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Implementation factor mapping of a pilot study of point-of-care C-reactive protein testing for respiratory tract infections in community pharmacy

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ABSTRACT

Background: Explicit consideration of implementation factors in community pharmacy service development may facilitate widespread implementation and sustainability.
Objectives: This study involved mapping the methodology for the pilot study of point-of-care C-reactive protein (CRP) testing to support pharmacists' management of respiratory tract infections in Western Australian pharmacies against an implementation factor framework, focussing on the resources and training program provided to participating pharmacy staff.
Methods: Phase 1 involved *post hoc* mapping of the pilot study methodology against the framework previously described by Garcia-Cardenas et al.; phase 2 was an *a priori* evaluation of the resources and training program, involving pre-training, post-training, and post-pilot questionnaires administered to pharmacists and pharmacy assistants/interns. A mixed model analysis compared pharmacists' responses at the three time points.
Results: Employment of comprehensive strategies to optimise service feasibility and sustainability was demonstrated across the five domains of 'professional service', 'pharmacy staff', 'pharmacy', 'local environment' and 'system'; further consideration of 'consumer' or 'patient' factors is needed to address issues such as patient refusal. Study pharmacists ($n = 10$) and pharmacy assistants/interns ($n = 5$) reported high levels of satisfaction with the training (100% 'good'/'excellent'). Pharmacists reported significantly improved attitudes towards, confidence in, and knowledge about CRP testing and service provision from pre- to post-training ($p < 0.05$). Positive perceptions were maintained at the post-pilot time point.
Conclusions: Post hoc mapping of implementation factors highlighted potential strengths and deficiencies of the current service model. Systematic, prospective mapping, coupled with strategies to explicitly emphasise the patient perspective, may have value in optimising service implementation or modifying future service delivery models.

1. Introduction

In recent decades, community pharmacy practice has moved beyond its traditional role in the provision of medicines. In many developed countries, community pharmacies staffed by highly skilled pharmacists represent a valuable resource to deliver additional primary care services to health consumers.[1–4] However, to cement an integral place for Australian community pharmacies as 'health hub destinations of the future',[5] an expansion of the pharmacists' role is required, to enable them to practise to their full scope.[1] This expanded role has been realised in some countries but some Australian pharmacists have found progress frustrating to date.[1]

Management of upper respiratory tract infections (RTIs) using over-the-counter (OTC) medicines and patient education has long been within the scope of practice of community pharmacists, given their training and ready accessibility to the public. Community pharmacy management of RTIs in Australia is based on signs and symptoms and clinical assessment through patient interviews. There is currently no objective diagnostic testing available to pharmacists to differentiate typically self-limiting viral RTIs from bacterial RTIs requiring timely referral to a general practitioner (GP, or 'primary care physician') for further assessment and prescription of antibiotics. Point-of-care (POC) C-reactive protein (CRP) testing has been utilised in European primary care settings to differentiate bacterial

Abbreviations: AUD, Australian dollar; CRP, C-reactive protein; GP, general practitioner; NAD, neither agree nor disagree; OTC, over-the-counter; POC, point-of-care; RTI, respiratory tract infection; UK, United Kingdom; WA, Western Australia.

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and viral RTIs[6–9] and has been shown to be robust, reliable and cost-effective for this purpose.[7,10–14] Informed by the findings of a study in the United Kingdom (UK) that demonstrated that POC CRP testing in community pharmacies has the potential to reduce unnecessary RTI-related GP visits,[15] a pilot study of POC CRP testing to support the management of RTIs was undertaken in 2019, prior to the emergence of the SARS-CoV-2 (COVID-19) global pandemic, in community pharmacies in Western Australia (WA).[16] This study demonstrated that POC CRP testing was a feasible and well-accepted tool to enhance clinical decision-making and triage in patients presenting with signs and symptoms of RTIs in the Australian community pharmacy setting. POC CRP testing influenced participants' beliefs about their need for antibiotics for a RTI, suggesting a potentially important role for this service in supporting antimicrobial stewardship in Australian primary care. POC CRP testing may therefore serve to expand the scope of pharmacist practice in the OTC management of RTIs.[16]

Several recent reviews have highlighted a growing awareness of the factors that either facilitate or impede the implementation, delivery and sustainability of community pharmacy services, including those related to pharmacist remuneration.[17–21] Before actively adopting new programs such as POC CRP testing, community pharmacists need to know that the service will be a viable and sustainable investment for the pharmacy.[22] They also need the requisite knowledge and skills to provide the service and the assurance that it will integrate seamlessly into their existing service model[17]; be sought and valued by, and meet the expectations of health care consumers[17,18,20]; and be remunerated appropriately.[17,18] Community pharmacies do not exist in isolation, and there is a wide range of micro, *meso* and macro factors influencing community pharmacy practice. These factors are related to individual practitioners, the community pharmacy as an institution and community pharmacy as part of a health care system, respectively.[23] These factors must be considered in the implementation of any new or expanded service because a lack of analysis and understanding of barriers at any of these levels may ultimately result in suboptimal uptake and poor long-term sustainability of even promising service delivery models, as was perhaps the case for the "*Health Destination Pharmacy*" model implemented in Australian community pharmacy in the 2010s.[24]

Garcia-Cardenas et al. expanded on this concept to describe a model of five 'domains' encompassing the layered and interrelated factors that may serve either as facilitators or barriers to the implementation process and outcomes of a professional service, namely the 1) professional service itself, 2) pharmacy staff, 3) pharmacy, 4) local environment, and 5) system (see Fig. 1).[25] A recently published systematic review on factors influencing national implementation of innovative practices in community pharmacy highlighted the need for more robust piloting of innovations to overcome operational issues.[26] Consideration of the implementation factors described by Garcia-Cardenas et al.[25] in the development of professional community pharmacy services may assist in improving their robustness and better facilitate successful future widespread implementation and sustainability.

Using the model described by Garcia-Cardenas et al.[25] as a theoretical framework, this study describes the *post hoc* mapping of the methodology for the pilot study of POC CRP testing to support pharmacists' management of RTIs in community pharmacies in WA. Given that the pilot study methodology was developed using a pragmatic approach, the current study was part of the *post hoc* critical evaluation of the strengths and deficits of the service model in an attempt to optimise feasibility and sustainability in anticipation of future wide-scale studies and potential implementation at jurisdictional or national levels. In view of the highly context-specific nature of the implementation factors in Domain 1 (professional service) and Domain 2 (pharmacy staff), this paper specifically focuses on the development and evaluation of the resources related to the service and training program for the pharmacy staff involved in the study.

