BMJ Open

Compliance with pathology testing guidelines in Australian general practice: protocol for a secondary analysis of electronic health record data

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-024223
Article Type:	Protocol
Date Submitted by the Author:	15-May-2018
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Keywords:	Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health informatics < BIOTECHNOLOGY & BIOINFORMATICS, PATHOLOGY, PRIMARY CARE

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Pathology testing in Australian general practice and compliance with guideline recommendations: A study protocol for a secondary analysis of electronic health record data

ABSTRACT

Introduction In Australia, general practitioners usually provide the first point of contact for patients with non-urgent medical conditions. Appropriate and efficient utilisation of pathology tests by general practitioners forms a key part of diagnosis and monitoring. However over- and under- utilisation of pathology tests have been reported across several tests and conditions, despite evidence-based guidelines outlining best practice in pathology testing. There are a limited number of studies evaluating the impact of these guidelines on pathology testing in general practice. The aim of our quantitative observational study is to define how pathology tests are used in general practice and investigate how test ordering practices align with evidence-based pathology guidelines.

Methods and analysis Access to non-identifiable patient data will be obtained through electronic health records from general practices across three primary health networks in Victoria, Australia. Numbers and characteristics of patients, general practices, encounters, pathology tests, and problems managed over time will be described. Overall rates of encounters and tests, alongside more detailed investigation between subcategories (encounter year, patient's age, gender, and location, and general practice size) will also be undertaken. To evaluate how general practitioner test ordering coincides with evidence-based guidelines, five key candidate indicators will be investigated: full blood counts for patients on clozapine medication; international normalised ratio (INR) measurements for patients on warfarin medication; glycated haemoglobin (HbA1c) testing for monitoring diabetes; vitamin D testing; and thyroid function testing.

Ethics and dissemination Ethics clearance to collect data from general practice facilities has been obtained by the data provider from the RACGP National Research and Evaluation Ethics Committee (NREEC 17-008). Approval for the research group to use these data has been obtained from Macquarie University (5201700872). This study is funded by the Australian Government Department of Health Quality Use of Pathology Program (Agreement ID: 4-2QFVW4M). Findings will be

reported to the Department of Health and disseminated in peer-reviewed academic journals and presentations (national and international conferences, industry forums).

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The study population will be drawn from a large region in Victoria, Australia, and is expected to contain a large sample population (data from approximately 350 general practices), along with a large number of demographic variables (e.g., region, gender, age).
- Electronic health records contain a vast amount of information on patients, allowing us to control for potential interacting or predictive variables on patient outcomes using statistical modelling.
- Some electronic health record fields may not be completely standardised across practices and could contain inconsistencies and missing information; which may limit the volume of data that can be extracted and analysed.
- Some medications being investigated in this study may be prescribed and/or monitored by specialists, which may result in cases being missed.

INTRODUCTION

In Australia, general practitioners (GPs) are usually the first point of contact for patients with non-emergency health problems. They play an important role in the early detection, prevention (including shared-care arrangements) and treatment of disease (1). Pathology tests are a key part of general practice assisting GPs in diagnosing, screening, treating, and monitoring diseases. The past decade has seen an increase in both visits to and problems managed by GPs in Australia, resulting in an estimated 24.2 million additional pathology tests being ordered in 2015-2016 compared to 2006-2007 (2).

Appropriate and timely utilisation of pathology tests can improve the quality and outcome of patient care. However, both over- and under- utilisation of pathology tests have been frequently observed in a range of clinical scenarios (3,4). Several guidelines have been established to encourage better utilisation of pathology tests among GPs across Australia, the US, Canada, and the UK. These include

initiatives such as *Choosing Wisely* (5)*, National Institute for Health and Clinical Excellence (NICE)* (6), and *Royal Australian College of General Practitioners (RACGP) Guidelines for preventative activities in general practice* (7). Currently, there is little evidence on how test ordering practices by GPs align with these recommendations and guidelines in Australia, and elsewhere. A survey of 600 US doctors revealed only 21% of doctors were familiar with the *Choosing Wisely* campaign. However doctors aware of the campaign had a lower proportion of unnecessary pathology testing (8). In Australia, increased awareness of best-practice in vitamin D test ordering is reported to have contributed to a reduction in healthcare costs and potentially unnecessary tests (9). Considering the importance of pathology testing for managing diseases, a better understanding of how pathology testing by GPs coincides with evidence-based guidelines will be invaluable for the success of management and disease-prevention strategies.

