


BMJ Open Protocol on establishing a prospective enhanced surveillance of vaccine preventable diseases in residential aged care facilities in Central Queensland, Australia: an observational study

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To cite: Hashan MR, Chapman G, Walker J, *et al.* Protocol on establishing a prospective enhanced surveillance of vaccine preventable diseases in residential aged care facilities in Central Queensland, Australia: an observational study. *BMJ Open* 2022;**12**:e060407. doi:10.1136/bmjopen-2021-060407

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2021-060407>).

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Received 20 December 2021
Accepted 29 April 2022



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ABSTRACT

Introduction Infectious diseases are a major cause of mortality and morbidity among the highly vulnerable occupants of residential aged care facilities (RACFs). The burden of vaccine preventable diseases (VPDs) among RACFs residents is mostly unknown and there is a lack of quality data from population-based prospective VPD surveillance in RACFs. The increasing burden of emerging and existing VPDs (eg, COVID-19, influenza, pneumococcal, pertussis and varicella-zoster) necessitates the establishment of an active enhanced surveillance system to provide real-time evidence to devise strategies to reduce the burden of VPDs in RACFs.

Method and analysis This study proposes a prospective active enhanced surveillance that will be implemented in RACFs across the Central Queensland (CQ) region. The study aims to measure the burden, identify aetiologies, risk factors, predictors of severe outcomes (eg, hospitalisations, mortality) and impact of the existing National Immunization Program (NIP) funded vaccines in preventing VPDs in this vulnerable population. CQ Public Health Unit (CQPHU) will implement the active surveillance by collecting demographic, clinical, pathological, diagnostic, therapeutic and clinical outcome data from the RACFs based on predefined selection criteria and case report forms as per routine public health practices. Descriptive statistics, univariate and multivariate regression analysis will be conducted to identify the predictors of morbidity and clinical outcomes following infection.

Ethics and dissemination The study has been approved by the CQHHS Human Research Ethics Committee (HREC) (reference number HREC/2021/QCQ/74305). This study involves data that is routinely collected as part of the surveillance of notifiable conditions under the Public Health Act 2005. The CQHHS HREC approved a request to waive consent requirements of study participants as researchers will be provided non-identifiable data. The findings from the study will be actively disseminated through publication in peer-reviewed journals, conference presentations, social and print media, federal, state, and local authorities to reflect on the results that may facilitate revision of policy

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ To the best of our knowledge, this is the first active enhanced vaccine preventable diseases (VPDs) surveillance by a regional public health unit to monitor the burden of VPDs among elderly residents in residential aged care facilities (RACFs) in Australia.
- ⇒ This study will generate crucial data to prompt rapid adoption of public health measures during the ongoing COVID-19 pandemic among the vulnerable elderly population in RACFs.
- ⇒ Successful implementation of RACF active enhanced VPD surveillance in Central Queensland could be an exemplar for other regional areas of Australia to devise appropriate strategies to mitigate the burden of VPDs.
- ⇒ This study will include only the RACFs in Central Queensland, hence the findings from the study may not be generalisable for all RACFs across the country due to variation in demographic and disease risk characteristics.

and highlight the stakeholders, funding bodies both locally and internationally.

BACKGROUND

Infectious diseases are one of the leading contributors to the increasing burden of morbidity and mortality among elderly populations.¹ People living in the residential aged care facilities (RACFs) are more prone to infections compared with those living in the community.² In Australia, approximately three-quarters (71%) of the burden from vaccine preventable diseases (VPDs) is attributable to combined pneumococcus, influenza, pertussis and varicella zoster infections, resulting in substantial morbidity and mortality.³ Over the past decades, burden of VPDs increased significantly accounting for



almost one-third (32%) of the disease burden among frail individuals aged ≥ 65 years.^{3,4} The incidence of VPDs among these susceptible groups increased predominantly with influenza and varicella-zoster infection particularly among the Australian Indigenous population compared with the non-Indigenous.³ The fatal burden of pneumococcal disease and pertussis was also considerably higher across individual levels due to the inherent case-fatality nature of the disease process.³ Older adults living in congregate settings such as RACFs harbour a multitude of risk factors like age-related immunosenescence, decreased capacity to mount an immune response, multiple comorbidities and concomitant disabilities. Collectively, these contribute to an increased risk of infection and severity, subsequently progressing to severe outcomes like hospitalisations and deaths in these RACF residents.^{5–8} Moreover, during the COVID-19 pandemic, we have observed devastating death tolls across many countries among older adults residing in these congregants closed settings.^{9–11}