2. Methods

This paper describes a sub-analysis of the larger prospective interventional pilot study, the full methodology of which has been reported elsewhere.[16] In summary, a service incorporating POC CRP testing was trialled in 131 patients aged 18–64 years, with either an RTI-related product request or RTI signs and symptoms, presenting to five community pharmacies in metropolitan Perth, WA, between June and August 2019. These patients were also considering seeing a GP for a prescription for antibiotics.

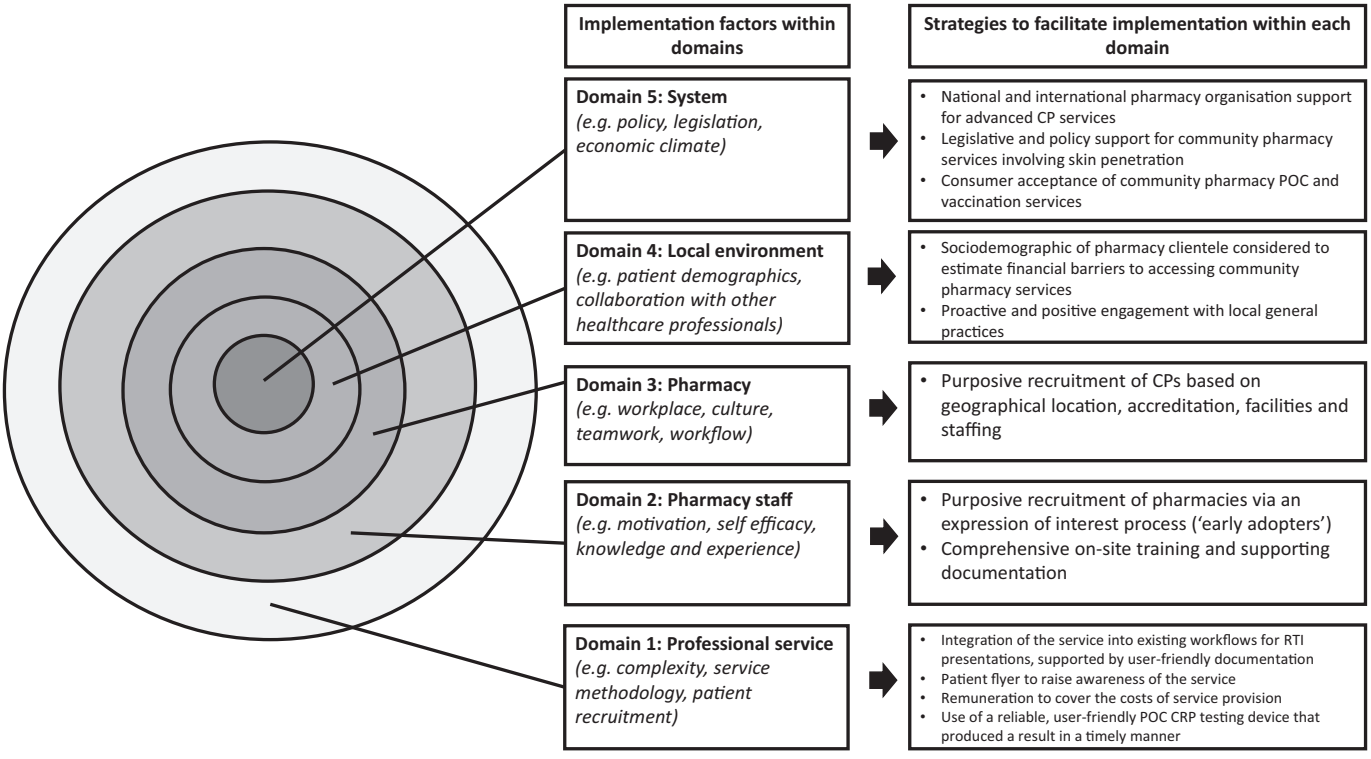


Fig. 1. Strategies to facilitate implementation of a POC CRP testing service based on mapping of the study methodology against the five domains of implementation factors as described by Garcia-Cardenas et al.[25]

Exclusion criteria were a history of rheumatoid arthritis or other autoimmune conditions associated with increased baseline CRP levels, an immunocompromised state, or use of a medication affecting immune response. Presenting signs and symptoms included cough, blocked/stuffed or runny nose, headache, aches and pains, sneezing and fever. The five pharmacies met defined criteria (discussed in more depth under the relevant domains in the *post hoc* mapping results below) and were purposively selected from 126 respondents to an expression of interest.[16] Trained pharmacists utilised POC CRP levels, combined with routine clinical assessment, to make recommendations on RTI management, including the provision of OTC medicines for symptomatic relief, non-pharmacological self-care advice (*e.g.* rest and hydration) and, when appropriate, GP referral. Participating patients completed a questionnaire on their perspectives immediately following receipt of the service, and were followed up with telephone calls from the pharmacists (on day 3) and researchers (on day 5) to investigate their clinical outcomes and longer-term perceptions of the service. Weekly tally sheets were used to evaluate service provision and uptake.

The current study involved two phases: (1) *Post hoc* mapping of the pilot study methodology (an investigation that was formulated after the completion of the original pilot study), and (2) An *a priori* evaluation of the resources and training program (planned before the beginning of data collection in the pilot study).[27]

2.1. Post hoc mapping of the pilot study methodology

The pilot study methodology was developed *via* an iterative, inductive approach, which involved the research team addressing each of the factors with potential to impact the success of service implementation and sustainability. While the domains of the Garcia-Cardenas et al.[25] model were not addressed explicitly during the development of the project methodology, nor in chronological order, a systematic process was undertaken whereby the potential barriers to service implementation were considered and, where necessary, strategies implemented to address them. In a *post hoc* analysis at the completion of the study, the implementation factors were retrospectively mapped to the domains of the Garcia-Cardenas et al.[25] model, and presented from the broadest domain (Domain 5: system) to the narrowest (Domain 1: professional service). This model was selected for its relative simplicity and relevance; it was developed by authors with strong insights into the Australian community pharmacy context, and the research team had previous experience applying this model in the Australian setting.[28] The mapping exercise was conducted as a qualitative analysis, utilising a thematic, deductive approach.[29] The contents of the research proposal, project team meeting minutes and documentation developed as part of the project were thematically analysed, with the identified implementation factors and strategies implemented to address those factors categorised using the five domains of Garcia-Cardenas et al.[25] model as 'themes' and the implementation factors within each domain as 'subthemes'. Advantage was taken of the flexibility of the published model in the use of the terms '*e.g.*' and '*etc.*' (for example, '*The pharmacy domain covers a range of implementation factors related to the setting in which the service is implemented (e.g. workplace, culture, teamwork, workflow, etc)*' (p499),[25] with the researchers including setting-specific implementation factors not explicitly listed in the original paper.[25] Mapping was undertaken independently by two researchers (LC, TFS) and visualised using an adaptation of the figure from the original paper[25] (see Fig. 1); findings were corroborated by the remainder of the research team. Any differences were discussed until consensus was reached.

