Investigating inequities in cardiovascular care and outcomes for Queensland Aboriginal and Torres Strait Islander people: protocol for a hospital-based retrospective cohort data linkage project

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ABSTRACT

Introduction Cardiovascular disease (CVD) represents a significant burden of disease for Aboriginal and Torres Strait Islander people, a population that continues to experience a lower life expectancy than other Australians. The aim of the Better Cardiac Care Data Linkage project is to describe patient care pathways and to identify disparities in care and health outcomes between Aboriginal and Torres Strait Islander people and other Queensland residents diagnosed with CVD in the state of Queensland.

Methods This is a population-based retrospective cohort study using linked regional, state and national health and administrative data collections to describe disparities in CVD healthcare in primary and secondary prevention settings and during hospitalisation. The CVD cohort will be identified from the Queensland Hospital Admitted Patient Data Collection for admissions that occurred between 1 July 2010 and 31 June 2016 and will include relevant International Classification of Disease codes for ischaemic heart disease, congestive heart failure, stroke, acute rheumatic fever and rheumatic heart disease. Person-level data will be linked by Data Linkage Queensland and the Australian Institute of Health and Welfare (AIHW) in accordance with ethical and public health approvals to describe the patient journey prior to, during and post the hospital admission.

Analysis This project will focus largely on descriptive epidemiological measures and multivariate analysis of clinical care standards and outcomes for Aboriginal and Torres Strait Islander people compared with other Queenslanders, including identification of risk factors for suboptimal care and change over time. Variation in care pathways and patient outcomes will be compared by Indigenous status, sex, age group, remoteness of residence, year of index hospitalisation and socioeconomic status. Cox models for time-to-event data and mixed models or generalised estimating equations for longitudinal data will be used to measure change over time where temporal effects exist.

Ethics and dissemination Ethical approval has been granted by Human Research Ethics Committees of the Prince Charles Hospital (HREC/15/QPCH/289) and the AIHW (EO2016-1-233). The Northern Territory Department of Health and Menzies School of Health Research have also provided reciprocal ethical approval of the project.
INTRODUCTION

Aboriginal people and Torres Strait Islander people are the First Nations peoples of the lands now known as Australia and represent 3.3% (n=800 000) of the Australian population.1 Colonisation has resulted in ongoing devastation, dispossession and oppression2 for Aboriginal and Torres Strait Islander people, who continue to experience one of the lowest life expectancies of any population in high-income countries and universal health systems.3 Cardiovascular disease (CVD) remains the highest contributor to the gap in life expectancy.3

Nationally, over one-quarter of Aboriginal and Torres Strait Islander people live with CVD.4 While the CVD mortality rate fell by 49% during 1998 and 2017 for Aboriginal and Torres Strait Islander people, CVD mortality rate for this population is 1.5 times that of other Australians.56 Aboriginal and Torres Strait Islander people have an elevated CVD hospitalisation rate, particularly among women and those from remote areas, compared with other Australians.47 In Queensland, the Australian state with the second largest Aboriginal and Torres Strait Islander population,6 CVD accounts for one-quarter of deaths in Aboriginal and Torres Strait Islander people.3 They are also more likely to die of CVD before the age of 50 years than other Queenslanders (25% vs 3%, respectively).9

National statistics suggest the level of access to cardiac care is improving for Aboriginal and Torres Strait Islander people, although still far from optimal (Australian Institute of Health and Welfare, 2018b). An estimated 31% of Aboriginal and Torres Strait Islander people (38% in Queensland) had an annual health assessment during 2017–2018, more than double the 2010–2011 proportion. National data also suggest that Aboriginal and Torres Strait Islander people are similarly likely to undertake cardiac diagnostic services compared with other Australians, those with confirmed or suspected CVD are less likely to see a specialist.10 Analysis of linked administrative data from New South Wales (NSW) revealed 33% of Aboriginal and Torres Strait Islander peoples received revascularisation after hospitalisation for acute myocardial infarction (MI), significantly less than other people from NSW,11 which may be explained by differences in remoteness and age profiles.12 Similarly, Aboriginal and Torres Strait Islander people hospitalised for MI in NSW had excess 1-year mortality compared with other NSW patients with MI, although this appeared to be explained by a higher burden of comorbidity among the Aboriginal and Torres Strait Islander cohort.13 In the Northern Territory, linked data have been used to demonstrate higher lifetime health costs of stroke for Aboriginal and Torres Strait Islander people compared with other Northern Territory residents.14