Until recently, the survey-based *Bettering the Evaluation and Care of Health (BEACH)* study provided the most comprehensive data on Australian GP activity (2). However, its cross-sectional design prevented it from reporting longitudinal patient level changes and outcomes. The BEACH study was discontinued in 2016, and has since left a gap in our understanding of GP activity; particularly in relation to pathology test ordering. The extensive use of computers by Australian GPs has prompted interest in the use of electronic health record (EHR) data as a research source for monitoring the quality of GP services, and has led to research and publications based on EHR data (10). The Australian Department of Health funded NPS Medicinewise MedicinesInsight dataset contains a national collection of electronic health records (EHRs) from 650 practices covering over 3,300 GPs and nearly 3.6 million active patients (11).This dataset has been used in several population health research projects, and has demonstrated the value of EHR data in research (12). This study will use EHR data from the POLAR Data Space, containing de-identified data from consenting general practices collected on behalf of Australian PHNs from approximately 350 practices. POLAR Data Space has added measures to ensure robust and accurate data, and implements standardised terminologies to make the data more approachable for research use. This study, undertaken in collaboration with POLAR Data Space Research Consortia and its associated Primary Health

Networks (PHNs), will facilitate a comprehensive analyses of general practice activity and its relationship to pathology testing in Australia through EHR data.

Objectives:

The objectives of this study are to:

1. Describe general practice activity and characteristics of pathology test ordering based on electronic health record data;
2. Investigate compliance with evidence-based guidelines to determine the appropriateness and quality use of pathology in general practice.

METHODS AND ANALYSES

Study design

A retrospective observational study of Australian general practice health records and pathology testing data.

Data source

Data to be used in this study will be provided by the POLAR Data Space (10). POLAR Data Space collects de-identified data from consenting general practices on behalf of Australian PHNs: including Gippsland, Eastern Melbourne, and South Eastern Melbourne PHNs. Data are extracted from approximately 350 practices in urban and rural regions in Victoria, Australia. The primary purpose of the data collection is to provide information to improve patient care at the practice level and population health initiatives at the PHN level. POLAR Data Space has ethics approval for the collection, storage and de-identification of the data which it makes available for approved research governed by the involved PHNs.

The data source will include pooled general practice patient data extracted from Best Practice, Medical Director, and Zedmed EHRs. Data will include de-identified demographic information about

patients and general practices, as well as visit records (diagnosis, past history, medications) and pathology test records (test name and result). Both historical and current information about patients will be acquired, providing a longitudinal record.

Study Population

The study population will consist of all patients who visited any of the general practices included in the study, and had their visit recorded in the practices' EHR software.

Variables

The following criteria will be adopted to accurately describe general practice activity and ensure data quality: (i) A patient will be distinguished by a unique (non-identifiable) patient code recorded within a general practice and included if determined to be an active patient (i.e. has visited the GP three or more times in the past two years, not deceased; (ii) An encounter (i.e. consultation, visit) will be defined as a patient visit recorded by a doctor or nurse during which an action (e.g. consultation, prescription) is performed, and will be identified through a variable indicating the visit type (e.g. surgery, administrative, phone call); (iii) A pathology test will be defined as either a panel of interrelated tests (e.g. full blood count) or an individual test (e.g. troponin test); (iv) Where possible, standardised records such as Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine (SNOMED) terminologies will be prioritised to identify variables; otherwise, free-text data will be searched for terms of interest (e.g. "diabetes" or its abbreviated forms in the diagnosis field, excluding "not diabetes").

Analyses

Data examination and analysis will be performed using Stata/MP 15.1 (StataCorp, College Station, Texas, USA). The methods outlined in this protocol are structured according to the *Strengthening the Reporting of Observational Studies in Epidemiology* (STROBE) checklist of items to be included in observational studies (13).

Characteristics of general practice activity and pathology testing

In line with Objective 1 of this study, we will analyse and describe Australian general practice characteristics and activity. These characteristics can subsequently be compared to reports on national demographics and healthcare statistics, such as *Australian Institute of Health and Welfare*'s (AIHW) annual reports.

Sample population characteristics will be reported. This will include describing the characteristics of patients, general practices, encounters, tests, and problems managed across time. Subsequent analyses will describe overall median rates of encounters and tests, alongside more detailed investigation between subcategories (encounter year, patient's age, gender, and postcode, and number of active general practitioners in practice) using the following indicators: encounters per patient per year, and tests per encounter.

The differences between subcategories will be further described as incidence rate ratios by generalised linear modelling (Poisson or negative binomial, whichever is appropriate).

Best practice guidelines-based analyses

In line with Objective 2 of this study, we will describe the extent to which pathology ordering practices among Australian GPs aligns with evidence-based pathology testing guidelines. Five initial candidate indicators have been identified for analyses.

1) Monitoring patients on clozapine medication

Rationale:

Clozapine is a highly effective antipsychotic drug that is used for managing chronic schizophrenia. However, clozapine use can result in neutropenia in nearly two percent of patients, and agranulocytosis in one percent (14); warranting close monitoring of patients taking clozapine. Although clozapine is prescribed by specialists, monitoring is more frequently managed by GPs through shared-care arrangements (15). After 18 weeks of initiation and monitoring under a specialist, GPs can also prescribe clozapine. Australian guidelines recommend patients on clozapine medication have blood tests for white blood cell and neutrophil counts weekly for the first 18 weeks of initiation,

and monthly thereafter (16,17). Furthermore, a patient cannot obtain clozapine from the pharmacist without a recent blood test. Currently, the state of monitoring for patients on clozapine medication is not known.

