



RESEARCH ARTICLE

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BACKGROUND PROCESSES TO OBTAIN ETHICAL AND DATA LINKAGE APPROVAL FOR A DATA DRIVEN QUALITY IMPROVEMENT PROGRAM TO PREVENT HOSPITALISATION AND IMPROVE CARE OF PEOPLE LIVING WITH HEART DISEASE

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ABSTRACT

The use of state-wide linked data is growing in research as it can provide an efficient and cost-effective way to obtain robust data from large populations. However, acquiring linked data from multiple states and territories in Australia have rarely been done due to the complexities regarding the different ethical requirements across the jurisdictions. The paper provides an overall understanding of the development and complex processes that were undertaken in order to obtain and link state-wide administrative data for the quality improvement in primary care to prevent hospitalisations and improve Effectiveness and efficiency of care for people living with heart disease (QUEL) study.

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INTRODUCTION

Over the past couple of decades, there has been increased interest among researchers in using linked data (Bohensky, 2010), to achieve greater health outcomes due to the significant development in the electronic recording of health care data. Australia is one of the few countries including Canada, England, Scotland, Denmark and the US, (Emery, 2017), which has invested many resources in linked data due to its growing interest in the research field. Linked data is usually used in large studies across the health care system to assess the health service use, provision of care and clinical outcomes (Bohensky, 2010). This can be achieved by bringing data from multiple sources to create a complete health sequence of individuals (Bohensky, 2010 and Emery, 2017). By linking general practice data with hospital admissions, Medicare Benefits Schedule, Pharmaceutical Benefits Scheme and death index data, we are now able to answer research questions that involve various levels of care and gain a comprehensive understanding of clinical care and outcome.

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Our partnership team has been working collaboratively for the past 3 years as the National Secondary Prevention Alliance with an aim to improve patient care in the primary care setting. As a result, QUEL was established to test the implementation of a data-driven structured quality improvement program in primary care, where practices are supported to enhance efficiency and outcomes by better using their routinely collected data. To enable linkage for QUEL, we went through several processes that included multiple applications to several data linkage centres, data custodians and ethics committee. Amongst them getting approval to link hospital administrative data was most challenging as each state had its own data linkage centre and each centre had its own application and approval process (Mitchell, 2015). Therefore, the aim of this manuscript is to describe the processes and complexities, specifically associated with obtaining the ethical and data linkage approvals for hospital administrative data with a waiver of consent for QUEL study.

MATERIALS AND METHODS

QUEL study: QUEL is a cluster randomised controlled trial with an overall aim to boost the quality of coronary heart disease management delivered in primary care through the

implementation of a 12-week practice-level quality improvement intervention and assess whether it reduces hospitalizations and health outcomes in a cost-effective way. Approximately 200 general practices (100 in each arm) and about 40,000 patients will be recruited with 12 and 24-month follow-up. For this study, patient data from general practices will be collected through Pen Computer Systems (Pen CS) and linked with emergency departments and hospital admissions extracted through state-level data linkage centres; as well as Pharmaceutical Benefits Scheme (PBS) for medication prescription, Medicare Benefits Scheme (MBS) for medical service utilisation and national death index (NDI) extracted through the Australian Institute for Health and Welfare (AIHW). However, obtaining the approvals for the emergency department and hospital admissions data is usually most challenging as it needs to ensure the privacy of the individual patient is protected and no identifiable information is disclosed during the process (Mitchell, 2015).

Stakeholders of the hospital administrative data: Linkage of the health administrative data usually requires approval from three stakeholders: 1) state data linkage centre 2) data custodian and 3) ethics committee.(3) There are six data linkage centres throughout Australia that assess the technical and ethical feasibility of linkage studies and works with researchers to prepare and finalise the application to obtain approval from relevant data custodians. Ethics committees work independently to the data linkage centres and require separate applications to further assess whether the study is ethical. For QUEL, we obtained approvals for the linked data from New South Wales (NSW) and Queensland, working closely with the state data linkage centres, namely Centre for Health Record Linkage (CHeReL) for NSW and Public Health Act (PHA) for Queensland. We submitted the data linkage application to CHeReL first, as the application process and forms were well defined and structured in NSW. With assistance from CHeReL, we obtained approval from the data custodians to enable linkage of the admitted patient data collection (APDC) and emergency department data collection (EDDC). The data custodian for both NSW APDC and EDDC linked data was the Health System Quality, Performance and Innovation Division, NSW Ministry of Health. Only upon receiving the data custodian approvals, we were able to submit ethics application to our preferred ethics committee. For this study, we chose the NSW Population & Health Services Research Ethics Committees as it was the only committee that had previously dealt with data linkage studies. A waiver of consent was also submitted along with the ethics application and to qualify for the waiver, we ensured that our application met all the requirements of The National Statement on Ethical Conduct in Human Research (4); some of those requirements were: a) involvement in the research carries no more than low risk to participants b) the benefits from the research justify any risks of harm associated with not seeking consent c) it is impracticable to obtain consent. (4) Following an extensive review process, ethics approval was obtained along with the waiver of consent, which was then shared with CHeReL for their record.