Despite the growing evidence regarding the epidemiology of CVD and the patterns of cardiac care among Aboriginal and Torres Strait Islander people, important gaps remain. Little is known about the level of cardiac care received by Aboriginal and Torres Strait Islander people in Queensland and the relationship between preventive, secondary preventive and tertiary care and service use, healthcare costs and patient outcomes. The aims of this study were to describe cardiac care for Aboriginal and Torres Strait Islander people in Queensland, to identify services and patient groups most at risk of suboptimal cardiac care, and to investigate the economic and health impacts associated with these gaps in care. Findings will inform health service planning and integration for improvements in equity of care for Queenslanders and will provide a benchmark against which future strategies to improve cardiac care and outcomes for Aboriginal and Torres Strait Islander people can be assessed.

RESEARCH QUESTIONS

The aims of this study were to (1) describe the patterns and inequities in CVD care and outcomes for Aboriginal and Torres Strait Islander people compared with other Queenslanders hospitalised for CVD in Queensland (2010–2016), and examine the variations across population strata (age groups, sex, area-level socioeconomic groups and residential remoteness categories); (2) investigate whether disparities in CVD care contribute to the elevated CVD hospitalisation and excess mortality rates for Aboriginal and Torres Strait Islander people compared with other Queenslanders; and (3) investigate whether healthcare system expenditure is higher among those who receive guideline-discordant compared with guideline-concordant CVD preventive and in-hospital therapeutic care for Aboriginal and Torres Strait Islander and other Queenslanders. The findings from our research questions will be used for health service planning and establishment of targets for future evaluations and monitoring purposes.

POLICY CONTEXT

Closing the gap in life expectancy between Aboriginal and Torres Strait Islander peoples and other Australians has been a priority for the Council of Australian Governments since 2009,15 but despite some improvement, the gap is still greater than required to meet the target set for 2031.16 In March 2013, the Australian Health Ministers’ Advisory Council announced that improving cardiac health for Aboriginal and Torres Strait Islander people was a priority towards closing the health gap. The National Better Cardiac Care for Aboriginal and Torres Strait Islander People project identified five priority areas, with 21 performance indicators, to reduce CVD to achieve this.17 In response, the Queensland state government developed a local Better Cardiac Care implementation strategy for Aboriginal and Torres Strait Islander people.
people^{18} that initiated this data linkage project to develop a more complete understanding of the gaps in the patient care pathway and the impact on service use and patient outcomes for Aboriginal and Torres Strait Islander people for five common and serious CVD conditions: ischaemic heart disease (IHD), stroke, congestive heart failure (CHF), acute rheumatic fever (ARF) and rheumatic heart disease (RHD).

METHODS

Study setting

The state of Queensland is situated in the north east of Australia, where 4.6% of the Queensland population identify as Aboriginal and Torres Strait Islander people, representing 28.7% of the national Indigenous population. In Queensland, one-third of Aboriginal and Torres Strait Islander people live in major cities (33%, 66 600), half in regional areas (51%, 109 100), 1 in 14 (7%, 14 300) in remote areas and 1 in 10 (9%, 20 100) in very remote areas.^{19} As in the rest of Australia, Queensland’s health system is a multifaceted combination of public and private providers.^{20} Overall management of the public health sector is the responsibility of the state government’s Department of Health and implementation is undertaken through 16 regional hospital and health services (HHS).^{21} In contrast, the majority of primary care and a considerable proportion of hospital care is provided by private sector providers.^{20} Aboriginal and Torres Strait Islander health services have complex funding arrangements through federal, state and territory governments, including subsidies provided through the nationally funded Medicare Benefits Scheme (MBS) and Pharmaceutical Benefits Scheme (PBS).^{20}

Study design

This is a retrospective cohort study of people with a first hospitalisation of five CVDs (IHD, stroke, CCF, ARF and RHD) identified from the Queensland Hospital Admitted Patient Data Collection (QHAPDC). The first eligible hospital admission is referred to as the index admission. The study will use linked regional, state and national health and administrative data collections to investigate preventive primary healthcare before the index admission; acute care after the index admission; and in-hospital outcomes to assess the continuum of care provided against the clinical guidelines and best practice standards for primary and secondary prevention and in-hospital care. Where there are available data to do so, clinical care will be compared with the clinical guidelines current at the time: the Essential Service Standards for Equitable National Cardiovascular Care for Aboriginal and Torres Strait Islander People (ESSENCE)^{22} and the Australian Guideline for Prevention, Diagnosis and Management of Acute Rheumatic Fever and Rheumatic Heart Disease, Second Edition.^{23}