Analysis:

The study population will be patients who are being prescribed clozapine by the GP (and therefore also needing to be monitored). The timeframe will include records after the first entry of the prescription into the EHR software, and before medication is discontinued (or patient is deceased or is no longer an active patient). The demographic characteristics of patients on clozapine medication as well as number of full blood counts for these patients will be described overall, by patient gender, age, and location, general practice size, and year of test. The number of full blood counts per patient per year will also be described, overall and by the demographic characteristics, by counting the number of full blood count tests conducted for each patient on clozapine medication for each available year. Subsequently, the median number of full blood count tests per patient per year will be calculated, with the inter-quartile range. For patients with more than one test, the time between tests will be determined. Subsequently, median time between tests will be calculated, with the inter-quartile range. As clozapine may also be prescribed by specialists, it may not be possible to determine when the medication was initiated through the EHR software. Consequently, it may not be possible to differentiate patients who require weekly tests from patients who require monthly tests. Nonetheless, it is expected patients on clozapine medication will have at least one full blood count test within approximately four to six weeks of a prior test; which will indicate compliance with guidelines.

2) Measuring international normalised ratio (INR) levels for patients on warfarin medication

Rationale:

Warfarin is a highly effective and widely-used anticoagulant in Australia. However, it is also one of the most common causes of prescribed medication-related mortality, due to its risk of causing bleeding (18). Best practice guidelines recommend that the initiation of warfarin medication should be accompanied by frequent International Normalised Ratio (INR) measurements until a stable

therapeutic range is reached. After INR levels are stable, testing frequency should be once every four to six weeks: unless a change (e.g. initiation of another medication) which can affect INR levels occurs (19,20). Failure to correct INR levels is associated with increased mortality (21).

Analysis:

The sample population will be patients with a warfarin prescription. Only data entered after the first instance the prescription is recorded in the GP's computer and before the patient permanently stops the medication (or death) will be considered for analysis. As the pathology test frequency and repeat interval requirements for patients treated with warfarin are similar to the requirements for clozapine, similar reporting standards will be used. As with clozapine medication, it may not be possible to differentiate patients who are initiating warfarin medication from those who have reached stable INR levels. Despite this, based on best practice guidelines, it is expected that patients on warfarin medication will have at least one INR measurement approximately within four weeks of a prior measurement; which will be the criteria used to determine compliance with guidelines.

3) Glycated haemoglobin (HbA1c) testing for management of diabetic patients

Rationale:

It is estimated that over one million Australians are diagnosed with diabetes, 85% of whom have type 2 diabetes (22). Poor management of diabetes can lead to a range of complications, including cardiovascular and renal diseases, and retinopathy (23). Best practice guidelines recommend recurrent glycated haemoglobin (HbA1c) testing in at least half-yearly intervals for patients with diabetes (24). HbA1c levels are a good indicator of long-term blood glucose control over the previous 8-12 weeks. Uncontrolled glucose leading to high HbA1c levels may indicate increased risk of diabetes-related complications. As such, under-testing may be associated with failure to identify complications.

Analysis:

The sample population will be patients diagnosed with type 2 diabetes. Only data after the diagnosis being recorded and before death will be included. The analyses will be conducted and reported in a

similar structure as outlined previously for clozapine and warfarin medication pathology testing guidelines. Based on the best practice guidelines, it is expected that a minimum of two HbA1c tests will be conducted in a year for patients diagnosed with diabetes.

4) Frequency of vitamin D testing

Rationale:

A study on vitamin D testing found a considerable number of potentially unnecessary vitamin D tests ordered by Australian GPs (25). This has led to changes in funding programs and the establishment of guidelines, suggesting only patients at risk of complications that may arise due to low vitamin D levels (e.g. pregnant women, older patients at risk of falls, patients with osteoporosis) should be tested (26). Ultimately, an overall reduction of vitamin D tests was observed (9); however, studies on whether the tests are being ordered according to the guidelines are limited (27).

Analysis:

To understand if vitamin D tests are being ordered according to guidelines, population and demographic characteristics associated with higher vitamin D testing will be investigated. The sample population will be all patients; from which patients who had a vitamin D test will be identified and flagged (as the outcome variable). Univariate and multivariate logistic regression models will be fitted to identify any variation in vitamin D testing by the demographic characteristics of patients, diagnoses, and general practices. Differences will be reported as odds ratios and their 95% confidence intervals. Descriptive characteristics (patient's gender, age, and location, general practice's size, and year of test) of the sample population will also be described.

