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Improving diagnostic antimicrobial stewardship in respiratory tract infections: a protocol for a scoping review investigating point-of-care testing programmes in community pharmacy

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ABSTRACT

Introduction Diagnostic uncertainty regarding the cause of respiratory tract infections (RTIs) multiplies the problem of unnecessary use of antibiotics and antimicrobial resistance in primary care. Point-of-care testing (POCT) programmes have been recognised as a potential stewardship strategy to optimise antimicrobial use in primary care. There is a need for greater understanding of community pharmacy-based POCT programmes in reducing the unnecessary use of antimicrobials in patients with RTIs. This review systematically maps out evidence around the effectiveness, feasibility and implementation challenges of POCT programmes in community pharmacy to improve safe antimicrobial use in RTIs.

Methods and analysis The Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews checklist and the Arksey and O'Malley methodology framework will guide the reporting of this review. We will systematically review studies with either randomised controlled trial, non-randomised controlled trial, before–after study, observational study or pilot feasibility study design. Medline, Emcare, PubMed, Health Technology Assessment, Cochrane Central Register of Controlled Trials and Google Scholar databases will be used to search for articles. Three reviewers will independently screen, review and select studies with POCT programmes involving community pharmacists for antimicrobial stewardship in RTIs. Summary statistics and random effects model, if data permit, will be used to summarise the effectiveness, feasibility and cost-effectiveness of the POCT programme. The Consolidated Framework for Implementation Research will capture POCT implementation drivers.

Ethics and dissemination This review study does not require research ethics approval. Findings will be disseminated through national and international conferences, seminars and publication in a peer-reviewed journal.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The most current Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews guides the systematic reporting of this review.
⇒ Limiting the study to only English-language articles has the potential of missing relevant studies.
⇒ The limited number and suboptimal quality of studies may prevent generation of rigid conclusions on the effectiveness and feasibility of implementing point-of-care testing programmes in community pharmacy to improve antimicrobial stewardship in respiratory tract infections.

INTRODUCTION

Patients with symptoms of respiratory tract infections (RTIs) commonly visit their primary care clinicians, including community pharmacists, and are often treated with antibiotics unnecessarily. When RTIs are viral in origin, symptomatic treatment can produce the greatest benefits.[1] Evidence shows that general practitioners (GPs) prescribe antibiotics for RTIs at much higher rates than recommended in therapeutic guidelines: acute rhinosinusitis: 41% vs 0.5%–8%; acute otitis media: 89% vs 20%–31%; and acute pharyngitis or sore throat: 94% vs 19%–40%.[2] Diagnostic uncertainty regarding the cause of RTIs potentially contributes to the burden of inappropriate use of antibiotics and the growing antimicrobial resistance in primary care.[3] Provision of point-of-care diagnostic tools and technologies has been recognised as a promising antimicrobial stewardship programme to address diagnostic uncertainty and optimise antimicrobial use in RTIs. According to the WHO, diagnostic antimicrobial stewardship tools are clinical diagnostic tests that help appropriately diagnose infectious diseases, help in the surveillance of bacterial resistance and enable taking decision of appropriate antimicrobial therapy.[4]

RTIs of bacterial origin can cause severe complications if diagnosis is delayed. An example of these RTIs is acute pharyngitis or sore throat, which is potentially caused by group A streptococci. This infection can be severe and has a risk of late complications including scarlet fever, rheumatic fever on rare occasions and acute glomerulonephritis.[5] Early treatment with antimicrobials is associated with fewer complications.[6] Group A streptococci lead to 700 000 worldwide deaths annually.[6 7] Interestingly, only around 20% of sore throat infections (ranging from 5% to 15% in adults and from 20% to 30% in children) are caused by group A streptococci. However, up to 70% of sore throat cases are treated with inappropriate antibiotics.[7 8] The limited capacity of primary care clinicians in detecting specific causative organisms such as group A streptococci by point-of-care testing (POCT) is a challenge to appropriately treating acute pharyngitis and undertaking rational antibiotic decisions.[8 9]