Study population

The study population will be any person identified in the QHAPDC with a Queensland residential postcode who had a hospital admission between 1 July 2010 and 30 June 2016 and a primary or other diagnosis code of International Classification of Diseases codes (I20–I25), stroke (I61, I63 and I64), CHF (I50), ARF (I00–I02) and RHD (I05–I09).

Data sources

The research questions will be addressed by linking 11 Queensland datasets and three national datasets to the study population (table 1). The resultant linked deidentified dataset will include data from 1 July 2005 to 31 December 2018. Once the study population is identified, a project-specific linkage key will be assigned to each individual in the cohort by Data Linkage Queensland (DLQ), to link with other datasets. Other datasets considered that were not included due to the recentness of the collection were Queensland Non-admitted Patient Data Collection and Queensland Cardiac Outcomes Registry. Datasets that we planned to include but were unable to obtain custodian approval for included: Queensland Medical Laboratory and Sullivan and Nicolaides Pathology.

Data linkage process

DLQ will link the records using personal identifiers, including full name, full residential address, sex, full date of birth and date of death (where applicable) to those in the Master Linkage File for datasets provided securely to DLQ (figure 1). These datasets include Emergency Department Information System (EDIS)/Emergency Data Collection (EDC), Specialist Outpatient Patient Data Collection (SODC), Queensland Death Register (QDR), Rheumatic Heart Disease Register and RHD Enhanced Surveillance Database. For Ferret, Best Practice Primary Healthcare Database (BP), Queensland Laboratory (AusLab), National Hospital Costing Data Collection (NHCDC) and Costing Funding Values (CFV), DLQ will supply the linking variables and the project specific linkage key to the Queensland Health data custodians to extract the approved data. Once extracted, the custodians will remove the identifiers and send the approved variables with the project-specific linkage key back to DLQ via a secure link. DLQ will then transfer the linked datasets to the Secure Unified Research Environment (SURE) supported by the Sax Institute for analysis by the project team. For the national datasets, MBS, PBS and National Death Index (NDI), DLQ will provide the linking variables and project specific linkage key to the Australian Institute of Health and Welfare (AIHW) data custodians who will link and extract the approved data and transfer the deidentified dataset to SURE.

Data will be deterministically and probabilistically linked at the unit record level by DLQ and AIHW in accordance with ethical and public health approvals, and privacy considerations. All data-specific activities (ie, storage, quality assurance and analysis) will be done within SURE. Data quality reports of the linkage pairing will be provided by DLQ and AIHW.

From the study population, six separate retrospective cohorts will be created each comprised of people with their first-ever hospitalisation for (1) CVD, (2) IHD, (3) CHF, (4) stroke, (5) ARF and (6) RHD. The first-ever CVD cohort (table 2) will include Queensland residents who had their first (index) hospital admission for one of the five CVDs, as indicated in the principal or other diagnosis fields in the QHAPDC, during July 2010 and June 2016. To maximise the likelihood that individuals enter the cohort at their first-ever CVD hospital admission, we will exclude those who had a hospital admission with a CVD principal or other diagnosis in the 5-year period prior to the index admission (referred to as the ‘lookback’ period). Individuals could only enter the study up until 30 June 2016 to ensure all individuals had a minimum of 2 years follow-up data to measure service use, cost and outcomes. The single disease cohorts will be created using the same approach; that is, individuals will enter the cohort at the index hospitalisation for the specific disease (eg, IHD) and will be excluded if they had a hospital admission in the lookback for the same specific disease (eg, IHD).
As this is a whole-proportion hospitalised with CVD within 28 days of index.

important differences in survival estimates, as well as the cohorts, we are similarly powered to detect minimally IHD, CHF and stroke cohorts, but not the RHD and ARF an annual health check and those who did not. For the a minimally important difference of 0.5 Strait Islander cohort receive an annual health check,10

between groups.