The burden of vaccine preventable infectious diseases among the RACF residents is mostly unknown. A prospective cohort study found an overall incidence of infection of 4.6/1000 resident days in 10 selected RACFs from Western Australia.¹² A retrospective surveillance system including four RACFs in Victoria, Australia reported an annual average of 4.16 episodes per 1000 occupied bed-days (95% CI 3.92 to 4.41).¹³ The incidence of pneumonia among older adults aged ≥ 65 years reported to be as high as 274 per 100 000 population with a 6.1% case fatality rate among hospitalised cases.¹⁴ Recurrent outbreaks of pertussis in the RACFs were reported in 2004–2005 with an attack rate of 15.7% among residents.^{15–17} Earlier researchers reported serology confirmed infection of pertussis among adults aged ≥ 65 years with an incidence rate of 19.7 per 100 person-years. The incidence of varicella-zoster has also been identified as one of the leading notifiable diseases reported among elderly Australians for more than two decades. Varicella-zoster in the elderly population often manifests as shingles adversely impacting the quality of life of RACF residents.^{18,19} The Australian NIP supports government-funded vaccines against pneumococcal, varicella-zoster and seasonal influenza for elderly Australians.²⁰ However, adult vaccination coverage (50%–70%) is much lower compared with childhood vaccination rates (90%) despite the introduction of an updated nationally funded programme in May 2015. Moreover, a recent report by the Australian Aged Care Quality Agency found that nearly two-thirds of the RACF residents do not receive optimum coverage of the NIP-funded vaccines.²¹

Surveillance of infectious diseases is an essential epidemiological tool to estimate the burden of disease, monitor the trends, identify outbreak events and prompt case investigations to control the spread of pathogens.^{22–24} Rapid identification of outbreaks from existing or emerging organisms following syndromic, case-based active surveillance facilitates immediate public health interventions to curb the disease transmission and mitigate disease

burden.²⁵ In Australia, effective infection control across the RACFs is mandated by the²⁶ Aged Care Act 1997, and Public Health Units are responsible for the surveillance of notifiable conditions under the Public Health Act 2005 to provide infection control and prevention advices to RACFs.²⁷ However, under-notification pervades from several influencing factors, and ‘notified fraction’ varies by jurisdiction over states, territories, facilities, case definition, patient characteristics and variability in reporting practices.^{3,28} It is critical for generating evidence-based information to provide timely feedback for developing strategies to decrease the burden of infection within enclosed settings of RACFs.^{4,26} To date, there has not been any prospective active surveillance in Australian RACFs to determine the burden of infectious diseases among residents. Moreover, there has not been any population-level data on the impact of NIP-funded vaccines in preventing infectious disease burden among elderly residents in Australian RACFs.

To address these, we have established an active enhanced VPD surveillance among RACF residents in Central Queensland (CQ), Australia. Our aim is to define the disease burden, aetiologies, risk factors and to evaluate the impact of NIP-funded vaccines in preventing VPDs (eg, COVID-19, influenza, pneumococcal, pertussis) in this vulnerable population.

RATIONALE

The findings will help to optimise regional public health preparedness for vaccine preventable infections and provide generalisable population representative data and, therefore, useful for other regional Public Health Units and operating agencies. If the data from this enhanced surveillance project demonstrate that active enhanced surveillance is effective in reducing the burden of infectious diseases both in terms of morbidity, mortality and is a cost-effective strategy in the regional settings of CQ, this model can be replicated in other regional areas of Australia. Thereafter, nationwide adoption of the programme will facilitate appropriate evidence-based strategies to mitigate the burden of infectious diseases.

OBJECTIVES

Primary objectives

This study aims to generate scientific evidence on the burden of vaccine preventable infectious diseases among elderly populations and to formulate a practical solution to prevent infectious disease-related mortality and morbidity among RACF residents in CQ through translational research in a regional Public Health Unit.