2.2. Evaluation of resources and training program

The evaluation of the resources and training program was conducted as an *a priori* analysis and involved administration of pre-training, post-training, and post-pilot questionnaires to the pharmacy staff involved in the study. The 10 study pharmacists and five pharmacy assistants/interns completed a paper-based questionnaire immediately prior to the training. As a POC CRP testing service in pharmacy was novel at the time of the pilot study, the questionnaires were purposively designed. The questionnaires were developed following a review of the literature about CRP and the implementation of a POC CRP testing service internationally.[6,10,11,15,30] The draft questionnaires were reviewed by three pharmacy academics and four independent external pharmacists for face and content validity.

The questionnaire consisted of five basic demographic questions (age, gender, pharmacy experience) and 12 statements to explore their knowledge, confidence and attitudes regarding POC CRP testing in the community pharmacy. For the purposes of analysis, the 12 statements were grouped into three categories addressing: a) attitudes towards CRP testing service provision, b) confidence in operational and service provision-related matters, and c) knowledge about CRP and CRP testing. The same questionnaire was administered immediately after the approximately 2-h training session to evaluate its short-term impact and effectiveness, and again at the completion of the pilot study (eight weeks later) to explore the adequacy of the training in preparing pharmacy staff for delivery of the service. The post-training questionnaire included four additional statements regarding the participants' perceptions of the quality of the training, and the post-pilot questionnaire also included five questions relating to translation of the training into service provision. Participants indicated their agreement with all statements on five-point Likert scales ('Strongly agree' to 'Strongly disagree').

Descriptive statistics (frequency and percentage) were reported, and a mixed model analysis was undertaken using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA) to compare the pharmacists' pre-training, post-training and post-pilot results. A p-value of <0.05 was considered statistically significant.

This study was approved by the Curtin University Human Research Ethics Committee (HRE2019–0139; 21 March 2019) and registered on the Australian New Zealand Clinical Trials Registry (ACTRN 12619000965101). All pharmacy managers, pharmacists and pharmacy assistants and interns provided written informed consent for their involvement in all aspects of the study.

3. Results

3.1. Post hoc mapping of the pilot study methodology

The implementation factors that were considered within each domain, and the strategies to facilitate implementation and address potential barriers are summarised below and in Fig. 1.

3.1.1. Domain 5: system

Mapping of the study methodology revealed reference to three implementation factors under the 'system' domain – 'policy', 'legislative support' and 'consumer acceptance'. It was identified that the timing of the POC CRP testing trial allowed the research team to leverage existing facilitators for the development and implementation of the service and therefore, while these implementation factors were addressed within the study methodology, there was no need for novel strategies to address this domain.

Existing facilitators included promotion of the pharmacist's role by national and international pharmacy organisations; an absence of legal impediments and the presence of procedures and practice standards to support POC testing in community pharmacy; and public acceptance of new advanced roles for community pharmacists. National[31] and international[32] pharmacy bodies are actively promoting improved integration of community pharmacy into primary healthcare, with community pharmacists practising to their full professional scope for the benefit of the community. There were a number of precedents of successful trials of POC testing in community pharmacy,[33–35] and the expansion of the community pharmacist's role into POC blood testing and interpretation of the results was well-accepted by the public, with some pharmacies already offering cardiovascular risk assessment involving testing of blood glucose and lipid levels.[36] High levels of consumer acceptance of pharmacist-administered vaccination also provided support for a more 'tactile' role for community pharmacists in patient care.[37] There were no legal

impediments to development and delivery of these services under Australian legislation, with vaccination services legally supported by Structured Administration and Supply Arrangements in WA.[38] Professional pharmacy practice standards also existed to support services involving skin penetration, addressing issues such as needle stick injury, infection control and hand hygiene.[39] These standards could be directly translated to POC CRP testing, complementing the POC training and resources available to health professionals more broadly.[40]

The impact of these service implementation facilitators were evidenced by the enthusiasm demonstrated by local community pharmacists regarding the potential of the service and their self-efficacy to successfully offer it. One hundred and twenty-six expressions of interest were received from pharmacies in metropolitan, regional and rural WA for five pilot sites, despite the fact that only metropolitan pharmacies were eligible for inclusion. This further suggests the future potential for service implementation outside the confines of the pilot study.

3.1.2. Domain 4: local environment

The study methodology was identified as having addressed two of the implementation factors within the domain of 'local environment'. The first of these was 'patient demographics', with attempts made within the study methodology to explicitly explore the influence of this factor on service implementation. For example, it was believed that different sociodemographic profiles among the clienteles of each pharmacy may impact the acceptance and uptake of the service, in that lower household income may have posed a barrier to consumers accessing RTI management (and therefore POC CRP testing) *via* community pharmacy if it involved out-of-pocket expenses, rather than *via* GP or emergency department services (where care could be accessed at little or no cost). Of 126 pharmacies that expressed an interest in participating, the final five pilot pharmacies were purposively selected from a shortlist based on a number of characteristics, including variations in size, geographical location and banner group. The manager of each shortlisted pharmacy was questioned about their perceptions of the sociodemographic status of their pharmacy clientele prior to their selection. Examination of census data indicated that this approach resulted in the selection of pharmacies in five suburbs with variable sociodemographic profiles.[41] While broadly similar to the Australian population overall, differences were noted between the suburbs in several key characteristics, including median age (which ranged from 34 to 45 years), median weekly household income (AUD 1328 to AUD 2290), highest education levels (12.4–18.6% high school completion only), family composition (34.2–56.4% couple families with children), employment status (50.5–63.0% full-time employed) and cultural diversity (37.9–72.6% Australian born; 0.2–1.6% indigenous Australians).[41] Importantly, the POC CRP testing service was successfully delivered by all five pharmacies, although there were significant differences in the rates of service uptake and provision across the sites, which may have been due to a number of factors.[16] The relationship between community sociodemographic profile and service implementation could be explored more fully in a larger study with more significant sociodemographic variations than those seen within the pilot study, which was limited to the metropolitan area of a single city.