Preliminary analysis indicates there are over 180000 Queensland residents who were hospitalised for the first time for IHD, CHF, stroke, RHD or ARF during July 2010–June 2016, of whom over 5800 are identified as Aboriginal and Torres Strait Islander people. For the condition-specific cohorts, the cohort size varies from approximately 4200 (first IHD cohort) to 380 (first ARF cohort). Assuming 35% of the Aboriginal and Torres Strait Islander cohort receive an annual health check,10 a minimally important difference of 0.5 days in average length of stay or 1 day in time to CVD readmission, and an alpha of 0.001, we will have >90% power (beta 0.10) to statistically detect differences in these outcomes between Aboriginal and Torres Strait Islander people who received an annual health check and those who did not. For the IHD, CHF and stroke cohorts, but not the RHD and ARF cohorts, we are similarly powered to detect minimally important differences in survival estimates, as well as the proportion hospitalised with CVD within 28 days of index. As this is a whole-of-population cohort, we are unable to alter the cohort size. As such, underpowered analyses (ie, some RHD and ARF analyses) will be considered exploratory, and interpretation and reporting of the results will be cautiously conducted, with due consideration given to the limitations of the data and the plausibility of findings in light of existing published data.

Identifying Aboriginal and Torres Strait Islander people

Indigenous status is collected at point of care in Queensland hospitals using the standard question for Indigenous identification, ‘Are you of Aboriginal or Torres Strait Islander origin?’. This is typically coded in health datasets as ‘Aboriginal and Torres Strait Islander origin’, ‘Aboriginal but not Torres Strait Islander origin’, ‘Torres Strait Islander but not Aboriginal origin’, ‘neither Aboriginal or Torres Strait Islander’ and ‘not stated or unknown’, as it is in the QHAPDC. In the Queensland healthcare system, Aboriginal and Torres Strait Islander people have the right to self-identify or not, at each healthcare presentation. Incomplete and inconsistent reporting of Indigenous status usually results in an under-estimation of the Indigenous population and their use of services, which has an impact on the accurate planning and delivery of services to Aboriginal and Torres Strait Islander people.31

National best practice guidelines for analysis of linked administrative data related to Aboriginal and Torres Strait Islander people published by the AIHW recommends the use of algorithms that draw on multiple data to enhance the completeness and accuracy of Indigenous status information.32 It is recommended that multiple algorithms be explored and outcome measures using each of the algorithms be compared to determine the sensitivity of the approach used. We will use three of the recommended algorithms and, for each individual in the study, will draw on Indigenous identification information from all QHAPDC records (2005–2018) (table 3). The QHAPDC has reasonably high levels of accuracy (>80%) for Indigenous status and is considered gold standard among administrative datasets for Indigenous identification data.33 Additionally, we will use a fourth algorithm, using MBS data to enhance the QHAPDC majority-based algorithm.

Preliminary data suggest the three different AIHW Indigenous status algorithms based on QHAPDC data only yielded different proportions of Indigenous women in the QHAPDC, with an absolute difference of 0.8% (n=1468).

Other covariates

Covariates measured in this study include person-level factors (eg, sex and age), service-level factors (eg, HHS and type of facility) and area factors (remoteness and area-level socioeconomic status):

► Sex (male/female) captured in the index hospitalisation record.

► Age, which will be derived from birth date (day (DD) / month (MM) / year (YYYY)) and index hospitalisation admission date (DD/MM/YYYY), both of which can be captured in the index hospitalisation record.
Remoteness of residence will be measured using the Australian Remoteness Index of Areas, based on the Statistical Area (SA2) of an individual’s residential address, as captured in the index hospitalisation record. Individuals will be categorised as living in major cities, inner regional, outer regional, remote and very remote areas of Australia.34

Area-level socioeconomic status will be measured using the Index of Relative Socioeconomic Advantage and Disadvantage, based on the SA2 of an individual’s residential address, as captured in the index hospitalisation record. This 100-point index will be categorised into quintiles, with quintile 1 representing the most disadvantaged and quintile 5 representing the most advantaged.35

Comorbidities will be identified in the hospitalisation records in the 5 years prior to the index hospitalisation and will be measured as the presence/absence of specific conditions deemed important to the development or prognosis of cardiovascular disease (eg, hypertension and diabetes).