5) Thyroid Function Tests

Rationale:

Thyroid dysfunction can occur due to over- or under-function of the thyroid gland, and can lead to cardiovascular diseases or subclinical hypothyroidism (remains asymptomatic) (28). Guidelines recommend assessing thyroid dysfunction by initial thyroid-stimulating hormone (TSH) tests, which

may be followed up by free triiodothyronine (fT3) and free thyroxine (fT4) tests to assist with diagnosis if an abnormal TSH result is observed (29). Otherwise, fT3 and fT4 tests are not recommended without a prior TSH test. In Australia, there are currently no screening guidelines for when and how frequently TSH tests should be conducted among adults. The benefit of screening for thyroid disease, or even treating subclinical hypothyroidism, remains uncertain (30). It would be valuable to understand the demographics for and frequency of TSH test ordering by Australian GPs.

Analysis:

To describe thyroid function test use by Australian GPs, patients with TSH, fT3, and fT4 tests will be identified from the data. The associations with population characteristics and diagnoses in TSH, fT3, and fT4 testing will be investigated and reported by univariate and multivariate logistic regression models, similar to the reporting of vitamin D testing outlined previously. In addition to the population and general practice demographics, the odds of fT3 and fT4 testing by prior TSH test result, and normal/abnormal TSH test will also be analysed.

The descriptive characteristics for TSH, fT3, and fT4 tests will be described overall, and by patient gender, age, and location, general practice size, and year of test. The number of fT3 and fT4 tests will be further described by TSH testing status: without a prior TSH test, simultaneously ordered with a TSH test, and following a reported TSH test. Where TSH test results are available, fT3 and fT4 tests following TSH testing will be further described by whether the initial TSH test was normal or abnormal.

Sample size considerations

The study will be based on a dynamic cohort, with the number of practices, GPs, and patients expected to rise. Current estimates suggest that the study will have data from 350 general practices. Therefore, it is expected that there will be ample scope to detect significant variation in practices across patient and general practice demographic domains.

DISCUSSION

Pathology tests play an important role in general practice. There are guidelines outlining best practice for utilising tests, although the role of these guidelines in decision making is not well established.

A limitation of using electronic health records is that recording of clinical data is not always well-standardised, resulting in variation and inconsistencies in the information available (31). Issues may arise due to free-text data with no standard formatting, absence of recorded comorbidities and diagnoses or missing data (32), which are addressed by prioritising standardised terms and adopting stringent criteria to define variables. The POLAR program already codes and organises significant amounts of extracted data, and LOINC and SNOMED, both of which are available, provide standardised pathology tests and diagnoses. Another limitation of this study is that the study population will be drawn from only one region of Australia (Victoria), and the results may not be nationally representative.

This research will help define the extent to which evidence-based best practice guidelines influence decision making in general practices. To date, difficulties in obtaining patient data from EHR softwares have hindered studying pathology test ordering in general practice. This study will be one of the first in Australia to extensively investigate the impact of best practice guidelines on GP testing patterns. The study can ultimately lead to better efficiency in pathology testing and improvements in patient outcomes by providing much needed information on the adherence of GPs to pathology testing guidelines.

Ethics and Dissemination

Ethics clearance to collect data from general practice facilities has been obtained by the data provider from the RACGP National Research and Evaluation Ethics Committee (NREEC 17-008). Approval for the research group to use these data has been obtained from Macquarie University (5201700872). The data will be de-identified and reported at an aggregate level, and the results will neither identify GPs nor patients.

The results of this study will be reported to the Australian Government's Department of Health, disseminated in peer-reviewed academic journals, and presented in national and international

conferences and industry forums. The involvement of the PHNs in the research process also allows for the research findings to inform their activities at an early stage, reducing the usual 'research into practice' delay.

Contributors

This study is jointly undertaken through a collaboration between Centre for Health Systems and Safety Research at Macquarie University, the Royal College of Pathologists of Australasia Quality Assurance Programs, POLAR Data Space (Outcome Health, Eastern Melbourne PHN, Gippsland PHN and South Eastern Melbourne PHN). AG initiated the project and led the development of the Quality Use of Pathology Program (QUPP) grant proposal. AG, JIW, LL, LP, TB, CP, and NR are chief investigators on the project and have contributed to the grant proposal and protocol in their area of expertise. From the PHNs, MS, RW, and ED contributed their expertise in general practice to the protocol. AM, from Outcome Health, has contributed his expertise in EHR data to the protocol. RAH, GS, and GSF are members of the project team and contributed to the protocol in relation to describing the procedures of data collection, validation, and analyses procedures. RAH and GS prepared the first draft of this protocol based on the grant proposal. All authors have reviewed and approved the final version of this protocol.

Funding

This study is independently executed through funding by a grant from the Australian Government Department of Health, Quality Use of Pathology Program (Agreement ID: 4-2QFVW4M). This Australian national grants program aims to improve health and economic outcomes from pathology tests.

Competing Interests

None declared.