'Collaboration with other healthcare professionals' was the other implementation factor addressed within this domain. From the beginning of the study, there was an awareness of the need to foster strong collaborative relationships with local GPs to whom patients with elevated CRP levels would be referred. While the intention of the service was to complement existing primary care services, the research team and the profession understood the potential for concern among GPs that pharmacists were attempting to encroach on their scope of practice.[19,20,26,43] To address this concern, and ensure proactive and consistent messaging about the role of the service in patient care, a letter enlisting support was delivered to all GP practices surrounding the participating pharmacies. In addition, the research team and participating pharmacists proactively offered to personally visit general practices to discuss the service with interested staff; such visits were undertaken on an 'as required' basis at the request of a general practice. A standard referral form was also developed to ensure consistent and complete transfer of relevant information to GPs (either the patient's regular GP, or a local GP of the patient's choice if the patient was without a regular GP but required timely referral) when referral was indicated based on the pharmacist's assessment and/or the patient's CRP result.

3.1.3. Domain 3: pharmacy

As with 'patient demographics' within Domain 4, the purposive selection of pilot pharmacies allowed for exploration of the 'workplace' implementation factor within the 'pharmacy' domain, including feasibility of the service. Conversely, variation in service delivery was closely controlled in relation to some of the other factors, including 'workplace', 'teamwork' and 'workflow', in that clear strategies were elucidated in the pilot study - namely, the inclusion criteria for pharmacy participation - in an attempt to optimise the delivery of the POC CRP testing service. Expressions of interest were limited to pharmacies in the Perth metropolitan area to permit in-pharmacy support and follow-up by the research team during the pilot phase if necessary. Pilot pharmacies had to be accredited under the Australian Quality Care Pharmacy Program (an Australian community pharmacy continuous quality improvement program) and meet all of the requirements to provide vaccination services, including sharps disposal facilities, a needle stick injury protocol and infection control protocol.[38] Adequate facilities, namely a private consultation area, and appropriate staffing levels were required. The pharmacies needed to be staffed by two pharmacists who were willing to participate in the study and who had valid first aid certification, and a pharmacy assistant or intern to assist with participant screening and recruitment. The availability of these key personnel during 'business hours' throughout the pilot study period and staffing arrangements to facilitate availability of these staff for POC CRP testing were ascertained *via* specific questioning.

3.1.4. Domain 2: pharmacy staff

Within the 'pharmacy staff' domain, strategies were identified within the study methodology that addressed two of the implementation factors – 'motivation' and 'self-efficacy, knowledge and experience'. Pharmacies were recruited *via* an expression of interest circulated *via* local community pharmacy professional organisations to attract 'early adopters' of new services, who were believed to be more likely to be invested in successful service provision (*i.e.* 'motivated' to successfully provide the service).

'Self-efficacy, knowledge and experience' was facilitated by the provision of training and resources to the pilot pharmacies. Key study personnel (pharmacists and pharmacy assistants/interns) completed an approximately 2-h on-site training session on the clinical and operational aspects of POC CRP testing and integration of the service into existing RTI management pathways prior to study commencement. Protocols, guidelines, referral templates and questionnaires were also developed by the research team to support personnel training and service integration. A total of 23 resources, which comprised the pharmacy training package, were developed – 11 directly related to the CRP testing service implementation and delivery (and therefore potentially translatable to wide-scale service implementation) and 12 related to the conduct of the study. These documents are summarised in Table 1. Of note, a resource entitled *Guidance for pharmacists on the routine assessment and treatment approach for the management of upper respiratory tract infection in the community pharmacy*, was designed as continuing professional development for the pharmacists to ensure a consistent, contemporary, evidence-based approach to RTI assessment and management even in patients not receiving POC CRP testing. This guidance document, together with a specific algorithm to support interpretation of CRP results and provision of subsequent clinical recommendations (*Interpretation of results and clinical recommendation to patients*), were content validated by an expert infectious diseases physician. To ensure that resources were unambiguous, logical and practical, they were validated by seven pharmacists with varying practice backgrounds and levels of experience. This training package was also available in the pharmacy and served as a reference tool for study pharmacists for the duration of the study.

Table 1
Resources in the pharmacy training package mapped to the implementation factor domains (where relevant).

Resource	Implementation factor domain
Resources related to the CRP testing service implementation and delivery (i.e. translatable to wide-scale service implementation)	
• GP letter	• Domain 4: Local environment
• GP referral form	• Domain 4: Local environment
• Standard operating procedure for the CRP testing service	• Domain 2: Pharmacy staff
• Guidance for pharmacists on the routine assessment and treatment approach for the management of upper respiratory tract infection in the community pharmacy	• Domain 2: Pharmacy staff
• Interpretation of results and clinical recommendation to patients	• Domain 2: Pharmacy staff
• Alere Afinion™ CRP Quick Guide	• Domain 2: Pharmacy staff
• Training presentation PowerPoint slides	• Domain 2: Pharmacy staff
• Pharmacy recruitment flyer	• Domain 1: Professional service
• Patient journey – CRP testing service	• Domain 1: Professional service
• Patient participant information and consent form*	• Domain 1: Professional service
• Patient data collection form (including Day 3 follow-up)*	• Domain 1: Professional service
Documents related solely to the conduct of the study (not required for wide-scale implementation)	
• Pharmacy manager participant information and consent form	
• Study pharmacist participant information and consent form	
• Pharmacy assistant/intern participant information and consent form	
• Study pharmacist pre-training questionnaire	
• Study pharmacist post-training questionnaire	
• Study pharmacist post-pilot questionnaire	
• Study pharmacist interview guide	
• Pharmacy assistant/intern pre-training questionnaire	
• Pharmacy assistant/intern post-training questionnaire	
• Patient questionnaire	
• Patient telephone follow-up (Day 5)	
• Tally sheet for respiratory tract infection presentations	

* The patient participant information and consent form and patient data collection form could be modified and combined for integration into the workflow for service implementation outside the study. Patient contact details, demographic information, details of the presentation, CRP test result, recommendations made and outcomes of follow-up would be collected as the pharmacy's record of the professional service delivery for patient care, quality assurance and remuneration purposes.

A representative from Abbott Australia, the manufacturer of the Alere Afinion™ AS100 (the device used for POC CRP testing), attended each training session to demonstrate the POC CRP testing process and appropriate use of the analyzer. This 'hands on' training was complemented by a step-by-step standard operating procedure for pharmacist users.

3.1.5. Domain 1: professional service

Finally, there was evidence of strategies within the study methodology to address a wide range of implementation factors with the 'professional service' domain – namely 'service methodology', 'patient recruitment', 'remuneration' and 'complexity' (especially in relation to use of the POC CRP testing device).

