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ORIGINAL ARTICLE

Use of clinical guidelines in remote Australia: A realist evaluation

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Abstract

Aim: The aim of this evaluation was to assess the acceptability, accessibility, and compliance with the 2014 editions of the Remote Primary Health Care Manuals (RPHCM) in health care centres across remote areas of Northern and Central Australia.

Method: To undertake a comprehensive evaluation that considered context, the evaluation used a realist evaluation framework. The evaluation used a variety of methods including interviews and survey to develop and test a programme theory.

Results: Many remote health practitioners have adopted standardized, evidence-based practice because of the use of the RPHCM. The mechanisms that led to the use of the manuals include acceptance of the worth of the protocols to their clinical practice, reliance on manual content to guide their practice, the perception of credibility, the applicability of RPHCM content to the context, and a fear of the consequences of not using the RPHCMs. Some remote health practitioners are less inclined to use the RPHCM regularly because of a perception that the content is less suited to their needs and daily practice or it is hard to navigate or understand.

Conclusion: The evaluation concluded that there is work to be done to widen the RPHCM user base, and organizations need to increase support for their staff to use the RPHCM protocols better. These measures are expected to enable standardized clinical practice in the remote context.

KEYWORDS

clinical guidelines, evidence-based medicine, realist evaluation, remote healthcare, theory-based evaluation

1 | INTRODUCTION

The Remote Primary Health Care Manuals (RPHCM) are a collection of 5 manuals covering clinical protocols and procedures targeted at primary health care practitioners in rural and remote Australia. The 5 manuals comprise the following:

1. Central Australian Rural Practitioners Association Standard Treatment Manual (CARPA STM);

2. *Minymaku Kutju Tjukurpa*—Women's Business Manual (WBM);

3. Clinical Procedures Manual for remote and rural practice;

4. Medicines Book for Aboriginal and Torres Strait Islander Health Practitioners and Health Workers (Medicines Book); and

5. Reference Book for the RPHCMs (reference book).

The manuals are developed following a vigorous and extensive process involving expert volunteers, editorial committees, and a project team. The protocols and procedures in the manuals are adapted from current national guidelines to a remote context. The development of the RPHCM is governed by the principle of "by the user; for the user," which in practical terms means active involvement of users in content development. Between them, the manuals cover a comprehensive range of clinical issues relevant to rural and remote Australia. The manuals are available in hard copy and electronic versions.

To ensure on-going quality improvement and incorporate user feedback, regular evaluations of the use of the manuals have been undertaken. Three previous evaluations of the CARPA STM took place in 1992, 2001, and 2008. All identified high acceptance of the CARPA STM by remote primary health practitioners, across disciplines, with significant compliance with manual protocols demonstrated in remote clinics. However, the evaluations also identified that some remote

2 | WILEY— Journal of Evaluation in Clinical Practice
International Journal of Public Health Policy and Health Services Research

REDDY ET AL.

clinical practitioners lacked confidence in using the CARPA STM and found parts of the manual difficult to understand. It was recommended that organizations using the manual incorporate training in their use within their usual staff orientation process.

However, assessment of the entire RPHCM suite had not been undertaken. Evaluation of the entire suite was considered necessary to provide insight into whether or not remote primary healthcare staff considered the manuals accessible and acceptable and the level of compliance with the current manual protocols. It would also aim to determine reasons for the identified accessibility, acceptability, and compliance, or lack thereof. The evaluation results would inform the editorial review process and the publication processes. To this effect, an evaluation team was formed to assess impact of the 2014 editions (hard copies and electronic copies) of the RPHCM suite. Because of the comprehensive nature of this evaluation, a need to consider the context in the assessment and to test the theory of wide accessibility and acceptability of the manuals, a form of theory-based evaluation, realist evaluation, was used.