Comorbidity level, also informed by hospitalisation records from the 5 years prior to the index hospitalisation, is measured using the Elixhauser Comorbidity Index and categorised as ‘no known comorbidity’, ‘one known comorbidity’, ‘two known comorbidities’, ‘three known comorbidities’ and ‘four or more known comorbidities’.36

HHS area of the facility of the hospital that an individual was first admitted to for their index hospitalisation.

Outcomes

The following CVD outcomes will be examined:

1. Primary prevention—for the 5 years prior to the index hospitalisation, we will describe and quantify the annual rate of attendance to general practitioner (GP)/specialist appointments and completion of the adult health check from items in EDIS, EDC, MBS, SODC, Ferret and BP. PBS items will be used to determine what proportion of the study cohort were receiving medications prescribed for CVD.

2. Secondary prevention—for the 2 years post the index hospitalisation, we will quantify the average time to first disease management (emergency department, filling prescriptions, scheduled appointments and rehabilitation) and the proportion of the study cohort who saw a GP, Aboriginal and/or Torres Strait Islander health practitioner, practice nurse, allied health practitioner and/or specialist, for management of their CVD, using items from EDIS, EDC, PBS, AusLab, MBS, SODC, Ferret and BP. Individuals will be censored or removed from the denominator if they die during the follow-up period; this will be determined from the QDR and NDI. PBS data will be used to measure the proportion of the cohort who are on appropriate cardiac medications in the 30 days, 1 year and 2 years post-discharge from the index hospitalisation.

3. In-hospital therapeutic procedures for acute coronary syndrome (ACS)—for the index ACS admission, we will describe the proportion of the cohort that received diagnostic angiography, cardiac reperfusion and revascularisation within the index admission and within 30 days of the index admission.

4. Survival—for each cohort, we will quantify 30 day, 1 year and 2 year survival (excess mortality) using the QHAPDC, QDR and NDI.

### Table 3  N (%) Aboriginal and Torres Strait Islander people at their first QHAPDC record for cardiovascular disease, July 2010–June 2016 (preliminary data)

<table>
<thead>
<tr>
<th>Algorithm</th>
<th>Definition</th>
<th>Indigenous cohort</th>
<th>Proportion of total cohort (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ever Indigenous</td>
<td>An individual is assigned as being of Aboriginal and/or Torres Strait Islander origin if they are recorded as such on at least one QHAPDC admission record.</td>
<td>7338</td>
<td>4.0</td>
</tr>
<tr>
<td>Most recent admission</td>
<td>An individual is assigned as being of Aboriginal and/or Torres Strait Islander origin at their most recent recorded admission in the QHAPDC.</td>
<td>6054</td>
<td>3.3</td>
</tr>
<tr>
<td>Majority-based</td>
<td>An individual is assigned as being of Aboriginal and/or Torres Strait Islander origin if they are recorded as Indigenous on 50% or more of their QHAPDC admissions. Those missing Indigenous status from all their QHAPDC records are excluded.</td>
<td>5870</td>
<td>3.2</td>
</tr>
<tr>
<td>Majority-based (enhanced)</td>
<td>An individual is assigned as being of Aboriginal and/or Torres Strait Islander origin if they are recorded as such on 50% or more of their QHAPDC admissions. For those missing Indigenous status, information from the MBS is used to input this. Those missing Indigenous status from all their QHAPDC records and their MBS record are excluded.</td>
<td>Data not yet available to report</td>
<td></td>
</tr>
</tbody>
</table>
5. Service use—length of stay, readmission rates and post-in-hospital procedure complications will be measured using data from the QHAPDC.

6. Health system expenditure and out-of-hospital costs—using items from NHCDC and CFV, the average cost associated with each hospital admission will be determined. MBS and PBS items will be used to describe out-of-hospital costs for GP/specialist visits and relevant CVD medications.

Multivariable analyses will maximise the impact of the study by allowing us to (1) model variation in subgroups and investigate temporal trends, (2) examine interaction effects between person and system level factors, and (3) adjust for known and measured confounders to estimate causal effects between care receipt and outcomes. Measured and known confounders include the covariates listed previously, namely, age, sex, remoteness of residence, area-level socioeconomic status, pre-existing comorbidity level and HHS area. Due to the nature of routinely collected data, we will not have information or complete information on all potential confounders (eg, smoking status and Body Mass Index) and thus the causal effects derived from this study will be interpreted in the context of these data quality considerations. We will compare the prevalence of these confounders, or risk factors, for Aboriginal and Torres Strait Islander people with other patients to assess their greater risk of adverse outcomes and compare the difference in outcomes for Aboriginal and Torres Strait Islander people with other patients before and after adjustment for these risk factors in multivariable analysis to assess the extent to which adjustment for these risk factors reduces the disparity in clinical outcomes.