In terms of the 'service methodology', careful consideration was given to the development of the service to ensure its integration into existing care models was as seamless as possible. Existing workflow in relation to RTI presentations was modelled, and a flow diagram was developed to identify where the service could be offered by pharmacy personnel during interactions with relevant patients. This step-by-step *Patient journey* detailed what was required of pharmacy personnel from the time a patient presented to the pharmacy, through the informed consent process, CRP testing and interpretation of results, clinical recommendations, GP referral (when warranted), and patient follow-up, through to end-of-day procedures related to data collection. Additional strategies to facilitate 'patient recruitment' included development of a flyer for posting on the front counter or other prominent locations within the pharmacy to raise awareness among patients of the availability of the service, and the user-friendly design of documentation related to the pilot study (patient participant information sheets, consent forms and data collection forms). The patient questionnaires were face validated by seven consumers prior to the start of the study to ensure their accessibility. All resources were provided to the pharmacies in the training package to guarantee easy access at the time of patient presentation.

Pharmacies were remunerated for provision of the service to reflect this real-world requirement of service delivery, to cover the costs of the POC CRP testing device (purchase or lease), cartridges and the pharmacists' time. Remuneration was paid at milestones during the study - AUD 750 for the first 15 patients; AUD 750 for the next 10 and AUD 500 for the final five - up to a total of AUD 2000. Participants were not charged for receipt of the service, but were asked about their willingness to pay for the service in the future by the research assistant during their telephone follow-up.

The POC CRP testing device, the Alere Afinion™ AS100 Analyzer with Alere Afinion™ CRP Test Cartridges, was chosen due to its reliable analytical performance in validation studies, user-friendliness, portability, price and technical support.[44–46] It provides a CRP result from a 1.5 μl capillary blood sample within four minutes. It was considered that this timeframe was considered conducive to integration in community pharmacy workflows.

3.2. Evaluation of the resources and training program

All 10 study pharmacists and all five pharmacy assistants/interns completed the pre-training and post-training questionnaires; all pharmacists also completed the post-pilot questionnaire (100% response rates). The participants' characteristics are summarised in Table 2. The majority of participants were female (13/15, 86.7%). There was significant variation in pharmacy experience for both pharmacists and pharmacy assistants/interns; of note, seven of 10 pharmacist participants (70%) held management/leadership roles in the pharmacy.

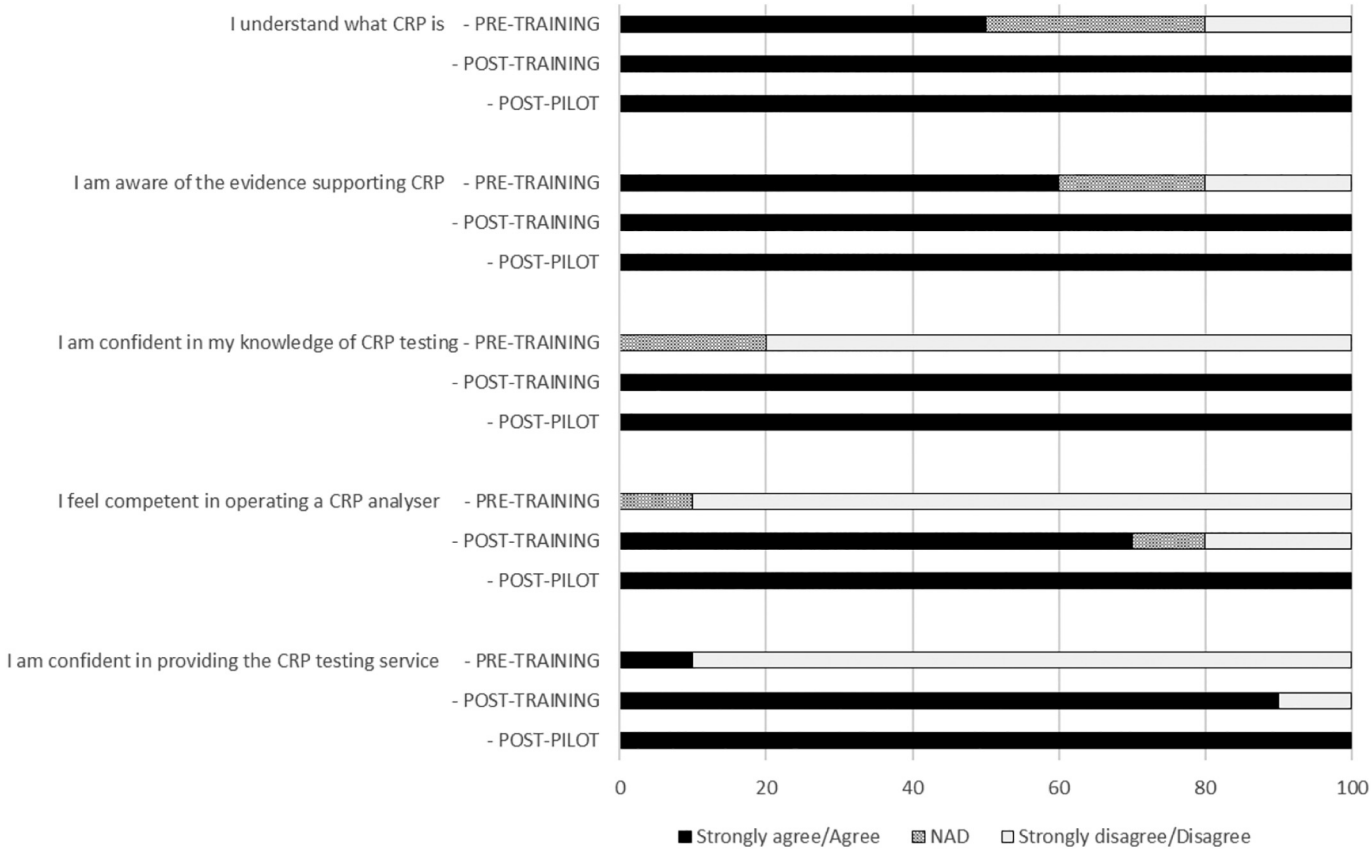
The study pharmacists' responses to the pre-training, post-training and post-pilot questionnaires regarding their attitudes towards, confidence in and knowledge about POC CRP testing and service provision are illustrated in Fig. 2 (a-c). Pre-training responses within the 'attitudes' and 'confidence' categories were variable, while there was a generally high level of agreement within the 'knowledge' category. A mixed model analysis demonstrated a statistically significant difference in the pre- and post-training responses against all statements ($p < 0.05$), with a higher level of agreement post-training.