2 | METHODS

The main objective of the RPHCM evaluation was determined to be to "assess the acceptability, accessibility and compliance with the RPHCM 2014 suite in remote primary health care centres across the remote areas of Northern and Central Australia using a combination of methods." Specific aspects of the development of the RPHCM suite guided the evaluation process, including the intense user involvement in the review and updating processes.

The evaluation was undertaken at selected remote healthcare centres that represented the range of clinical, organizational, and geographical contexts in which the RPHCM suite is used. This included both Aboriginal community-controlled and government-controlled centres, across the northern and central areas of Australia.

To undertake a comprehensive evaluation that considered context and included complex data gathering and analysis, the evaluation used a theory-based evaluation framework. The specific theory based framework used in this evaluation was a realist evaluation framework. A realist evaluation framework places considerable importance on the context and enables complex data gathering and analysis. Also, a programme theory providing a tentative explanation, as to the sequence of events leading to the programme outcomes, is developed.[1] The evaluation framework allows for this theory to be tested and then confirmed or revised. Details of the realist evaluation protocol have been previously published in this journal.[2] The published article outlines the process involved in implementing this evaluation. However, in the interest of making this article stand-alone, some details of the protocol are reiterated here in addition to the findings.

Since the evaluation covered various organizations and regions, obtaining ethical and organizational approval was a complex process. The evaluation team approached the government and Aboriginal community-controlled organizations individually to advise them of the evaluation plan and seek their permission to conduct the evaluation. Appropriate organizational research approval forms were submitted and approved. The evaluation team then obtained ethics

approval from the Central Australian and Top-End Human Research Ethics Committees, and the South Australian and Western Australian Aboriginal Health Research and Ethics Committees. In total, permissions were obtained from 6 organizations and ethics approval from 4 ethics committees.

As per the realist evaluation process,[1] a preliminary programme theory was developed. The guidance for formulating preliminary realist programme theory is to review previous research findings, literature, and converse with stakeholders. The authors on the basis of this recommendation used previous evaluation findings and feedback from RPHCM users and other stakeholders to construct the preliminary programme theory.[2] This theory needed to operate in the context of the challenges of remote health services such as isolation and workforce turnover. The preliminary theory was as follows[2]:

> Remote health practitioners have adopted standardised, evidence-based practice because of the use of Remote Primary Health Care Manuals (RPHCM). The mechanisms that lead to the use of the manuals include fear of consequences of not using RPHCM, confidence in using and understanding RPHCM content, reliance on manual content to guide their practice, the perception of credibility, and applicability of RPHCM content to the context.

> Some remote health practitioners regularly use the RPHCM in their daily practice because there is a lack of alternative resources for RPHCM content.

> Some remote health practitioners are inclined to use the RPHCM less regularly because of a perception that the content is less suited to their needs and daily practice.

The programme theory, which had been outlined as a flow diagram in the publication about the protocol,[2] is reproduced here (see Figure 1).

The evaluators then proceeded to test the programme theory. As this is a theory-based evaluation assessing a complex scenario, a variety of methods were used to collect data: face-to-face interviews, telephone interviews, online survey, and clinical audits.[2] This approach aligns with realist evaluation,[3] which favours a combination of methods to test the programme theory. Also, using a mix of methods enabled triangulation of data. This paper outlines the interview and survey data collection and analysis process only. The audit process and findings will be presented in a separate paper.

The interviews and survey identified and probed mechanisms that enabled adoption of standardized practice (or not). For logistical reasons, the evaluation used convenience sampling to identify clinic staff across disciplines who were interested and available for interview during the study period. The interviews were used to gain a general understanding of the acceptability and accessibility of the manuals (see appendices for interview questionnaire). A semistructured interview format constituting a series of open-ended questions allowed for minimum control of the respondent's answers while permitting accurate comparison across respondents.