1. Investigate the burden and aetiologies of vaccine preventable infection-related mortality and morbidity in people aged ≥ 65 years in RACFs in CQ.
2. Investigate the uptake and impact of new (eg, varicella-zoster), existing (eg, influenza, pertussis and pneumococcal) and emerging (COVID-19) vaccines in

preventing mortality and morbidity among RACF residents.

Secondary objectives

To estimate and compare healthcare cost (direct and indirect) with the adoption of enhanced surveillance system associated with vaccine preventable infections among this vulnerable group population.

METHODS AND ANALYSIS

Study design and surveillance settings of notifiable conditions

We commenced an active enhanced VPD surveillance system for selected notifiable VPDs in CQ, Australia in July 2021. The notifiable VPDs include COVID-19, influenza, pneumococcal disease, pertussis, varicella-zoster and will be identified on a predefined standardised clinical case definition. Each case for the disease of interest will be ascertained following the criteria as defined by the Communicable Diseases Network Australia guidelines.²⁹

COVID-19 case definition

A person who (1) tests positive to a validated specific SARS-CoV-2 nucleic acid test; OR (2) has the virus isolated in cell culture with PCR confirmation using a validated method; OR (3) undergoes a seroconversion to or has a significant rise in titre of SARS-CoV-2 neutralising or IgG antibody level (fourfold or greater).

Probable case: a person who has SARS-CoV-2 neutralising or IgG antibody and has had a compatible clinical illness and meets one or more of the epidemiological criteria as per suspected case definition

Influenza/Influenza-like illness case definition

A person who meets WHO case definition for influenza/influenza-like illness (ILI) as an acute onset of symptoms of respiratory infection with measured temperature $\geq 38^{\circ}\text{C}$ and cough within past 10 days with/without one of the following definitive laboratory evidence.

(1) Isolation of influenza virus by culture/detection of influenza virus by nucleic acid testing/detection of influenza virus antigen from appropriate respiratory tract specimen, (2) significant increase in antibody level or fourfold or greater increase in antibody titre or IgG seroconversion to influenza virus, (3) single high titre by complement fixation test or haemagglutination inhibition assay to influenza virus

Pneumococcal disease case definition

Infection of pulmonary parenchyma with *Streptococcus pneumoniae* is known as pneumococcal pneumonia. A pneumococcal disease (invasive) case will be confirmed with laboratory evidence showing isolation of *S. pneumoniae* by culture or detection by nucleic acid testing from a normally sterile site.

Pertussis case definition

A person experiencing clinical feature of coughing illness lasting 2 or more weeks or paroxysms of coughing

Table 1 Selection criteria of participants

Selection criteria	
Inclusion criteria	<ul style="list-style-type: none"> ▶ Diagnosis with one of the following notifiable diseases: influenza, pneumococcal, pertussis, varicella-zoster, COVID-19 ▶ Residents of aged care facilities aged ≥ 65 years ▶ Residing within the boundaries of CQHHS or managed by the CQPHU ▶ Cases between 1 July 2021 and 30 June 2023
Exclusion criteria	<ul style="list-style-type: none"> ▶ Cases of notifiable disease of investigation prior to 1 July 2021 or after 30 June 2023 ▶ Residents of community or aged care facilities ≤ 64 years ▶ Residents who were not at an aged care facility during the exposure or infectious period for the notifiable VPDs under surveillance.

CQHHS, Central Queensland Hospital and Health Service; CQPHU, CQ Public Health Unit; VPD, vaccine preventable disease.

or inspiratory whoop or post-tussive vomiting along with laboratory evidence showing (1) isolation of *Bordetella pertussis* or detection by nucleic acid testing or seroconversion in paired sera for *B. pertussis* or specific antigen in the absence of recent pertussis vaccination.

A case will be confirmed either only from the definitive presence of laboratory evidence or laboratory suggestive evidence and clinical feature.

Varicella-zoster case definition

A person manifesting vesicular skin rash with a dermatomal distribution that may be associated with pain in the affected area supplied by sensory nerves of the dorsal root ganglia. A case will be confirmed based on the concomitant presence of clinical evidence with one of the following laboratory evidences showing: (1) isolation of varicella-zoster virus or detection of varicella-zoster virus by nucleic acid testing or detection of varicella-zoster antigen by direct fluorescent test from skin or lesion swab.