Table 2
Characteristics of the study pharmacists ($n = 10$) and pharmacy assistants/interns ($n = 5$).

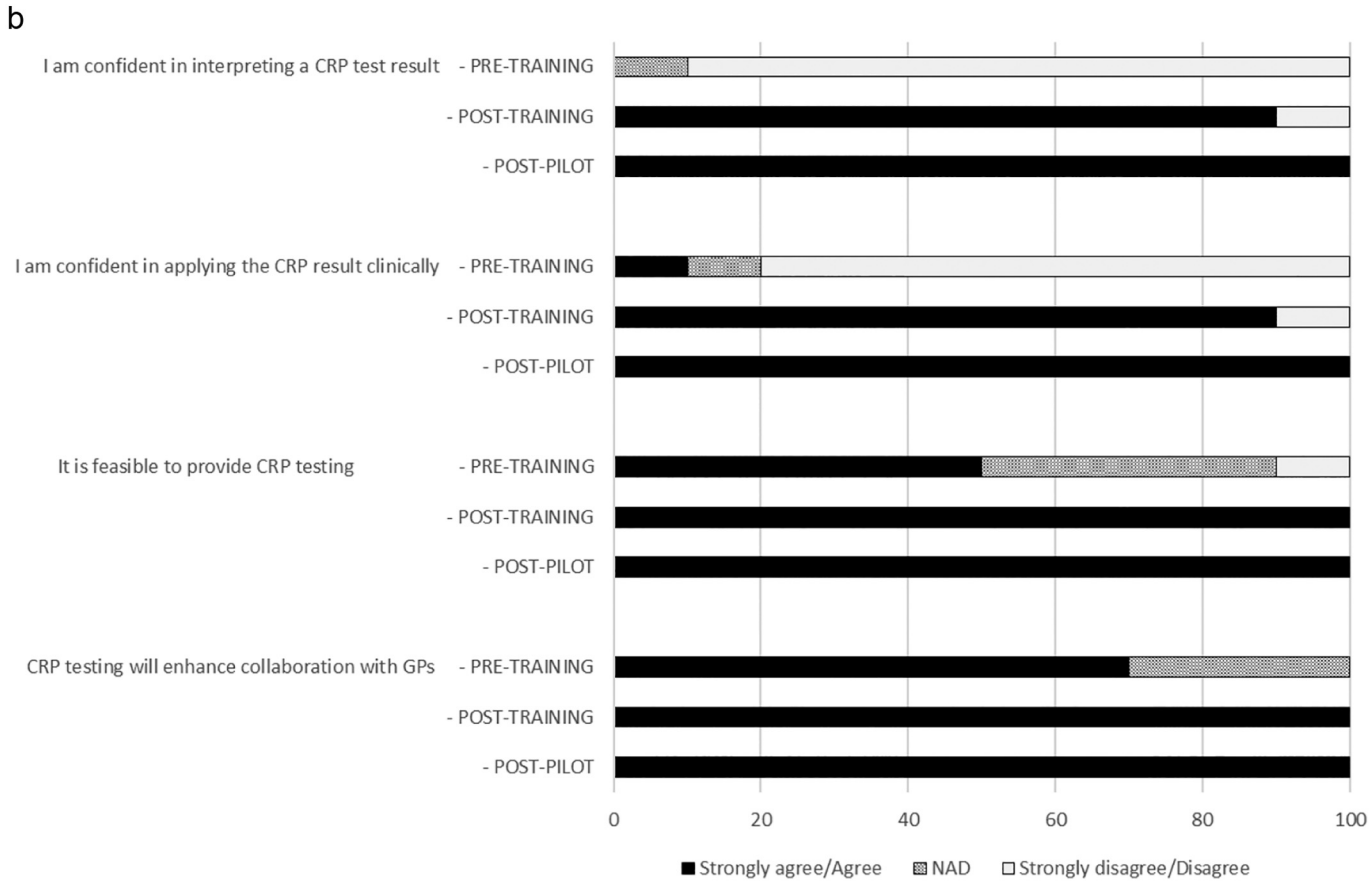
Characteristic	Frequency (%)*
Study pharmacists ($n = 10$)	
Age in years (median [range])	33.5 (22–53)
Female gender	8 (80%)
Years registered as a pharmacist (median [range])	9 (1 – 32)
Professional role	
Proprietor	3 (30%)
Manager	2 (20%)
Pharmacist-in-charge	2 (20%)
Employee pharmacist	2 (20%)
Professional services pharmacist	1 (10%)
Pharmacy assistants/interns ($n = 5$)	
Age in years (median [range])	24 (20–58)
Female gender	5 (100%)
Years working in community pharmacy (median [range])	4 (0.4–15)
Role	
Pharmacy assistant	3 (60%)
Pharmacy intern	2 (40%)

* Unless otherwise stated.

a


I understand what CRP is - PRE-TRAINING
- POST-TRAINING
- POST-PILOT
I am aware of the evidence supporting CRP - PRE-TRAINING
- POST-TRAINING
- POST-PILOT
I am confident in my knowledge of CRP testing - PRE-TRAINING
- POST-TRAINING
- POST-PILOT
I feel competent in operating a CRP analyser - PRE-TRAINING
- POST-TRAINING
- POST-PILOT
I am confident in providing the CRP testing service - PRE-TRAINING
- POST-TRAINING
- POST-PILOT
0 20 40 60 80 100
Strongly agree/Agree NAD Strongly disagree/Disagree

b


I am confident in interpreting a CRP test result - PRE-TRAINING
- POST-TRAINING
- POST-PILOT
I am confident in applying the CRP result clinically - PRE-TRAINING
- POST-TRAINING
- POST-PILOT
It is feasible to provide CRP testing - PRE-TRAINING
- POST-TRAINING
- POST-PILOT
CRP testing will enhance collaboration with GPs - PRE-TRAINING
- POST-TRAINING
- POST-PILOT
0 20 40 60 80 100
Strongly agree/Agree NAD Strongly disagree/Disagree