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BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-024223.R1
Article Type:	Protocol
Date Submitted by the Author:	26-Jul-2018
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Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	Evidence based practice, Pathology
Keywords:	Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health informatics < BIOTECHNOLOGY & BIOINFORMATICS, PATHOLOGY, PRIMARY CARE, Australia

Compliance with pathology testing guidelines in Australian general practice: protocol for a secondary analysis of electronic health record data

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Pathology testing in Australian general practice and compliance with guideline recommendations: A study protocol for a secondary analysis of electronic health record data

ABSTRACT

Introduction In Australia, general practitioners usually provide the first point of contact for patients with non-urgent medical conditions. Appropriate and efficient utilisation of pathology tests by general practitioners forms a key part of diagnosis and monitoring. However over- and under- utilisation of pathology tests have been reported across several tests and conditions, despite evidence-based guidelines outlining best practice in pathology testing. There are a limited number of studies evaluating the impact of these guidelines on pathology testing in general practice. The aim of our quantitative observational study is to define how pathology tests are used in general practice and investigate how test ordering practices align with evidence-based pathology guidelines.

Methods and analysis Access to non-identifiable patient data will be obtained through electronic health records from general practices across three primary health networks in Victoria, Australia. Numbers and characteristics of patients, general practices, encounters, pathology tests, and problems managed over time will be described. Overall rates of encounters and tests, alongside more detailed investigation between subcategories (encounter year, patient's age, gender, and location, and general practice size) will also be undertaken. To evaluate how general practitioner test ordering coincides with evidence-based guidelines, five key candidate indicators will be investigated: full blood counts for patients on clozapine medication; international normalised ratio (INR) measurements for patients on warfarin medication; glycated haemoglobin (HbA1c) testing for monitoring diabetes; vitamin D testing; and thyroid function testing.

Ethics and dissemination Ethics clearance to collect data from general practice facilities has been obtained by the data provider from the RACGP National Research and Evaluation Ethics Committee (NREEC 17-008). Approval for the research group to use these data has been obtained from Macquarie University (5201700872). This study is funded by the Australian Government Department of Health Quality Use of Pathology Program (Agreement ID: 4-2QFVW4M). Findings will be reported to the Department of Health and disseminated in peer-reviewed academic journals and presentations (national and international conferences, industry forums).

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The study population will be drawn from a large region in Victoria, Australia, and is expected to contain a large sample population (data from approximately 350 general practices), along with a large number of demographic variables (e.g., region, gender, age).
- Electronic health records contain a vast amount of information on patients, allowing us to control for potential interacting or predictive variables on patient outcomes using statistical modelling.
- Some electronic health record fields may not be completely standardised across practices and could contain inconsistencies and missing information; which may limit the volume of data that can be extracted and analysed.
- Some medications being investigated in this study may be prescribed and/or monitored by specialists, which may result in cases being missed.

INTRODUCTION

In Australia, general practitioners (GPs) are usually the first point of contact for patients with non-emergency health problems. They play an important role in the early detection, prevention (including shared-care arrangements) and treatment of disease (1). Pathology tests are a key part of general practice assisting GPs in diagnosing, screening, treating, and monitoring diseases. The past decade has seen an increase in both visits to and problems managed by GPs in Australia, resulting in an estimated 24.2 million additional pathology tests being ordered in 2015-2016 compared to 2006-2007 (2).

Appropriate and timely utilisation of pathology tests can improve the quality and outcome of patient care. However, both over- and under- utilisation of pathology tests have been frequently observed in a range of clinical scenarios (3,4). Several guidelines have been established to encourage better utilisation of pathology tests among GPs across Australia, the US, Canada, and the UK. These include initiatives such as *Choosing Wisely* (5)*, National Institute for Health and Clinical Excellence (NICE)* (6), and *Royal Australian College of General Practitioners (RACGP) Guidelines for preventative activities in general practice* (7). Currently, there is little evidence on how test ordering practices by GPs align with these recommendations and guidelines in Australia, and elsewhere. A survey of 600 US doctors revealed only 21% of doctors were familiar with the *Choosing Wisely* campaign. However doctors aware of the campaign had a lower proportion of unnecessary pathology testing (8). In Australia, increased awareness of best-practice in vitamin D test ordering is reported to have contributed to a reduction in healthcare costs and potentially unnecessary tests (9). Considering the importance of pathology testing for managing diseases, a better understanding of how pathology testing by GPs coincides with evidence-based guidelines will be invaluable for the success of management and disease-prevention strategies.

Until recently, the survey-based *Bettering the Evaluation and Care of Health (BEACH)* study provided the most comprehensive data on Australian GP activity (2). However, its cross-sectional design prevented it from reporting longitudinal patient level changes and outcomes. The BEACH study was discontinued in 2016, and has since left a gap in our understanding of GP activity; particularly in relation to pathology test ordering. The extensive use of computers by Australian GPs has prompted interest in the use of electronic health record (EHR) data as a research source for monitoring the quality of GP services, and has led to research and publications based on EHR data (10). The Australian Department of Health funded NPS Medicinewise MedicinesInsight dataset contains a national collection of electronic health records (EHRs) from 650 practices covering over 3,300 GPs and nearly 3.6 million active patients (11).This dataset has been used in several population health research projects, and has demonstrated the value of EHR data in research (12). This study will use EHR data from the POLAR Data Space, containing de-identified data from consenting general practices collected on behalf of Australian PHNs from approximately 350 practices. POLAR Data Space has added measures to ensure robust and accurate data, and implements standardised terminologies to make the data more approachable for research use. This study, undertaken in collaboration with POLAR Data Space Research Consortia and its associated Primary Health Networks (PHNs), will facilitate a comprehensive analyses of general practice activity and its relationship to pathology testing in Australia through EHR data.