Absolute risk measures will be reported for the cohort overall and by population groups. Where appropriate, relative measures may also be reported to compare subgroups (eg, Indigenous vs non-Indigenous) or temporal trends. The reporting of both absolute and relative measures of risk is commonly recommended as gold standard reporting practice as this gives a more comprehensive picture of inequities and the implications of it. The use of generalised linear models with the assumption of normal, gamma or Poisson distributions will be used for different variable types. Cox models for time-to-event data (eg, survival) and mixed models or generalised estimating equations for longitudinal data will be used to measure change over time, including where temporal effects exist. Variation in care pathways and patient outcomes will be compared by Indigenous status, sex, age group, remoteness of residence, year of index hospitalisation and socioeconomic status.

How this study will contribute to the evidence base
The higher incidence of and mortality from CVD for Aboriginal and Torres Strait Islander people (AIHW, 2018b) and for other underserved populations, and most Australian analyses of CVD using linked datasets have been conducted in NSW and Western Australia. This study will address these knowledge gaps by investigating these issues in detail for five cardiovascular conditions in a population-based study for the entire Queensland population. Additionally, it will examine the impact of adverse clinical care on service use, health system costs and patient survival across population groups to identify service gaps and at-risks groups. An Indigenous-majority cardiovascular advisory group will review study findings and propose priorities for research, practice and policy to improve cardiovascular care and reduce disparities in cardiovascular outcomes for Aboriginal and Torres Strait Islander people.

ETHICS AND DISSEMINATION
Ethical approval has been granted by the Prince Charles Hospital Human Research Ethics Committee (HREC/15/QPCH/289) and AIHW (EO2016-1-233) with reciprocal approval from the Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research (HREC 2019–3490). For Queensland datasets, consent by eight data custodians for 11 datasets was required to obtain Public Health Act approval (RD007588). For the Australian government datasets, a Public Interest Certificate was obtained. Appropriate safeguards will be implemented to maintain privacy of individual records, with analysis undertaken on non-identifiable data.

Interpretation and practical implications of the research findings will be guided by the advisory group, which includes Aboriginal and Torres Strait Islander people. The aggregated findings will be summarised in a report that will be disseminated to Queensland Health, policy makers, health service providers, community organisations and other key CVD stakeholders. The information will be presented at workshops and conferences and will be published in peer-reviewed journals.

PATIENT AND PUBLIC INVOLVEMENT
In 2015, Queensland Health established an advisory and data group with key stakeholders from government and Aboriginal controlled health services to commence the planning for this study. A combined clinical and Indigenous advisory group has since been established to provide ongoing guidance and advice to the research team on ensuring the integrity of our approaches and methods.

OTHER INFORMATION
Collaborative process
This was a targeted research project to support quality practice improvement in Queensland for CVD. The project brings together research, clinical and policy expertise to address a priority need. The collaboration of Queensland
Health’s Aboriginal and Torres Strait Islander Health Branch and Menzies School of Health Research, one of Australia’s leading medical research institutes dedicated to improving the health and well-being of Indigenous Australians, is an auspicious partnership to provide policy-enabled findings that will contribute to closing the gap in life expectancy between Aboriginal and Torres Strait Islander peoples and other Australians.

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Contributors TK, AD, LJW, SPM, RA, VM, JMK, TJ, WW, AK, AS, LS, LM, GG and DW were involved in conception and design of research. AD, LW, JRC, GG and RA secured funding for the project. SPM, TK, AD, JMK, VM and DW obtained ethics approval. SPM, TK and CT prepared the figures. TK, AD and SM drafted the manuscript with input from LJW, BP, JM, JRC and RA. All authors edited and revised the manuscript and approved the final version. TK, AD and BP had begun to prepare the datasets received for analysis and will conduct the statistical analysis. LW and JRC will provide statistical support. AD and SM have been primarily responsible for project management, with research administration support from TK, LJW, RA and GG.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Patient consent for publication Not required.

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