POCT can be defined as the 'provision of a test when the result will be used to make a decision and to take appropriate action, which will lead to an improved health outcome'.[10] The most important elements of POCT are getting rapid results and its communication to guide clinical decisions. Besides, POCT should guide subsequent actions that could impact patients' clinical management, including referral, triage and treatment decisions.[11–13] As POCT involves processes and mechanisms for screening and treatment decisions, it can be appropriately named as a POCT programme. For normalisation, POCT programmes need viable business models for sustainability, and any programme must fit with real-world clinical workflow and economic/incentive structures. The commonly used POCT programmes for management of RTIs include C reactive protein (CRP) and rapid antigen testing (RAT) programmes.

RATs can reliably identify bacteria such as group A streptococci which cause pharyngitis within 5–15 min. They can facilitate justified medical decision-making and can help clinicians avoid inappropriate antibiotic choice and prevent complications.[6 14 15] Likewise, CRP testing programmes can successfully differentiate bacterial RTIs from viral RTIs within 5 min.[16–18] CRP testing programmes have been shown to be robust, reliable and cost-effective in GP settings.[19–21] POCT programmes have potential benefits in reducing unnecessary and inappropriate antibiotic use by supporting clinicians' decisions with regard to antimicrobial treatment and appropriate patient referral between GPs and pharmacists.[22 23]

Community pharmacists are well positioned in primary care to provide POCT screening and treatment services to patients seeking RTI treatment and to efficiently refer patients who need further investigation for signs of bacterial infection to GPs.[24] Community pharmacists have been undergoing an expansion of their scope of service and practices to address the unmet needs of patient care, although this is mostly visible in developed countries.[25 26] POCT programmes could be an opportunity for community pharmacists to be better involved in antimicrobial stewardship (AMS) programmes for RTIs and to collaborate with GPs.

Evidence suggests that the adoption of CRP and RAT programmes by community pharmacists can improve the selection of appropriate antibiotic treatment, reduce the use of healthcare resources and enable health economic benefits.[16 23 27 28] A CRP testing programme in UK community pharmacies showed potential in reducing unnecessary RTI-related GP visits.[29] Despite potential AMS benefits, the uptake of POCT programmes in community pharmacies has been low worldwide. In most countries including in Australia, no POCT programmes are used as standard practice in community pharmacies for patients seeking RTI treatment. Due to lack of these programmes and policy support, community pharmacists cannot scientifically judge which patients with RTI should be referred to GPs or need just over-the-counter medicines for safe recovery. In an Australian nationwide survey, <15% of 613 surveyed community pharmacists used POCT programmes in patients with any infections.[30]

To date, it remains unclear to what extent POCT programmes are effective and feasible in the context of community pharmacy. The diversity of community pharmacies in terms of business models, pharmacy practice regulatory policies and rights for diagnostic use for patient safety may influence POCT use among community pharmacists.[31] The clinical skills of community pharmacists and patients' receptiveness of POCT services from community pharmacy also matter to the provision of a POCT programme in routine pharmacy practices.[32] However, the diverse factors that influence the implementation of POCT programmes in community pharmacy to improve antimicrobial stewardship remain largely unknown.

By searching PROSPERO, we found no systematic reviews related to POCT programmes in community pharmacy. As POCT programmes have gained global attention as potential tools to avoid unnecessary antibiotic use and associated risk of antimicrobial resistance in primary care, it is of utmost importance to comprehensively know if POCT programmes in community pharmacy are effective, feasible and implementable for antimicrobial stewardship. Considering the importance of diagnostic antimicrobial stewardship and the expansion of pharmacists' role in antimicrobial stewardship, this review study has been developed to provide synthesised evidence to inform future diagnostic stewardship policy directions for introducing POCT programmes in community pharmacy to optimise antimicrobial use in RTIs.