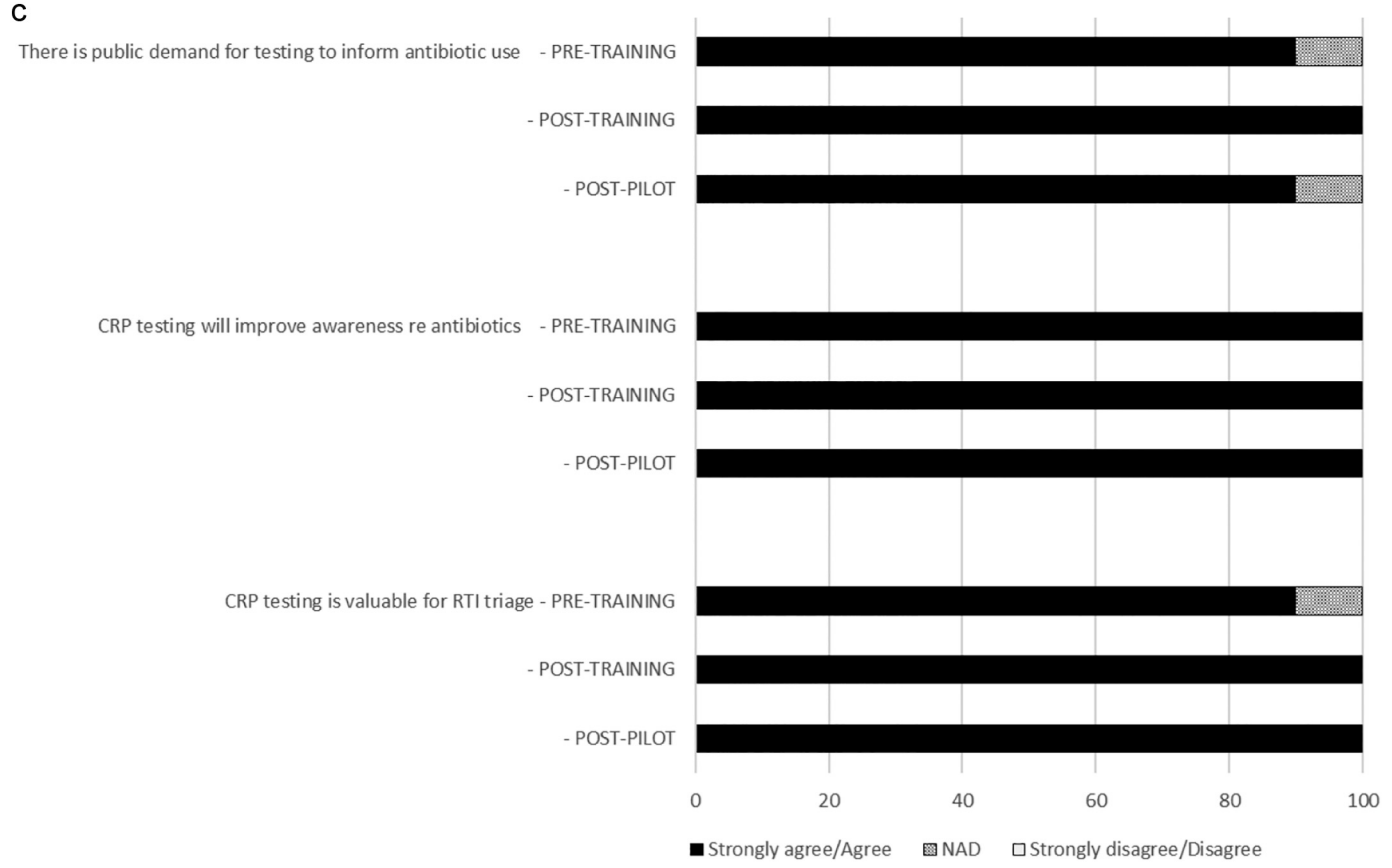


Fig. 2. Study pharmacists' (n = 10) responses to pre-training, post-training and post-pilot questionnaires in relation to a) attitudes towards CRP testing service provision, b) confidence in operational and service provision-related issues, and c) knowledge about CRP and CRP testing. Responses are in percent (%). CRP = C-reactive protein; GP = general practitioner; NAD = neither agree nor disagree; RTI = respiratory tract infection.

In the post-training questionnaire, there was 100% agreement (*i.e.* 'Strongly agree' or 'Agree') with the statements about the value of the training in increasing study pharmacists' knowledge about CRP and CRP testing, preparing them to deliver the service, and increasing their confidence and competence levels in providing the service. The training was rated 'good' by 3/10 (30%) and 'excellent' by 7/10 (70%) participants, with the only suggestion for improvement being to increase the time dedicated to training.

The high levels of agreement regarding attitudes towards, confidence in and knowledge about CRP testing and service provision were maintained from the post-training to post-pilot questionnaires. These results were supported by 100% agreement among participants with the statements regarding CRP testing: a) complementing routine assessment of a patient with a suspected RTI, b) assisting with clinical decision-making about the need for referral to a GP for antibiotics, c) integrating efficiently with work practices, and d) improving professional satisfaction as a pharmacist.

The questionnaire responses from the three pharmacy assistants and two pharmacy interns are summarised in Fig. 3 (Supplementary Material). The small number of participants precluded statistical analysis, however, there were good levels of agreement with all statements and a high level of satisfaction with the training, with 3/5 (60%) pharmacy assistant/interns rating it as 'good' and 2/5 (40%) as 'excellent'.

4. Discussion

This paper describes a novel approach to the consideration of implementation factors in the evaluation of a pilot study methodology for a POC CRP testing service to support RTI management in community pharmacy. *Post hoc* mapping of the methodology against the implementation framework of Garcia-Cardenas et al.[25] clearly demonstrated the comprehensive nature of the strategies employed to optimise the feasibility and sustainability of the service, as well as potential areas for future improvement. A particular focus on the factors within the 'professional service' and 'pharmacy staff' domains (Domains 1 and 2, respectively) resulted in the development and delivery of a training program and resources for service delivery that were well-received and satisfied the learning needs of pharmacy staff, and supported pharmacists in the successful delivery of the service in their pharmacies.

The authors have previously published data to support the feasibility of the POC CRP testing service in community pharmacy based on clinical and operational outcomes,[16] and high levels of satisfaction with the service among both patients[16] and pharmacist stakeholders.[42] It may be hypothesised that the careful consideration of the relevant implementation factors and the development of comprehensive strategies to address these factors may have contributed to these positive findings. The success of the pilot study may be at least partly attributed to the emphasis placed on Domains 1 and 2. Pharmacists' confidence,[18] self-efficacy[17] and belief in the value of the intervention[21] have been identified as important factors influencing the successful provision of services by community pharmacists. At the conclusion of the training session, pharmacy staff involved in this study expressed very positive attitudes towards the potential value of CRP testing, and high levels of confidence in their knowledge of CRP, ability to produce a CRP result and to use it in practice to support patient care. These positive responses were maintained throughout the pilot study, despite some acknowledged barriers and challenges to service delivery, including time and staffing constraints within the pharmacy.[16,42] This suggests that other facilitators, in addition to self-efficacy and knowledge, were in operation that promoted successful service provision by pharmacy staff in spite of these challenges. These may have included the convenience and usability of the resources provided to the pharmacies in the training package,

appropriate remuneration for service provision, and overall robustness of the service. Previous authors have identified lengthy documentation,[17] inadequate remuneration,[17,18] and general intervention complexity[21,26] as barriers to the provision of other community pharmacy services. It was also interesting to note that, while larger community pharmacies were selected for implementation of this service (based on having two pharmacists available at all times), it has been recently reported that smaller pharmacies (staffed by one pharmacist and pharmacy intern) were associated with higher intensity delivery of government-remunerated MedsCheck and Diabetes MedsCheck services.[47] This suggests the potential for successful provision of the service across a wider range of pharmacies into the future.