The interviews assessed all the manuals in the RPHCM suite, in both the hard copy and online versions. Access to staff and the period during which the interviews were organized was negotiated with
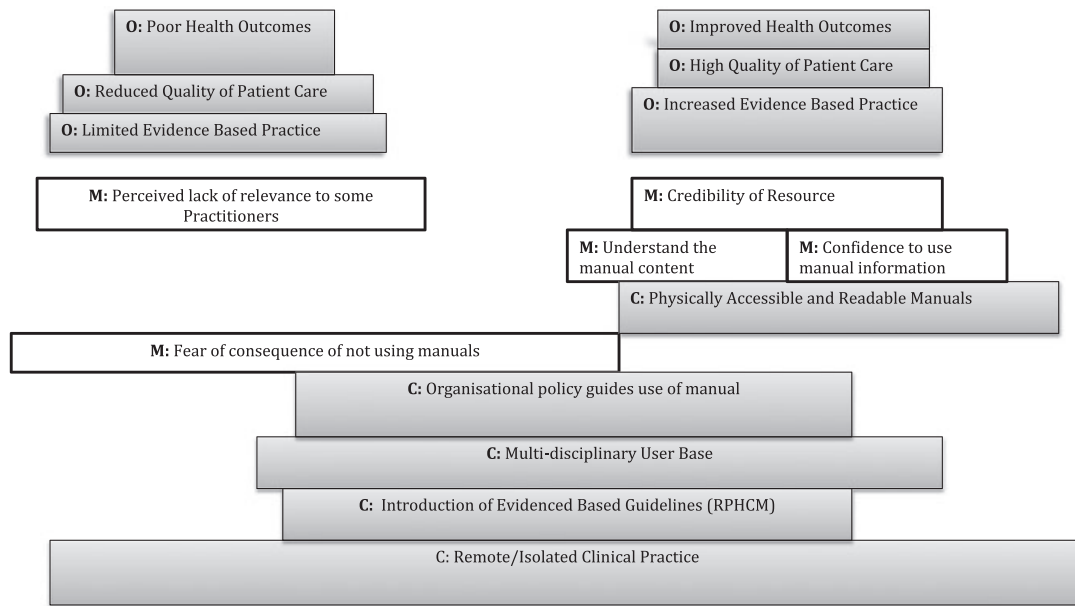
FIGURE 1 Remote Primary Health Care Manual (RPHCM) evaluation preliminary program theory

individual clinic managers or relevant staff within participating organizations. To enable timely and practical data collection, members of the evaluation team travelled to each region to conduct the interviews. The option of a telephone interview was offered to staff members who were unavailable during the team member's visit and to clinics that could not be travelled to easily by the evaluation team. An online survey replicating the interview questions was also made available to capture the views of people who were motivated to participate but were unable to do so through the interview options. However, there were only 2 survey responses. In addition to the interviews and survey, 2 focus group interviews were conducted in central locations to allow for maximum participation of geographically dispersed clinicians. Of the 128 participants, 117 participants were interviewed individually (102 face to face and 15 participants via phone or video interviews), 9 participants through focus group interviews, and 2 via online surveys.

Data analysis in realist evaluation involves arranging the data in context-mechanism-outcome (CMO) configuration patterns.[2] The patterns denote causal pathways leading to programme outcomes. The patterns are then used to test the preliminary programme theory and to confirm, revise, or refute the theory. For this evaluation, the

mechanisms that promoted acceptance of the RPHCM content were keenly explored. The evaluators used the NVivo 11 for Windows software package to organize coding of the single interview and focus group transcripts/survey results. To align with the realist evaluation methodology, coding of data was undertaken through the CMO framework. Two of the authors participated in the analysis, with one author involved in coding the transcripts and the other author verifying the coding. To frame the analysis, the preliminary programme theory was fragmented into CMO elements and interview and survey data were coded to these elements. Where new CMO elements or patterns were identified, new codes were created. Through an iterative process data were used to refine and revise the programme theory.[2]

In the initial phase of analysis, interview transcripts of 50 participants were chosen to identify relevant CMO configuration patterns that would, in turn, help in refining the preliminary programme theory. The 50 participants were chosen to represent different regions, professions, and experiences reflected in the larger participant sample (see Table 1 for attributes).