METHODS
We will use the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist[33] (online supplemental file 1) and Arksey and O'Malley's[34] seven component methodology framework to report this scoping review. We chose a scoping review design as this review (1) will map out

the breadth of evidence in the literature on the topic of POCT testing programmes in community pharmacy; (2) will investigate evidence around the effectiveness and feasibility of POCT testing programmes in community pharmacy; and (3) will inform future research directions to address evidence gaps. The following are the seven components: (1) identification of the aims of the research; (2) review of sources of data, search strategies and study design to identify studies of interest; (3) selection of studies; (4) extraction of data; (5) quality assessment of the selected studies; (6) data collation and analysis of the outcome of interest; and (7) proposing future direction of research. This study is planned to be conducted between 1 August 2022 and April 2023.

Identification of the aims of the research

This scoping review focuses on the following aims:

► To identify the breadth and scope of evidence assessing implementation of POCT in community pharmacy to optimise antimicrobial use.

► To map out evidence around the effectiveness, feasibility and cost-effectiveness of POCT programmes in community pharmacy to optimise antimicrobial use in primary care.

► To understand implementation challenges and opportunities for using POCT programmes among community pharmacists in routine pharmacy practices.

► To identify if evidence generated from published research is sufficient to inform policies supporting routine use of POCT programmes in community pharmacy for optimal antimicrobial use.

Review of sources of data, search strategies and study design to identify studies of interest

Sources of data

We will conduct a systematic search in six medical databases to identify relevant studies. These databases are Medline, Emcare, PubMed, Health Technology Assessment, Cochrane Central Register of Controlled Trials and Google Scholar. A uniform search strategy will be developed and applied to these databases. Databases will be accessed through the Deakin University library system.

Search strategy

The search strategy will follow the PICOT terminology:

► Population: [community pharmac* OR community pharmacist* OR community pharmacy].

► Intervention: [point-of-care testing OR rapid antigen test OR C-reactive protein OR diagnostic test OR CRP OR RAT OR RADT*].

► Outcome: [Antibiotic* OR Antibiotics OR Antimicrobial* OR Antibiotic prescribing OR Antimicrobial prescribing OR antibiotic use OR Antimicrobial use OR Antimicrobial stewardship].

► Time: the study publication period will be between 1 January 2012 and 31 December 2022. As POCT programmes have been considered potential antimicrobial stewardship programmes in the national

and international AMR action plan around 2012, we believe that evidence began from this period.

This common search strategy will be applied to all the databases selected for searching articles. Online supplemental file 2 shows the details of search strategy for all six databases.

Apart from database search, snowballing strategies will be applied to identify any relevant studies from review articles. Manual searches will be performed in relevant pharmacy and health service journals, with a focus on journals publishing antimicrobial stewardship work, to reduce the chance of missing relevant articles. Examples of such journals include *Research in Social and Administrative Pharmacy*, *International Journal of Clinical Pharmacy*, *Journal of Clinical Pharmacy*, *International Journal of Pharmacy Practice and Therapeutics*, *Journal of Pharmacy Practice and Research*, *European Journal of Hospital Pharmacy*, *The Pharmaceutical Journal*, *Journal of the American Pharmacists Association*, *Antibiotics*, and *Journal of Antimicrobial Chemotherapy*. Using the auto-alert system in individual databases until publication of this review, we will set an update of literature search to minimise the risk of missing any potential articles.

Study design of the selected articles

The selected studies will consist of implementation studies and/or feasibility studies with either randomised controlled trial (RCT), non-RCT, observational study (retrospective or prospective), cohort study (retrospective or prospective) or pilot study design. Qualitative studies that assess the perceptions of community pharmacists regarding POCT implementation for optimal antimicrobial use in community pharmacists will be included. The algorithm of the Effective Practice and Organisation of Care (EPOC) group criteria[35] will be used to determine the study design and to avoid any ambiguous terminology.

