling in ICU using inverse probability weights. Logistic regression will be used to examine factors associated with infection. These factors will include:

- Location of hospital: metro, remote etc.
- Age
- Gender
- Ward type
- Intubation
- Presence of peripheral vascular access device
- Presence of central vascular access device
- Indwelling urinary catheter

Outcome measures

The outcomes for each objective of the study are outlined in Table 2.

Table 2 *Key outcome measures*

	Objective	**Outcome measure**
Primary	To estimate the total	Total number of patients classified as having a

objectives	prevalence of HAIs among inpatients aged ≥18 in public acute care hospitals in Australia	HAI divided by the total number of patients surveyed, weighted by the probability of sampling
	To describe the HAIs by site, type of patient, specialty, type of facility and geographical location	Of the patients with a HAI, the proportion by • infection site • elective or emergency • gender • age • ward specialty • facility type
Secondary objectives	Prevalence of patients managed under transmission based precautions isolation in a single room	Total number of patients cared for under transmission-based precautions divided by the total number of patients surveyed, overall (weighted by the probability of sampling), by hospital, by ward specialty
	Prevalence of patients with an indwelling urinary catheter device	Total number of patients with a urinary catheter divided by the total number of patients surveyed, overall, by hospital, by ward specialty
	Prevalence of patients with vascular access device(s)	Total number of patients with a vascular access device divided by the total number of patients surveyed Of those with a vascular device, the proportion by type of device, overall, by hospital, by ward

		specialty
	Prevalence of patients with a multi drug resistance organism (infection or colonisation)	Total number of patients infected or colonised with a multi drug resistance organism divided by the total number of patients surveyed Of those with a multi drug resistance organism, the proportion by organism, overall, by hospital, by ward specialty

Ethical Considerations

This study has been approved by the Alfred Health Human Research Ethics Committee (HREC) (HREC/17/Alfred/203) through the National Mutual Assessment (NMA) process. The NMA is a system of single scientific and ethical review of multicentre human research projects in public health organisations in, Australian Capital Territory, New South Wales, Queensland, South Australia, Victoria and Western Australia. A separate approval was obtained from the Tasmanian Health and Medical Human Research Committee (H0016978) for participating Tasmanian hospitals.

Any risks or harms identified and associated with the study will be reported to the HRECs. Reporting of the study and progress, including audits, will be conducted consistent with the requests of the HRECs. Any modification to the study that have ethical implications will be forwarded to the HRECs for approval. In the main results paper for the study, we will also aim to estimate the resources required to obtain ethics approval and site specific authorisations.

Informed consent

A waiver of individual patient consent has been obtained for this study from the HRECs based on a number of considerations. These considerations are: there are no interventions and no harm or discomfort to the patient as a result of the project; the benefits of the research justify any risk of harm associated with not obtaining consent; results of the research are not individualised or indeed patient identifiable; the study requires no direct involvement of patients, rather it collates existing information obtained during their hospitalisation; and no new information will be obtained about individual patients, therefore results will have no significance for the individual welfare of patients.

Patient and Public Involvement statement

There was no patient or public involvement in the development of this study however the study was reviewed by patient and consumer representatives on the Human Research Ethics Committee. Whilst results will not be provided directly to the patients surveyed in the study, data will be provided back to each participating facility, policy representatives and disseminated through peer review publications and conferences.

Dissemination

Dissemination of knowledge gained from this study will be facilitated using a variety of modes. Each participating hospital will be provided with an individualised report highlighting their outcomes in comparison to other hospitals (deidentified) and aggregated data. Overall study findings will be presented through peer reviewed publications, presentations to jurisdictional policy representatives and relevant conferences.

Discussion

There is a dearth of national HAI data in Australia. Data from a multicentre PPS on urinary tract infections in Australia estimated the HAI rate of UTI was 1.4%, and the catheter associated UTI prevalence to be 0.9%.[16] Recently an estimate of the burden of HAI in Australia was generated from a systematic review of studies published between 2010 and 2016 and suggested the incidence of HAIs in Australia may be up to 165,000 per year.[17]

Although the Australian Commission for Safety and Quality in Health Care has a number of national initiatives to prevent HAI, it can be argued that these initiatives may be misdirected given the lack of national HAI data to inform and evaluate interventions. While administrative data will soon be used to measure HAIs in Australia[18], we contend that HAI surveillance cannot be adequately performed with this approach.[19 20]

The importance of reliable national HAI data in Australia cannot be underestimated. The CHAINS study is a small first step towards an improved understanding of the prevalence of HAIs in Australia. To identify, develop, implement and evaluate national HAI initiatives, reliable data based on validated methods must be used.

Strengths

This study has a number of strengths. First, it is based on established and validated methodology from the ECDC. Second, rather than rely on each hospital to collect and submit data, which is the common process in large PPS studies, this study will use the same trained and competent data collectors at each hospital. This greatly increases the likelihood of

consistency in data collection and application of HAI definitions and prevents any subjective influences that may occur at a hospital level. Third, the two stage cluster design, randomised sampling of patients at each facility, and the inclusion of facilities in six of the seven Australian jurisdictions will provide confident estimates of the prevalence of HAI. Fourth, data on the prevalence of device use, single room placement and transmission based precautions has never before been estimated in Australia and will generate new knowledge.

Limitations

Data collecting is limited to adult acute inpatients, no data is being collected from hospitals within the private sector, and to ensure timely collection of data at each site, patient level risk factor data (i.e. McCabe index data) is not being collected. Some active HAIs may be missed due to the random sampling of patients and the use of fever or current antimicrobial therapy as a screen to explore the presence of HAI.

As hospitals were purposively selected rather than a random sample, we cannot exclude selection bias. To examine this, we will compare administrative and infection prevention metrics of participating hospitals with those of non-participating hospitals in the same peer categories. Such metrics will include state/territory location, remoteness area, bed numbers, presence of high-risk units for HAIs (e.g. oncology, bone marrow transplantation and solid organ transplantation), healthcare-associated Staphylococcus aureus bloodstream infection rate (cases per 10,000 bed days), and hand hygiene compliance

Study status

Data collection is due to commence in August 2018.

Footnotes

Author contributions

Five authors (PLR, AS, AC, TB, BGM) are chief investigators and are involved in the design and implementation of the study. KM has provided expert advice on national point prevalence surveys and provided access to data collection tools and educational materials. PLR prepared the manuscript, all other authors contributed sections, critiqued and revised and approved the manuscript

Competing interests

None declared

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Data sharing statement

Any available unpublished data can be requested on contacting the authors.

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