Following the analysis and findings from the initial 50 interviews, a second stage of analysis of the data from the remaining 78 participants (including transcripts from the remaining face-to-face interviews,

TABLE 1 Attributes of 50 participants providing data for initial phase of interview analysis

Remote Health Experience		Organization		Profession		Region	
Less than 6 months	4	Government controlled clinics	27	AHP	9	Alice Springs	7
6 to 12 months	3	Aboriginal controlled clinics	23	Medical practitioner	10	South Australia	3
1 to 2 years	2			Midwife	1	Barkly District	5
2 to 5 years	12			RAN	21	Central Australia east	4
5 to 10 years	16			RAN & midwife	4	Central Australia West	5
10 to 20 years	9			RAN clinic manager	5	Katherine region	13
Greater than 20 years	4					Western Australia	4
						Top end west	7
						West Arnhem	2

Abbreviations: AHP, allied health professional; RAN, Remote Area Nurse.

4 | WILEY— Journal of Evaluation in Clinical Practice
International Journal of Public Health Policy and Health Services Research

REDDY ET AL.

phone interviews, focus group interviews, and results from the online survey) was undertaken to check if the preliminary findings aligned with the second stage of analysis.

3 | RESULTS

Following coding of transcripts of the initial 50 interviews, the following CMO configuration patterns emerged (Table 2).

Based on the above results, the mechanisms that promoted acceptability can be categorized as follows:

1. Importance for individual clinical practice;
2. Reliance on RPHCM protocols (to provide effective patient care); and
3. Compulsion to use RPHCM protocols (because of organizational policy and medico-legal reasons).

Across professional categories and organisations, remote clinical practitioners confirmed the immediate relevance of most of the RPHCM content to daily and individual clinical practice. The manuals focus on conditions, treatment, and management pathways relevant to remote clinical practice, and feedback has demonstrated that they are of great value in ensuring safe and effective treatment in this context. Participant feedback also indicated that the manual content was not only of significance with complex and serious presentations but also with routine presentations. For example, many nurses stated that they would refer to the manuals for medication

administration and management even if they had experience with the medication.

While many interviewees were experienced professionals, some were new to the remote context. Regardless of duration of practice, remote health practitioners reported a reliance on the RPHCM suite, especially the CARPA STM and WBM for a variety of reasons. The primary reasons were the contextual and clinical relevance of the manual content to their daily practice, the use of the manuals in training staff new to the remote context (meaning the manuals were seen to be a credible resource), and the perceived legal safeguard that referral to the manual content provided.

The wide availability of manuals in remote clinics, accessibility in the form of hard copy and online versions, and organizational endorsement of the manuals gave participants confidence to frequently refer to and rely on the RPHCM for their daily practice. For many, if there was not a comprehensive orientation to remote clinical practice, the CARPA STM and WBM were perceived to fill in the gaps. An interesting aspect of these results was that the reliance was not restricted to a particular profession but was common to members of all professions who were new to the remote context. However, nurses and Aboriginal Health Practitioner, if the experience was not a factor, relied on the manuals more.

Organizational preference for their employees to use the RPHCM suite (in many instances specifically the CARPA STM and WBM) in their clinical practice has led to regular use of the manual protocols. In other instances, use of the manuals in training and orientation programs with strict instructions to use the protocols outlined in the manuals to treat common presentations has compelled practitioners to refer to the manuals regularly. An interesting observation from clinic