Objectives:

The objectives of this study are to:

1. Describe general practice activity and characteristics of pathology test ordering based on electronic health record data;
2. Investigate compliance with evidence-based guidelines to determine the appropriateness and quality use of pathology in general practice.

METHODS AND ANALYSES

Study design

A retrospective observational study of Australian general practice health records and pathology testing data. The study will run for a period of approximately two years spanning from early 2018 to late 2019.

Data source

Data to be used in this study will be provided by the POLAR Data Space (10). POLAR Data Space collects de-identified data from consenting general practices on behalf of Australian PHNs: including Gippsland, Eastern Melbourne, and South Eastern Melbourne PHNs. Data are extracted from approximately 350 practices in urban and rural regions in Victoria, Australia. The primary purpose of the data collection is to provide information to improve patient care at the practice level and population health initiatives at the PHN level. POLAR Data Space has ethics approval for the collection, storage and de-identification of the data which it makes available for approved research governed by the involved PHNs.

The data source will include pooled general practice patient data extracted from Best Practice, Medical Director, and Zedmed EHRs. Data will include de-identified demographic information about patients and general practices, as well as visit records (diagnosis, past history, medications) and pathology test records (test name and result). Both historical and current information about patients will be acquired, providing a longitudinal record. It is expected that the data will span a period of over a decade, from early 2000's to early 2018.

Study Population

The study population will consist of all patients who visited any of the general practices included in the study, and had their visit recorded in the practices' EHR software.

Variables

The following criteria will be adopted to accurately describe general practice activity and ensure data quality: (i) A patient will be distinguished by a unique (non-identifiable) patient code recorded within a general practice and included if determined to be an active patient (i.e. has visited the GP three or more times in the past two years, not deceased; (ii) An encounter (i.e. consultation, visit) will be defined as a patient visit recorded by a doctor or nurse during which an action (e.g. consultation, prescription) is performed, and will be identified through a variable indicating the visit type (e.g. surgery, administrative, phone call); (iii) A pathology test will be defined as either a panel of interrelated tests (e.g. full blood count) or an individual test (e.g. troponin test); (iv) Where possible, standardised records such as Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine (SNOMED) terminologies will be prioritised to identify variables; otherwise, free-text data will be searched for terms of interest (e.g. "diabetes" or its abbreviated forms in the diagnosis field, excluding "not diabetes").

Analyses

Data examination and analysis will be performed using Stata/MP 15.1 (StataCorp, College Station, Texas, USA). The methods outlined in this protocol are structured according to the *Strengthening the Reporting of Observational Studies in Epidemiology* (STROBE) checklist of items to be included in observational studies (13).

Characteristics of general practice activity and pathology testing

In line with Objective 1 of this study, we will analyse and describe Australian general practice characteristics and activity. These characteristics can subsequently be compared to reports on national demographics and healthcare statistics, such as *Australian Institute of Health and Welfare*'s (AIHW) annual reports.

Sample population characteristics will be reported. This will include describing the characteristics of patients, general practices, encounters, tests, and problems managed across time. Subsequent analyses will describe overall median rates of encounters and tests, alongside more detailed investigation between subcategories (encounter year, patient's age, gender, and postcode, and number of active general practitioners in practice) using the following indicators: encounters per patient per year, and tests per encounter.

The differences between subcategories will be further described as incidence rate ratios by generalised linear modelling (Poisson or negative binomial, whichever is appropriate).

Best practice guidelines-based analyses

In line with Objective 2 of this study, we will describe the extent to which pathology ordering practices among Australian GPs aligns with evidence-based pathology testing guidelines. Five initial candidate indicators have been identified for analyses.

1) Monitoring patients on clozapine medication

Rationale:

Clozapine is a highly effective antipsychotic drug that is used for managing chronic schizophrenia. However, clozapine use can result in neutropenia in nearly two percent of patients, and agranulocytosis in one percent (14); warranting close monitoring of patients taking clozapine. Although clozapine is prescribed by specialists, monitoring is more frequently managed by GPs through shared-care arrangements (15). After 18 weeks of initiation and monitoring under a specialist, GPs can also prescribe clozapine. Australian guidelines recommend patients on clozapine medication have blood tests for white blood cell and neutrophil counts weekly for the first 18 weeks of initiation, and monthly thereafter (16,17). Furthermore, a patient cannot obtain clozapine from the pharmacist without a recent blood test. Currently, the state of monitoring for patients on clozapine medication is not known.