Our study area is the CQ region, which is composed of 117588 square kilometres of land area with a population approximately over 220 000. Approximately 14% of the population is aged ≥ 65 years and 6% of the population are Aboriginal and/or Torres Strait Islanders.³⁰ The region consists of 20 RACFs with a total capacity of 1361 residential aged care beds.³¹ Residents occupying these facilities meeting the selection criteria are included in our surveillance study. The selection criteria for the surveillance are listed in table 1. This active surveillance will continue over a period of 2 years from 1 July 2021 to 30 June 2023.

Public Health nurses experienced in communicable disease control will identify RACF residents with the conditions under surveillances as defined by liaising with RACFs staff. A minimum of weekly communication occurs with RACFs enrolled in the surveillance to inquire about probable or new cases of notifiable conditions. Additionally, the Public Health nurses monitor emergency department admissions and laboratory logs to identify further cases from RACF residents. Identifying a case triggers the

Table 2 Data variables for the case report form

Demographic data	Case details (eg, age, sex, ethnicity, marital status, ownership status of the residential aged care facility, location of the facility, type of facility, nature of services provided)
Clinical data	Onset of disease symptoms, presenting clinical symptoms, severity grade of signs and symptoms, duration of symptoms, hospital admission information, case identification method, notification decision, duration of hospitalisation, duration of intensive care provision
Pathological data	Laboratory diagnosis date, method of diagnosis, laboratory parameters, treatment provided, invasive or non-invasive ventilation, specimen used for diagnosis, date of collection, resistance pattern of the organism
Diagnostic and prognostic data	Date of diagnosis (clinical and laboratory diagnosis), place of acquired infection, exposure settings, source of infection, vaccination history, comorbid diseases, presence of any disease risk factors
Outcome	Completely or partially recovered, date of recovery, cause of death, date of discharge, date of death, development of disease sequelae, rehabilitation

subsequent collection of potential data to document in the case report forms (CRFs) (table 2). All information collected on CRFs is entered and stored in a secured electronic database (figure 1).

Earlier outbreaks reported an annual incidence rate of approximately 96.8 per 100 000 for ILIs across the RACFs in New South Wales, Australia. We expect approximately 212 cases that could meet case definition for ILI annually within our period of interest.²⁸ However, there is a paucity of data on non-influenza (pertussis, varicella-zoster) outbreaks among the RACF population. Data collected will be analysed by CQPHU epidemiologists. The analysis will be conducted to measure the outcome as per primary

and secondary objectives. The total number of cases will be calculated along with the cumulative incidence and prevalence to estimate the burden and morbidity as an indicator of notifiable VPDs. In addition, the indices of severity such as hospitalisation rates, case-fatality rates will be used to better understand the impact of these diseases within this population. Regression analysis will be conducted to identify the independent risk factors predicting morbidity and clinical outcome. Continuous and categorical variables will be reported using descriptive statistics. Group differences will be explored using independent sample t tests or Mann-Whitney U test for continuous variables or χ^2 test for categorical variables. All statistical tests will be two sided with a p value ≤ 0.05 considered as statistical significance. To estimate the impact of NIP-funded vaccines, we will collect the immunisation status of confirmed cases and we will use a test-negative case-control design.³² Our study settings for the notifiable VPDs will identify cases and controls appropriately based on laboratory surveillance data to estimate vaccine effectiveness (VE) and test negative case-control design as it is a convenient and suitable method across population levels for influenza and invasive pneumococcal disease.³³ The test-negative case-control design is an alternative modified method to measure VE in a cohort. It has been used for many VPDs during last decades, for example, influenza, pneumococcal, cholera, rotavirus, etc.^{34–38} Using laboratory-confirmed disease as outcome measure, test-negative case-control design is good approach to minimise misclassification bias and healthcare-seeking behavioural bias which are inherent in cohort studies. In this design method, subjects with positive test results for influenza are classified into cases, while subjects with negative results are classified as controls, and then vaccination status during the season can be compared between cases and controls. All the residents that are diagnosed with lab-confirmed notifiable disease of interest will be termed as cases and test-negative result will be noted as controls. Overall, the sample size depends on the incidence of VPDs of interest within the study population over the observation time. We will estimate the crude disease-specific VE using OR as effect