TABLE 2 CMO configuration patterns emerging from first phase of analysis

Context	Mechanism	Outcome
Difference in disease burden and patterns in remote health context Complicated, serious, or multiple conditions Manual useful as a tool for teaching and patient education Manuals enable practitioners to work outside previous experience Physically accessible and readable Complicated, serious, or multiple conditions Enable practitioner to work outside previous experience	Reliance on protocols Use manuals to gain reassurance and verification Relevant for individual clinical practice Use manuals to gain reassurance and verification Reliance on content	Use of the RPHCM leads to adherence to standardized practice
Practitioners guided by scope of practice Manuals enable practitioners to work outside previous experience Remote and isolated Multidisciplinary user base Remote and isolated clinical practice Registration guides use of manual Manual provides information to assist with differential diagnosis	Compelled to refer to manual content Reliance on protocols Significance for individual clinical practice Manual reflects clinical presentations i.e. content tailored to relevant clinical presentations. Fear of consequences if not using Significance for individual clinical practice	Regular use of the RPHCM leads to adherence to standardized practice
Complicated, serious, or multiple conditions Manual content unclear or difficult to follow RPHCM less relevant some practitioners Evidence and treatments in manual outdated Practitioner from the community Manuals not useful in all clinical situations Busy clinicians Medical practitioner disagrees with treatment outlined in manual	Lack confidence in or to apply manual content Reliance on existing clinical experience and knowledge Practitioner perception of patient views Practitioners feel uncomfortable looking at certain sections of manual because of cultural issues or familial ties or embarrassment Lack confidence in or to apply manual content Self-assuredness to examine without referring to manuals Reliance on medical practitioner	Lower use of protocols leads to risk of lesser adherence to standardized practice

Abbreviation: RPHCM, Remote Primary Health Care Manuals.

TABLE 3 Preliminary and refined programme theories

Preliminary program theory	Refined program theory
Remote health practitioners have adopted standardised, evidence-based practice because of the use of Remote Primary Health Care Manuals (RPHCM). The mechanisms that lead to the use of the manuals include fear of consequences of not using RPHCM, confidence in using and understanding RPHCM content, reliance on manual content to guide their practice, the perception of credibility, and applicability of RPHCM content to the context. Some remote health practitioners regularly use the RPHCM in their daily practice because there is a lack of alternative resources for RPHCM content. Some remote health practitioners are inclined to use the RPHCM less regularly because of a perception that the content is less suited to their needs and daily practice.	Many remote health practitioners have adopted standardised, evidence-based practice because of the use of the Remote Primary Health Care Manuals (RPHCM). The mechanisms that lead to the use of the manuals include acceptance of the worth of the protocols to their clinical practice, reliance on manual content to guide their practice, the perception of credibility, and applicability of RPHCM content to the context, as well as a compulsion, imposed by the organisational policies, for them to use the manuals. Many remote health practitioners regularly use the RPHCM in their daily practice because of the relevance of the protocols to the remote context and a lack of alternative resources to guide remote clinical practice. Some remote health practitioners are less inclined to use the RPHCM regularly because of a perception that the content is less suited their needs and daily practice and is hard to navigate or understand.

managers and experienced clinicians was how non-use of the RPHCM would make new staff stand out and lead to a perception of not fitting into the team or organizational culture.

The above sections discussed the mechanisms and pathways that led to regular and relevant use of the RPHCM and enabled standardized clinical practice in the remote context. However, feedback from some interviewees also identified that standardized practice by embedding the RPHCM protocols in daily clinical practice has not been firmly established in all areas. Reasons for lower or infrequent use of the RPHCM included disagreement with the treatment outlined in the protocols (more common among medical practitioners than other professions), difficulty in interpreting the content (common among those new to the remote context and the manuals), lack of information (in the case of uncommon conditions not covered in the manuals), availability of alternative resources (infrequent in the remote context), busy schedule (not having enough time to both refer to the manuals and treat the patient), and difficulty navigating the manuals (to identify the relevant section).