Analysis:

The study population will be patients who are being prescribed clozapine by the GP (and therefore also needing to be monitored). The timeframe will include records after the first entry of the prescription into the EHR software, and before medication is discontinued (or patient is deceased or is no longer an active patient). The demographic characteristics of patients on clozapine medication as well as number of full blood counts for these patients will be described overall, by patient gender, age, and location, general practice size, and year of test. The number of full blood counts per patient per year will also be described, overall and by the demographic characteristics, by counting the number of full blood count tests conducted for each patient on clozapine medication for each available year.

Subsequently, the median number of full blood count tests per patient per year will be calculated, with the inter-quartile range. For patients with more than one test, the time between tests will be determined. Subsequently, median time between tests will be calculated, with the inter-quartile range. As clozapine may also be prescribed by specialists, it may not be possible to determine when the medication was initiated through the EHR software. Consequently, it may not be possible to differentiate patients who require weekly tests from patients who require monthly tests. Nonetheless, it is expected patients on clozapine medication will have at least one full blood count test within approximately four to six weeks of a prior test; which will indicate compliance with guidelines.

2) Measuring international normalised ratio (INR) levels for patients on warfarin medication

Rationale:

Warfarin is a highly effective and widely-used anticoagulant in Australia. However, it is also one of the most common causes of prescribed medication-related mortality, due to its risk of causing bleeding (18). Best practice guidelines recommend that the initiation of warfarin medication should be accompanied by frequent International Normalised Ratio (INR) measurements until a stable therapeutic range is reached. After INR levels are stable, testing frequency should be once every four to six weeks: unless a change (e.g. initiation of another medication) which can affect INR levels occurs (19,20). Failure to correct INR levels is associated with increased mortality (21).

Analysis:

The sample population will be patients with a warfarin prescription. Only data entered after the first instance the prescription is recorded in the GP's computer and before the patient permanently stops the medication (or death) will be considered for analysis. As the pathology test frequency and repeat interval requirements for patients treated with warfarin are similar to the requirements for clozapine, similar reporting standards will be used. As with clozapine medication, it may not be possible to differentiate patients who are initiating warfarin medication from those who have reached stable INR levels. Despite this, based on best practice guidelines, it is expected that patients on warfarin medication will have at least one INR measurement approximately within four weeks of a prior measurement; which will be the criteria used to determine compliance with guidelines.

3) Glycated haemoglobin (HbA1c) testing for management of diabetic patients

Rationale:

It is estimated that over one million Australians are diagnosed with diabetes, 85% of whom have type 2 diabetes (22). Poor management of diabetes can lead to a range of complications, including cardiovascular and renal diseases, and retinopathy (23). Best practice guidelines recommend recurrent glycated haemoglobin (HbA1c) testing in at least half-yearly intervals for patients with diabetes (24). HbA1c levels are a good indicator of long-term blood glucose control over the previous 8-12 weeks. Uncontrolled glucose leading to high HbA1c levels may indicate increased risk of diabetes-related complications. As such, under-testing may be associated with failure to identify complications.

Analysis:

The sample population will be patients diagnosed with type 2 diabetes. Only data after the diagnosis being recorded and before death will be included. The analyses will be conducted and reported in a similar structure as outlined previously for clozapine and warfarin medication pathology testing guidelines. Based on the best practice guidelines, it is expected that a minimum of two HbA1c tests will be conducted in a year for patients diagnosed with diabetes.

4) Frequency of vitamin D testing

Rationale:

A study on vitamin D testing found a considerable number of potentially unnecessary vitamin D tests ordered by Australian GPs (25). This has led to changes in funding programs and the establishment of guidelines, suggesting only patients at risk of complications that may arise due to low vitamin D levels (e.g. pregnant women, older patients at risk of falls, patients with osteoporosis) should be tested (26). Ultimately, an overall reduction of vitamin D tests was observed (9); however, studies on whether the tests are being ordered according to the guidelines are limited (27).

Analysis:

To understand if vitamin D tests are being ordered according to guidelines, population and demographic characteristics associated with higher vitamin D testing will be investigated. The sample population will be all patients; from which patients who had a vitamin D test will be identified and flagged (as the outcome variable). Univariate and multivariate logistic regression models will be fitted to identify any variation in vitamin D testing by the demographic characteristics of patients, diagnoses, and general practices. Differences will be reported as odds ratios and their 95% confidence intervals. Descriptive characteristics (patient's gender, age, and location, general practice's size, and year of test) of the sample population will also be described. To obtain an understanding of the reasons for vitamin D testing, other tests ordered simultaneously will be identified and examined, as well as preceding medication prescriptions and diagnoses.