Selection of studies

All searched records, either derived from electronic databases or from manual snowballing, will be merged to remove duplicate citations. Three reviewers (SKS, SP and CLB) will independently screen titles and abstracts and review the full text in the Covidence systematic review software using the inclusion and exclusion criteria, as stated in the next sections. Articles will be excluded if it is clear from the title or abstract that the study does not meet the inclusion criteria. Discrepancies will be resolved over discussions among the three reviewers. If needed, we will contact the authors by email to obtain relevant articles, resolve any missing or unclear data, or for any clarification. We will use a PRISMA flow diagram to maintain transparency in the process of article selection and to record studies that remain in each stage of selection with valid explanation.

Inclusion criteria

Any study meeting all of the following criteria will be included:

► Population: only community pharmacists with any level of experience who have used POCT or shared their views and experience of using POCT in community pharmacy for optimal use of antimicrobials.

► Intervention: any kind of POCT (eg, CRP or RAT) that was used to diagnose RTIs with the purpose of optimising antimicrobial use; studies will be considered for inclusion if they meet all of the following conditions:

– POCT programmes were provided to patients or the public by community pharmacists to avoid unnecessary antimicrobial use in RTIs.

– Investigated either a single POCT test or multiple POCT test services with the primary objective of reducing antimicrobial use or consumption in RTIs.

– Evaluated either the effectiveness, cost-effectiveness, feasibility or implementation of POCT programmes, or the receptiveness among community pharmacists.

– Applied any mode of POCT service delivery with fees or without fees of the patient or the public.

– Conducted the POCT programme for any time frame or period.

► Setting: implementation of POCT programmes in community pharmacy or using GP–pharmacy practice agreements.

► Design: implementation study or feasibility study with either RCT, non-RCT, observational study (retrospective or prospective), cohort study (retrospective or prospective) or qualitative study design that assesses the feasibility of using POCT programme, including implementation challenges and facilitators or community pharmacists' perceptions regarding POCT programmes for antimicrobial stewardship in RTIs.

► Outcome: studies assessing either the effect, cost-effectiveness, feasibility, or implementation challenges and opportunities of using POCT programmes in community pharmacy for antimicrobial stewardship in RTIs.

► Country: studies conducted in any country.

► Time: studies conducted between January 2012 and 2022.

► Availability: full-text articles are available.

Exclusion criteria

► Studies published as editorial or case series or any conference abstracts which are not available as full text.

► POCT test delivered in settings other than community pharmacy.

► Articles not written in the English language.

► Studies involving patients with infections other than RTIs.

Extraction of data

A data extraction template will be created and piloted by data extractors (SKS, SP and CLB). This process will confirm that the extraction form has captured all the relevant information required for analysis and reporting. The extractors' feedback will be used to refine the form and finalise its usability and completeness. Duplicate data extraction will be performed independently and any disagreement that remains will be addressed through a discussion. A third reviewer will be approached if a consensus is not made. Two authors will extract and interpret the data. We will use the Template for Intervention Description and Replication checklist[36] to record details of the POCT intervention. Extracted data will include study demographics and general information (including study title, author, year and publication details), objectives, study design, period of study, participants of the study, study setting, POCT services and the characteristics (type, delivery strategy, timing, provider and recipient characteristics, effect, feasibility, acceptability, sustainability), POCT intervention outcomes (effect, effect size, CI, risk ratio), recommendations and conclusions. The results of the POCT intervention will be meticulously and comprehensively extracted to make them statistically analysable. In case of unclear or missing data or data presented in an unextractable form, we will contact the respective authors by email for clarification, with a 2-week response time limit. If the author does not respond, the case will be described as uncontactable. We will group POCT programmes based on infectious diseases for which they are being used for, the type of POCT programme, the bacteria that the POCT programme is targeting for diagnosis and the country.

Assessment of the quality of studies

SKS and CLB will assess and grade the quality of study as high, medium or low quality using evidence-based risk assessment tool. We will use the Cochrane risk of bias tools involving six criteria[37] to assess the quality of RCTs and determine the internal validity of RCTs. The Risk Of Bias In Non-Randomized Studies - of Interventions (ROBINS-I) risk assessment tools[38] will be used for non-randomised trials. This quality assessment will only be done if sufficient studies for meta-analysis are identified.