Years in remote clinical service and professional category commonly dictated the frequency of use of the manuals. Senior medical practitioners, for example, mainly referred to the manuals (CARPA STM or WBM) during on-call shifts to ensure that the referring nurse had followed the appropriate clinical protocol. Senior and experienced remote nurses only referred to the protocols for complex presentations. Irrespective of professional category, however, if someone was new to the remote context, the manual protocols were referred to more frequently.

Each manual in the suite varied in their usage depending on the profession using it and the focus of its content. That the CARPA STM was widely used across professional categories was already known from the previous evaluation, but this evaluation identified that the WBM was equally popular across professions and organizations. The Medicines Book was identified as invaluable to Aboriginal Health Practitioners but less so with other professional categories. The Clinical Procedures Manual was considered useful but was not used as frequently as the CARPA STM and WBM. The Reference Book was identified as being used less frequently than the other manuals in the suite.

While there was growing interest in the online version of the RPHCM suite (currently accessible through the RPHCM website),

overwhelmingly participants favoured continued availability of the hard copy version with many recounting how it was easy to use in the busy context in which they operated. They also liked the fact that copies of the manuals were available in all clinics (though in limited numbers) for them to access.

Following data analysis of the 50 interviews, analysis of the data from the remaining 78 participants was undertaken. While some new CMO configuration patterns emerged they were infrequent. The overwhelming CMO configuration patterns identified in the second stage of analysis matched what was uncovered in the first stage of analysis, thus confirming the themes and pathways that were articulated earlier.

Based on the 2 phases of analysis and the CMO configuration patterns identified, the preliminary programme theory was refined as such:

The programme theory (Table 3). is considered to be "refined" rather than "revised" as many elements from the preliminary programme theory were retained and most of the original elements were confirmed by data analysis. However, the refined programme theory did introduce new mechanisms supporting the increased use of the RPCHM protocols that were only identified only after data analysis. These mechanisms include an acceptance among remote health practitioners of the significance and relevance of the RPHCM protocols to their clinical practice and how the RPHCM protocols provided them with confidence to undertake safe and quality clinical practice. Yet the evaluation also uncovered or confirmed mechanisms that lead to lower use of the manuals and in consequence created impediments to firmly establish standardized clinical practice in the remote context. These negative mechanisms included a perception that some of the content was less relevant to certain practitioners and the lack of confidence in being able to use the content appropriately Figure 1.

4 | DISCUSSION

Given the evidence of low acceptability of clinical guidelines and poor adoption of standardized evidence-based clinical practice,[4,5] it was considered necessary to investigate the impact of the RPHCM suite. Adoption of a realist evaluation framework enabled closer examination

6 | WILEY—Journal of Evaluation in Clinical Practice
International Journal of Public Health Policy and Health Services Research

REDDY ET AL.

of the context and formulation of hypothetical pathways to explain the implementation of standardized practice in the remote context. The evaluation used a range of methods including interviews, survey, and clinical audits to assess the acceptability and accessibility of the 2014 editions. The results indicated that they were widely used and accepted in remote clinical practice. This article discusses the findings from the interview and survey component of the evaluation.

Across remote practitioner professions, and government and Aboriginal community-controlled organizations, the CARPA STM and WBM are seen to be essential to remote clinical service delivery. Previous evaluations had clearly identified the popularity and indispensable nature of the CARPA STM for remote clinical practice and remote clinical practitioners. This evaluation was not expected to conclude otherwise; however, significant developments had occurred since the last evaluation that were yet to be scrutinized. These changes include the complementary manuals being added to the CARPA STM to be collectively known as the RPHCM suite; the suite now being available in both hard copy and electronic versions; and the content of the manuals being expanded to include new protocols and changes to previous content.

The evaluation identified several mechanisms that lead to the use of the clinical guidelines (in this case, manuals) including a perception of credibility and applicability of content to the context, in which the clinicians operate. The adaption of clinical guidelines to the remote context meant users found the content highly relevant to their practice. Also, the perception of the credibility of the manuals by the users because of the type of contributors involved (clinicians with expertise and experience in remote clinical practice) meant better adoption of the manuals. With literature identifying low adoption of clinical guidelines in practice,[4,5] these findings, particularly the information about contextualizing the content, will be useful in the drive to increase adoption of clinical guidelines in clinical practice.