5) Thyroid Function Tests

Rationale:

Thyroid dysfunction can occur due to over- or under-function of the thyroid gland, and can lead to cardiovascular diseases or subclinical hypothyroidism (remains asymptomatic) (28). Guidelines recommend assessing thyroid dysfunction by initial thyroid-stimulating hormone (TSH) tests, which may be followed up by free triiodothyronine (fT3) and free thyroxine (fT4) tests to assist with diagnosis if an abnormal TSH result is observed (29). Otherwise, fT3 and fT4 tests are not recommended without a prior TSH test. In Australia, there are currently no screening guidelines for when and how frequently TSH tests should be conducted among adults. The benefit of screening for thyroid disease, or even treating subclinical hypothyroidism, remains uncertain (30). It would be valuable to understand the demographics for and frequency of TSH test ordering by Australian GPs.

Analysis:

To describe thyroid function test use by Australian GPs, patients with TSH, fT3, and fT4 tests will be identified from the data. The associations with population characteristics and diagnoses in TSH, fT3, and fT4 testing will be investigated and reported by univariate and multivariate logistic regression models, similar to the reporting of vitamin D testing outlined previously. In addition to the population and general practice demographics, the odds of fT3 and fT4 testing by prior TSH test result, and normal/abnormal TSH test will also be analysed.

The descriptive characteristics for TSH, fT3, and fT4 tests will be described overall, and by patient gender, age, and location, general practice size, and year of test. The number of fT3 and fT4 tests will be further described by TSH testing status: without a prior TSH test, simultaneously ordered with a TSH test, and following a reported TSH test. Where TSH test results are available, fT3 and fT4 tests

following TSH testing will be further described by whether the initial TSH test was normal or abnormal.

Sample size considerations

The study will be based on a dynamic cohort, with the number of practices, GPs, and patients expected to rise. Current estimates suggest that the study will have data from 350 general practices. Therefore, it is expected that there will be ample scope to detect significant variation in practices across patient and general practice demographic domains.

Patient and Public Involvement

There was no involvement of patients or the public in this study.

DISCUSSION

Pathology tests play an important role in general practice. There are guidelines outlining best practice for utilising tests, although the role of these guidelines in decision making is not well established.

A limitation of using electronic health records is that recording of clinical data is not always well-standardised, resulting in variation and inconsistencies in the information available (31). Issues may arise due to free-text data with no standard formatting, absence of recorded comorbidities and diagnoses or missing data (32), which are addressed by prioritising standardised terms and adopting stringent criteria to define variables. The POLAR program already codes and organises significant amounts of extracted data, and LOINC and SNOMED, both of which are available, provide standardised pathology tests and diagnoses. Another limitation of this study is that the study population will be drawn from only one region of Australia (Victoria), and the results may not be nationally representative. One other limitation is related to the indicators being measured. Medications, such as clozapine and warfarin are generally prescribed by specialists, whom might also continually monitor the patient's status. In such cases, observed compliance with guidelines in general practice may be low. Furthermore, a patient monitored by a general practitioner may have occasional visits to their specialist, who may order the tests, rather than the GP.

This research will help define the extent to which evidence-based best practice guidelines influence decision making in general practices. To date, difficulties in obtaining patient data from EHR softwares have hindered studying pathology test ordering in general practice. This study will be one of the first in Australia to extensively investigate the impact of best practice guidelines on GP testing patterns. The study can ultimately lead to better efficiency in pathology testing and improvements in patient outcomes by providing much needed information on the adherence of GPs to pathology testing guidelines.

Ethics and Dissemination

Ethics clearance to collect data from general practice facilities has been obtained by the data provider from the RACGP National Research and Evaluation Ethics Committee (NREEC 17-008). Approval for the research group to use these data has been obtained from Macquarie University (5201700872). The data will be de-identified and reported at an aggregate level, and the results will neither identify GPs nor patients.

The results of this study will be reported to the Australian Government's Department of Health, disseminated in peer-reviewed academic journals, and presented in national and international

conferences and industry forums. The involvement of the PHNs in the research process also allows for the research findings to inform their activities at an early stage, reducing the usual 'research into practice' delay.

Contributors

This study is jointly undertaken through a collaboration between Centre for Health Systems and Safety Research at Macquarie University, the Royal College of Pathologists of Australasia Quality Assurance Programs, POLAR Data Space (Outcome Health, Eastern Melbourne PHN, Gippsland PHN and South Eastern Melbourne PHN). AG initiated the project and led the development of the Quality Use of Pathology Program (QUPP) grant proposal. AG, JIW, LL, LP, TB, CP, and NR are chief investigators on the project and have contributed to the grant proposal and protocol in their area of expertise. From the PHNs, MS, RW, and ED contributed their expertise in general practice to the protocol. AM, from Outcome Health, has contributed his expertise in EHR data to the protocol. RAH, GS, and GSF are members of the project team and contributed to the protocol in relation to describing the procedures of data collection, validation, and analyses procedures. RAH and GS prepared the first draft of this protocol based on the grant proposal. All authors have reviewed and approved the final version of this protocol.

Funding

This study is independently executed through funding by a grant from the Australian Government Department of Health, Quality Use of Pathology Program (Agreement ID: 4-2QFVW4M). This Australian national grants program aims to improve health and economic outcomes from pathology tests.

Competing Interests

None declared.

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