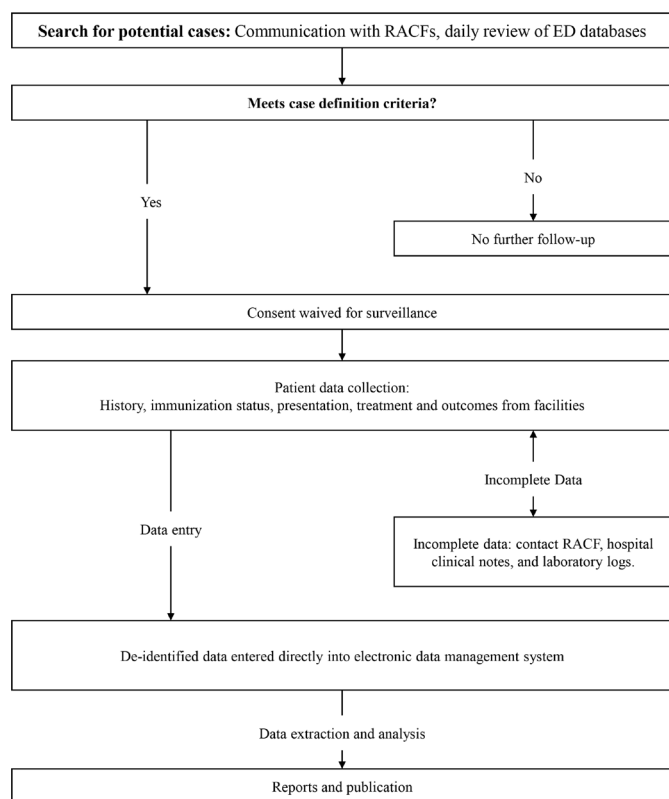


Figure 1 Method for surveillance of vaccine preventable diseases (VPDs) in residential aged care facilities (RACFs) using waiver of consent model.

size where $VE = (1-OR) \times 100\%$, comparing the odds of vaccination among disease-positive study participants by the odds of vaccination among disease-negative participants.^{33–39} Multivariable logistic regression models will be used to obtain confounder-adjusted VE for each disease, regressing on health outcomes based on exposure status, age, gender and relevant confounders of interest. To address the secondary objectives, we will explore expenditure incurred following hospitalisation from the notifiable VPDs that could be avoided and conduct a health economic analysis on the suitability of this preventive surveillance model as the retrieved data permit. Administrative data set submitted to Queensland State Government for funding referred to as activity-based funding data will be used to estimate and compare healthcare costs. The Independent Hospital Pricing Authority publishes an annual National Efficient Price (NEP) determination for public hospital services for each coming financial year.⁴⁰ The NEP underpins activity-based funding across Australia for Commonwealth-funded public hospital services. This uses ICD-10-AM codes mapped to the diagnosis-related groups (DRG) with differing levels of complexity. Each DRG code is mapped to national weighted activity units, which are inflation-adjusted price points as deemed by the NEP determination of price weights and adjustments.⁴¹ Ultimately, each DRG code provides an estimate of efficient price of care for that person based on many patient-specific factors.

Ethics and dissemination

The study has been approved by the CQHHS Human Research Ethics Committee (HREC) (reference number HREC/2021/QCQ/74305). This study involves data that is routinely collected as part of the surveillance of notifiable conditions under the Public Health Act 2005.²⁷ The CQHHS HREC approved a request to waive consent requirements of study participants as researchers will be provided non-identifiable data. The findings from the study will be actively disseminated through publication in peer-reviewed journals, conference presentations, social and print media, federal, state, and local authorities to reflect on the results that may facilitate revision of policy and highlight the stakeholders, funding bodies both locally and internationally.

Surveillance findings will be disseminated via manuscripts in peer-reviewed journals, presentations and/or posters in conferences. An interim annual report will be generated and presented in the CQHHS internal meetings and educational sessions and RACFs forums in CQ. The final results will be reported to inform federal, state and local policy. We also aim to include community engagement via social media (ie, Facebook, Twitter), print and electronic media (ie, newspaper, television, radio).