While the manuals were widely accepted in remote clinical practice, official endorsement of the manuals, especially the CARPA STM and WBM, also compelled remote health practitioners to actively use the manuals. However, certain professions like medical practitioners have found the manuals of limited significance in certain instances and use alternative resources to guide their practice. Yet, across professional categories and organizations (government and community controlled), the CARPA STM and WBM are seen to be essential to remote clinical service delivery and there is no alternative to the RPHCM suite that matches its breadth and focus in the remote context. Further, the hard copies continue to be the preferred version for use in remote clinics even with the advent and availability of the electronic (html) version. The need for hard copy publication will continue into the foreseeable future because of the overwhelming support for them from the evaluation participants.

Information obtained from this evaluation identified issues with the manual content (antibiotics table, index, cross references, and certain protocols). The evaluation team has taken this feedback to the committee that oversees the publication of the manual and relevant contributor groups for consideration, with some items being actioned in anticipation of the publication of the next edition. Comments about format and layout are also being actively considered.

Important feedback from the interviews was the barrier that registration and user login created for efficient access to the online manual content. This issue has already been addressed with the removal of registration and user login requirements.[6] There has been positive feedback from users regarding this initiative.

While the RPHCM are intended to be a useful resource for remote clinical practice, the RPHCM project is mindful that the manuals have increased in page numbers with each new edition. For example, the first published CARPA STM could fit into a pocket but has now evolved to be a hard-bound text of some size. Because of the preference for hard copy versions and a need to limit further increases in size (to allow for portability), the manuals cannot provide treatment protocols for all the conditions that present in the remote context. Consequently, a balance must be found between comprehensiveness and a need to maintain the user-friendly format (portability) of the hard copy versions.

A convenience sampling approach was used to recruit participants for this study. This approach was deemed practical considering the large geographical area and the number of clinics this evaluation had to cover. Also, the approach was considered as having less inherent bias than a purposive sampling approach because it did not preselect all its participants. However, the convenience sampling approach meant that some participants were not able to be included and their views not considered in the study. This could limit some of the findings from this study. However, the recruitment strategy ensured that a substantial number of participants from the same and different professional groups across different clinics were included. This meant that different views were considered in the analysis and refinement of the programme theory thus providing credibility to the findings from this study. Further to this, to address any issues in reporting of the findings and to ensure the reliability and validity of this article, draft manuscripts were reviewed against the RAMESES II standards for reporting realist evaluation findings.[7]

Incorporating evaluation findings into the development of the RPHCM will potentially lead to improved quality of future editions, with tailoring of content for practitioners. This may, in turn, lead to improved acceptance, more frequent use, and increased availability and accessibility of the manuals to remote healthcare practitioners. The other potential outcome is increased compliance with the RPHCM protocols by remote staff, because of both the increased quality and the consideration of end user's feedback. Any process that improves the quality of care and enables standardized best practice in remote locations may have a net benefit for those communities, particularly for populations with such a substantial illness burden[8,9] as that experienced by Aboriginal and Torres Strait Islander peoples living remotely.

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REDDY ET AL.

WILEY— Journal of Evaluation in Clinical Practice
International Journal of Public Health Policy and Health Services Research

7

evaluation team with the logistics of remote travel, accommodation, and clinic orientation. The RPHCM project, including the evaluation, is funded by the Australian Government Department of Health.

CONFLICT OF INTEREST

All the authors, when this evaluation was conducted, were RPHCM project staff. However, various measures were adopted by the authors to ensure integrity of research including peer review of the protocol by an external realist evaluation expert and oversight of the evaluation by research and governance committees.

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