Data collation and analysis of the outcome of interest

We will use an evidence synthesis method[39] to map out existing evidence related to POCT use in community pharmacy for antimicrobial stewardship. The results of the included articles will be tabulated and summarised in table format with the above-defined outcome measures of effectiveness, feasibility, cost-effectiveness and implementation challenges. Descriptive summary of the results will be generated for each outcome measure and research question. For effect measures, all categorical variables (eg, antimicrobial use) of the trials will be reported in the same unit with 95% CI. Continuous variables will be recorded with mean difference and 95% CI. Median and IQR would be better descriptors if the primary sources of data did not check for or report normality. If studies have adequate data for calculation, summary statistics will be

recorded and analysed. Meta-analysis may be performed to determine the effect of the POCT programme if enough quality studies are found. Relative risk will be the measure of combined intervention effects. We will summarise and report each outcome of interest in this review.

Analysis of outcomes of interest

We will summarise and analyse the results reported in the selected studies using summary statistics, including descriptive statistics.

► Breadth and scope of evidence: number of selected studies based on outcome measures, study design, country and, if appropriate, quality of study; this will determine the breadth of evidence assessing the implementation of POCT programmes in community pharmacy for optimal antimicrobial use in RTIs.

► Effect of POCT programme: reduction in unnecessary or inappropriate antibiotic use governed by test results will be the measure of effectiveness of POCT programmes. Other effect measures will be (1) the total number of POCT tests received by patients, (2) the proportion of positive POCT results that led to initiation of antibiotics and (3) the proportion of negative results that led to avoidance of antibiotic treatment. In addition, the frequency of false-positives or false-negatives and their effects on patients will be sought if reported. Complications from antibiotic prescriptions for false-positive POCT test results and complications for not prescribing antibiotics for false-negative results will also be descriptively measured if data suggest. The level of patient satisfaction with the POCT services provided by the pharmacist will also be measured from quantitative and qualitative data if available. The hypotheses based on those secondary variables will be considered exploratory hypotheses. Meta-analysis may be performed if there is an adequate number of high-quality and medium-quality studies. Given adequate RCTs and meta-analysable data are available, a random effects model will be used to measure the pooled estimates of POCT intervention effects using OR and 95% CI. Forest plots and I^2 statistics will measure across-study heterogeneity. Subgroup analyses will determine the sources of heterogeneity (eg, POCT strategies, implementation approaches, sample size, design, study quality).

► Feasibility of POCT programme: feasibility measures will be descriptively presented from the findings and conclusions of the selected studies. Clinical, operational and economic feasibility will be explored from the selected studies. Feasibility data include simplicity, reliability and accuracy of the test, whether the test helps pharmacists' clinical decision-making, and the barriers to and facilitators of use of POCT programmes in community pharmacy. Clinical outcomes that may be assessed if reported include (1) pharmacists' advice and rates of patient referral to GPs as a direct result of POCT; (2) patient outcomes (eg, satisfaction, rate of infection recovery without antimicrobials); and (3) associations between POCT results and RTI outcomes. Operational outcomes include the rate of POCT service provision and the uptake by patients, acceptability by consumers and the potential of the POCT service to undertake AMS. Descriptive statistics will be used to measure the feasibility of the POCT programme.

► Cost-effectiveness of POCT programme: the incremental cost-effectiveness ratios of the POCT per quality-adjusted life year gained and per antimicrobial prescription avoided will be the measure of cost-effectiveness. Cost-effectiveness measures will be calculated for a subgroup of studies based on type of POCT programmes (eg, CRP or RAT) as well. The Consolidated Health Economic Evaluation Reporting Standards guideline will be used when reviewing the reporting of the economic outcomes of the studies.[40]

► Implementation challenges, facilitators and opportunities of the POCT programme: data will be analysed using an implementation science framework, Consolidated Framework for Implementation Research, to present reported implementation challenges and opportunities to inform the design of future implementation studies.[41] Factors influencing implementation of POCT programmes in community pharmacies by inner and outer contexts[41] will be extracted. The implications of the false-negative and false-positive cases and the safety factors considered to address these cases in community pharmacy will be extracted and analysed if reported by the eligible studies.