Patient and public statement

Both RACFs staff and residents are considered as consumers in this project. As part of this active

enhanced surveillance near-real time data on vaccine preventable infectious diseases are collected from the participating RACFs. Key contact persons from the participating RACFs are contacted on a weekly basis. Moreover, any possible VPD case/clusters are immediately managed and relevant public health messages are shared with the RACF residents and staff.

DISCUSSION

We commenced this active enhanced surveillance study through the regional Public Health Unit to generate evidence-based data across highly susceptible residents in RACFs to estimate the burden of VPDs. The higher burden of infections among residents within RACFs significantly increases morbidity and the risk of adverse outcomes such as hospitalisations and case fatalities.^{28–42–44} This prospective enhanced active surveillance will be of substantial importance to regional Australia, particularly for the vulnerable older residents within RACFs. At present, there is no prospective surveillance system in Australia to monitor the VPD trends in the older adults residing in the aged care facilities.

With such limited prevalent estimates available, the establishment of an active surveillance system for the vulnerable residents in RACFs to mitigate the burden of the disease is necessitated. During 2018–2019, there were 70 536 RACFs in Australia providing residential care services to 242 612 older adults at an annual cost of 12.3 billion dollars.⁴⁵ Queensland reported RACFs usage rate of 70.6 per 1000 target population (aged ≥ 65 years, 50–64 years for indigenous) within its region.⁴⁵ The unknown burden of notifiable VPDs and incurring healthcare expenditure accentuates the stress on the overall health system. Pre-existing financial and systematic resource limitations provide no incentive for RACFs to adhere to rigorous infection control practices across the industry.⁴⁶ Such deplorable situations became evident as more than three-quarters of the COVID-19 pandemic deaths tolls occurred among the residents in care facilities in Australia.⁴⁶ Apart from the infrastructure limitations, infection surveillance is difficult to achieve in RACFs due to multiple influencing factors such as variation in testing and reporting practices using traditional methods (eg, review of charts, passive reporting of vaccine preventable notifiable diseases), disease severity, patient characteristics in care seeking, available diagnostics, which require frequent intersectoral coordination with multiple sources (eg, hospitals, pathology, general practitioner) to collect complete information. Therefore, the most practical and rigorous method for infection surveillance in RACFs is to establish an enhanced prospective regional population-based surveillance programmes such as the Active Bacterial Core surveillance system in the USA.⁴⁷ Our surveillance model will incorporate a

systematic timely collection of notifiable VPDs data from the RACFs addressing the undernotification issues and ensuring data quality by the regional Public Health Unit team. Additionally, periodic analysis and reporting to federal, regional state and local authorities will be of paramount public health importance in devising immediate planning, action, programme evaluation and policy formulation along with generation of novel research hypotheses.

Currently, the exact burden of notifiable infectious diseases in CQ aged care facilities is unknown. This information is essential for optimising clinical and public health policy and practice. The prospective model would identify the exact number of notifiable infectious disease cases in RACF within the CQ region. This identification will ultimately trigger outbreak responses, where appropriate, and implementation of immediate preventative measures, such as early lockdown of the facility, isolation and infection control. Furthermore, the findings will inform intermediate and long-term indicators for the burden of vaccine preventable notifiable infectious diseases; vaccine/immunisation coverage in RACFs, the rate of specific vaccine preventable infectious diseases and guide targets for immunisation coverage. It is an urgent priority to generate evidence-based data to adopt pragmatic interventions in order to reduce the disease-associated morbidity and mortality.

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Contributors GK, RB conceptualised the study. GK, MRH, GC developed the protocol. MRH, GC wrote the first draft of the protocol. GK, MK, GC, JW, SJD, JA were involved in study implementation. MK, DA, NS contributed in critical revision of the manuscript. DA, NS provided statistical expertise. All authors reviewed and edited the final draft for intellectual content. GK supervised the study.

Funding This work was supported by a Queensland Advancing Clinical Research Fellowship awarded to Prof. Gulam Khandaker by Queensland Health's Health Innovation, Investment and Research Office (HIIRO), Office of the Director-General. No award/grant number.

Competing interests None declared.

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

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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