The application process was slightly different for Queensland data linkage application through Public Health Act (PHA). Queensland Health had separate data custodians for the admitted patient data and the emergency department data. An application was first submitted to the data custodian for Queensland Health Admitted Patient Data Collection

(QHAPDC), the Queensland Statistical Services Branch (SSB). Once approved, the same application was forwarded to the data custodian for Emergency Department Information System (EDIS), Queensland Health Hospital Access Analysis Team (HAAT), to obtain relevant approvals. Additional ethics approval from Queensland was not required as the Queensland Health Innovation, Investment and Research Office (HIRO), who is responsible for consultation, development, review and approval of State-wide research ethics and research governance policies in Queensland, accepted the ethics approval from the NSW Population & Health Services Research Ethics Committee based on the fact that the waiver of consent was considered in accordance with the National Statement on Ethical Conduct in Human Research and the HREC approval was related to the whole study including the Queensland Health data. Finally, the application that was approved by the two data custodians along with a copy of the ethics approval was submitted to HIRO. HIRO then provided an overall approval to enable linkage in Queensland, which was shared with SSB to prepare both QHAPDC and EDIS datasets request for QUEL.

RESULTS AND DISCUSSION

After finalising the study protocol, the entire process took a 0.5FTE trained research officer about 12 months to secure required approvals from the state data linkage centres, data custodians and ethics committees for the linkage with a waiver of consent. For NSW, the CHeReL application consisting of 11 documents alone took 3 months to prepare and a further 2 months to review. Once the data linkage was approved, the application to NSW population and health services research ethics committee required completion of an additional 26 documents to cover privacy issues, variable lists, investigator CVs, evaluation forms and funding evidence amongst others. The whole process of ethics approval from initial submission took approximately 9 weeks. For Queensland, preparing the PHA applications was also time-consuming and required massive administrative effort. The first PHA application to Statistical Services Branch (SSB) took approximately 4 months to prepare which included extensive reviews between the research officer and SSB before submitting the final application to QHAPDC data custodian for approval. Despite the lengthy preparation and review process, QHAPDC data custodian provided approval within only three days and EDIS data custodian from the Queensland Health HAAT provided approval in just one day. The final application for overall approval to HIRO took about 9 weeks from the time of initial submission to approval. New South Wales and Queensland data linkage centres differ in terms of the application process as well as approval timeframes. Although different forms were used for each application; the information provided in them were almost identical and required a lot of duplication e.g. providing justification for requesting a waiver of consent, requested datasets, data storage, data transfer security, etc. Amongst the two, Centre for Health Record Linkage (CHeReL) had a well-structured application process with a step-by-step instruction in their website. Hence, it was easier for the researcher to follow the instructions and prepare the application. On the other hand, for Queensland, it would greatly help researchers if there was a clear instruction of the data linkage application process. However, both data linkage centres had excellent staff supporting the researchers with their expertise and guidance throughout the process. The process of data linkage can be made efficient and easily accessible by

introducing a common application nationally. Streamlining the application will not only reduce the administrative efforts of duplicating information, but it will also cut down the waiting time massively. Clear instructions can also be very helpful especially in the data linkage centre's websites to help navigate through the various stages of the processes. Although these background processes for QUEL study were lengthy and complex, it was essential for the researcher to be precise and diligent in completing the applications. Now that all relevant approvals are obtained, QUEL is ready to start recruitment and move on to the next step of the trial that is delivering quality improvement workshops to participating general practices. During recruitment, we will continue additional background processes for commonwealth data linkage via Australian Health and Welfare Institute (AIHW) and set up the Secured Unified Research Environment (SURE) for secure transfer and storage of linked data.

Conclusions

Large Randomised Controlled Trials, such as QUEL, involving record linkage, is achievable because of the existing infrastructure but massive administrative efforts and longer time-frame between application and approvals make such projects very challenging and time-consuming.

However, data linkage has the potential to more accurately determine the impact of health strategies on robust outcomes in the real world. If the administrative burden of the application processes can be reduced, we will be able to study the clinical performance of health services in both primary care and hospitals across the nation more easily and readily, and also to evaluate new policies for better health outcomes.

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