Subgroup analysis

We will undertake a subgroup analysis of the outcomes of interest in this review if adequate data are available. An exploratory subgroup analysis could be performed by (1) POCT type such as CRP or RAT, (2) type of RTIs, (3) country, (4) study design, (5) type and brand of test and (6) sample employed if available (nasopharyngeal or oropharyngeal).

Patient and public involvement

Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Patients were not directly involved in our research, but the studies included in this review may include patient populations.

DISCUSSION

To the best of our knowledge, this is the first scoping review to explore evidence on POCT programmes in community pharmacy for antimicrobial stewardship in RTIs. This study explores the effectiveness, feasibility and implementation challenges of POCT use by community pharmacists for optimal antimicrobial use in patients with RTIs in primary care. We anticipate that the findings will produce multiple benefits

to antimicrobial stewardship researchers, stakeholders and policymakers in order to make informed decisions about the provision of POCT programmes in community pharmacy as part of primary care antimicrobial stewardship programmes.

First, this review will provide a global overview of community pharmacy-based POCT programmes to avoid unnecessary antimicrobial use in RTIs, as well as potential evidence gaps on the topic to inform practice and policy around the provision of routine POCT services in community pharmacy.

Second, evidence supports that there are several factors[42 43] influencing the implementation and provision of POCT programmes to foster antimicrobial stewardship programmes in primary care. However, the factors remain unknown in the context of community pharmacy, and research in the area remains scant. Physician–pharmacist interprofessional issues, intercountry and intracountry variations in pharmacy practices, and policies and regulations for diagnostic use may affect the feasibility of use of POCT programmes among community pharmacists. This review will present global and country-specific evidence regarding the effectiveness, feasibility and implementation challenges of POCT programmes for optimal antimicrobial use in RTIs.

Third, diagnostic stewardship has the potential to improve doctor–pharmacist collaboration for antimicrobial stewardship in primary care. A GP–pharmacist antimicrobial stewardship model has highlighted the implementation of POCT programmes using collaboration between GPs and community pharmacists to improve antimicrobial stewardship in Australian primary care.[44] Our review may provide evidence and progress in the field of GP–community pharmacist collaborative implementation of POCT programmes.

Fourth, our review could provide valuable insights for the future design of implementation trials on POCT programmes in community pharmacy. This review may be useful for antimicrobial stewardship funders to understand the importance of research funding for innovations in POCT programmes in community pharmacy. Findings from a global lens will inform future needs of research, strategies, community pharmacy practice and policy changes in the provision of POCT programmes in community pharmacies for antimicrobial stewardship in RTIs in primary care.

Our study uses the PRISMA-ScR checklist[33] and the Arksey and O'Malley's framework[34] for methodological rigour. We will use six databases for a comprehensive search to get relevant articles around the world. Subject experts on antimicrobial stewardship and health economics, microbiologists, infectious disease physicians, and pharmacists have been part of this multidisciplinary review team and will guide analysis of data and interpretation of results.

There is a limitation to this review. We will only include English-language articles as no team members have been able to read in any other language. This may lead to missing few relevant articles. An insufficient number of studies may restrain the measurement and reporting of a few outcomes of interest in the review.

In summary, the progress in the field of diagnostic stewardship is central to address the growing burden of antimicrobial resistance caused by overuse of antimicrobials in RTIs in primary care. This review could have implications by informing primary care clinicians including pharmacists, researchers and health policymakers about strategic directions for future implementation of POCT programmes in community pharmacies at a local or national scale to avoid unnecessary antimicrobial use in RTIs.

ETHICS AND DISSEMINATION

This scoping review does not need any formal ethical approval as no personal or primary data are being collected during the study. The findings will be presented at national and international conferences, scientific meetings, and seminars, and will be published in a peer-reviewed journal.

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