Conversely, areas where stakeholder feedback indicated a need for modification of the delivery model may represent domains where consideration of implementation factors was potentially deficient, or outside the scope of a pilot study. Patient refusal, due to either inadequate time on the patient's part or poor understanding of the service, was one of the main reasons previously identified for service non-provision.[16,42] While it was not within the scope of the present study to determine the associations between sociodemographic profiles and health-seeking behaviour, it was interesting to note that the rate of patient refusal was highest in the pharmacy with the highest proportion of full-time workers in their local community.[16] Because of their work commitments, these consumers may have been unable to commit the time required to receive the service having been unaware of the availability of POC CRP testing prior to entering the pharmacy, as reported by some of the participating pharmacists.[42] While a pragmatic approach was adopted in relation to patient-related implementation factors within Domains 1 (a flyer to promote patient recruitment) and 4 (questioning pharmacists regarding their patients' sociodemographic status), more comprehensive strategies could have been implemented to address both of these domains. Other authors have highlighted the potential of media campaigns, especially focussed on the intended benefits of community pharmacy services, to raise awareness about such services.[17,20,26] The study pharmacists also recognised that this would be an important strategy for future implementation.[42] In the pilot study, however, broad promotion of the service to raise public awareness of its availability (to aid patient recruitment [Domain 1]) and to justify the required time allocation on the patient's part was not considered appropriate within the confines of a feasibility study.[16] It could have created demand for the service that could not be met within a pilot study in five pharmacies.

While previous models have identified that facilitators and barriers to successful provision of community pharmacy services exist at the individual patient level (such as their knowledge, beliefs and skills),[48] and these factors have been comprehensively described by other authors,[20] strict application of the published Garcia-Cardenas et al.[25] framework by pragmatic researchers may not have fully identified this as a deficit in the study methodology. This is perhaps due to the absence of an explicit 'consumer' or 'patient' domain at the model's core, a feature common to other frameworks for implementation of pharmacy services.[49] Based on the findings of the POC CRP pilot study,[16] such a domain would emphasise the patient perspective more explicitly than simply recruitment and demographic considerations, and ensure that patient (or 'consumer') factors at an individual, rather than at sociodemographic level, are not overlooked among broader consideration of local environmental factors. This domain may encompass factors such as patient expectations of community pharmacy services,[17,18] ease of access to other health care services, confidence and/or trust in the pharmacist's ability,[18] fear of harm (*e.g.* invasiveness of POC testing, privacy concerns) and willingness to pay.[20] The authors therefore advise caution in the application of the Garcia-Cardenas et al.[25] framework in isolation in prospective development of study methodologies. While our *post hoc* mapping identified some areas of relative deficiency of the POC CRP testing service, other concurrent strategies (for example, consumer engagement during service development using a co-design methodology[50]) may better inform the demand for its widespread implementation and therefore optimise future service feasibility and sustainability.

Limitations of this sub-study included the retrospective mapping against a single, purposively selected implementation factor framework; future studies should consider prospective mapping to confirm the validity of this approach, and potentially consider other implementation frameworks.[51] While there was a 100% response rate to the pharmacy staff questionnaires and the results of these questionnaires were very positive, these must be interpreted with caution due to the low numbers of participants and the purposive recruitment of interested pharmacies as 'early adopters'. These participants may have been especially invested in successful service implementation, potentially biasing their opinions and introducing threats to the questionnaire validity in relation to statistical regression and self-selection bias. In addition, factors external to the study that occurred during the eight-week pilot period (for example, external continuing professional development opportunities) may have introduced history and maturation effects and influenced the findings between the post-training and post-pilot questionnaires. Whilst an in-depth exploration of the pharmacists' perspectives has been reported elsewhere,[42] a full exploration of the roles and perspectives of the small number of pharmacy assistants and interns involved in assisting with patient engagement with the CRP testing service was beyond the scope of the pilot study, as they were not directly responsible for service implementation and delivery.

The feasibility study of the POC CRP testing service was conducted before the emergence of the COVID-19 global pandemic. Successful modification of the service model for application in a post-COVID world will involve consideration of factors across all five domains. These will include, for example, a shared understanding of the significance of COVID-19 infection in a vaccinated community, better data about the prognostic role of CRP testing at different time points in COVID-19 disease and reporting pathways for community pharmacy for COVID-19 as a notifiable disease in Australia (all Domain 5); the possible need for increased personal protective equipment during service delivery (Domain 3); and integration of POC COVID-19 testing into the service model (Domain 1).

Scale-up of the POC CRP testing service for widespread implementation may also require that factors be addressed at different levels - for example, potential concerns about encroachment on GPs' scope of practice that were addressed at a local level within the pilot study by communication with local GP practices (Domain 4) may need to be addressed at a system level *via* cooperation between relevant professional organisations to support systemic statewide or national implementation (Domain 5). This would ensure a clear and consistent high-level understanding regarding the intent of large scale implementation - not to duplicate the existing roles of GPs nor to direct all patient flow to pharmacies, but to provide a complementary and structured approach to the management of patients who choose to self-present to a community pharmacy and promote timely referral when appropriate. Nonetheless, application of a formal implementation factor framework would provide rigour to service revision and help ensure that crucial factors, which are potential barriers to implementation, are not overlooked in the process.

5. Conclusion

Post hoc mapping of the methodology for a pilot study of a POC CRP testing service to support RTI management in community pharmacy demonstrated consideration of, and employment of strategies to address implementation factors across all domains of an implementation factor framework, especially those relating to the professional service and pharmacy staff. The positive outcomes of the pilot study may be attributed in part to this comprehensive approach, although some aspects of service delivery were poorly interrogated through this lens alone. This study confirmed the potential value of a systematic, prospective mapping approach to service implementation in future studies, complemented by additional strategies to better elucidate the individual patient perspective.

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Declaration of Competing Interest

None.

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Appendix A. Supplementary data

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