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# **Evaluating impact of clinical guidelines using a realist evaluation framework**

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#### **Abstract**

Rationale, aims and objectives The Remote Primary Health Care Manuals (RPHCM) project team manages the development and publication of clinical protocols and procedures for primary care clinicians practicing in remote Australia. The Central Australian Rural Practitioners Association Standard Treatment Manual, the flagship manual of the RPHCM suite, has been evaluated for accessibility and acceptability in remote clinics three times in its 20-year history. These evaluations did not consider a theory-based framework or a programme theory, resulting in some limitations with the evaluation findings. With the RPHCM having an aim of enabling evidence-based practice in remote clinics and anecdotally reported to do so, testing this empirically for the full suite is vital for both stakeholders and future editions of the RPHCM.

Methods The project team utilized a realist evaluation framework to assess how, why and for what the RPHCM were being used by remote practitioners. A theory regarding the circumstances in which the manuals have and have not enabled evidence-based practice in the remote clinical context was tested. The project assessed this theory for all the manuals in the RPHCM suite, across government and aboriginal community-controlled clinics, in three regions of Australia.

**Conclusion** Implementing a realist evaluation framework to generate robust findings in this context has required innovation in the evaluation design and adaptation by researchers. This article captures the RPHCM team's experience in designing this evaluation.

# Introduction

Clinical guidelines are a vital tool for health practitioners in improving the quality of health care delivery across various clinical situations [1,2]. Field and Lohr [1] define clinical guidelines as 'systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances'. Clinical guidelines are perceived to standardize care and enable evidence-based medical practice [3]. Successful implementation of quality clinical guidelines should decrease variation within the everyday clinical practice and, as a result, optimize the health of the patients and communities in which the guidelines have been adopted [4].

#### Remote primary health care manuals

The Remote Primary Health Care Manuals (RPHCM) are a suite of five manuals consisting of the Central Australia Rural Practitioner Association Standard Treatment Manual (CARPA STM),

Minymaku Kutju Tjukurpa – Women's Business Manual, Clinical Procedures Manual for remote and rural practice, Medicines Book for Aboriginal and Torres Strait Islander Health Practitioners and Health Workers and the Reference Book for the Remote Primary Health Care Manuals. These are protocols and procedures¹ designed to support the quality of care and evidence-based best practice in primary health care centres in central, northern and remote Australia. Intended for primary care practitioners in remote Aboriginal and Torres Strait Islander communities [5], they cover a range of clinical areas of importance in this context, or with differing management to metropolitan areas. They are available in hard copy and electronically (www.remotephcmanuals.com.au).

The idea for a set of clinical protocols for the remote context was first formulated in early 1990s, generated by a need to support clinicians to address conditions prevalent in Central Australia: acute pneumonia, gastroenteritis, infections and respira-

<sup>&</sup>lt;sup>1</sup> Protocols and Procedures developed using national or local clinical guidelines where they exist.

tory disease, and to ensure consistent best practice in an environment of high health workforce turnover. Also, a significant proportion of the patients presenting to remote clinics and local hospitals in Central Australia are aboriginal, who have a higher disease burden and socio-economic disadvantage compared to the non-aboriginal population [5,6]. At that time, clinical guidelines were rare and essentially unavailable in the context of remote practice, which presented unique and challenging clinical circumstances. As a result, the first edition of the CARPA STM was published in 1991, a pocket-sized set of protocols developed for clinicians, by clinicians [7].

The Minymaku Kutju Tjukurpa - Women's Business Manual (WBM) focuses solely on women's health, including screening, obstetrics, gynaecology, infertility, menopause and contraception. It was published in 1991, during the same period as the CARPA STM, in response to aboriginal cultural conventions for separate management of women's health issues. The Clinical Procedures Manual for remote and rural practice provides detailed information on how to perform procedures outlined in the CARPA STM and was first introduced in 2001. The Medicines Book for Aboriginal and Torres Strait Islander Health Practitioners and Health Workers, introduced in 2005, covers medicines recommended in the CARPA STM and the WBM, and other medicines commonly used in remote primary health care centres. The Medicines Book is focused on education, utilizing culturally appropriate illustrations and simple language. The reference book was first introduced in 2004 and details the evidence base for protocols found in the manuals. These manuals together comprise the RPHCM suite.

The uptake of the RPHCM suite has flourished over time, and the manuals have become highly popular in all parts of Australia. Members of the editorial committee, who direct the development and publication of the manuals, along with reviewers of the content, are sourced from all over Australia to cater to the needs of a broad variety of remote practitioners. In Australia's northern territory, the CARPA STM and WBM are officially endorsed by government policy and legislation for use by remote area nurses, midwives and Aboriginal and Torres Strait Islander health practitioners [6]. They are also used extensively in staff orientation and training. Organizational policy and/or clinician preference also dictate the frequent use of the RPHCM in remote areas of Western Australia, South Australia and Queensland. The manuals are also used internationally in New Zealand and Angola, South Africa and Papua New Guinea. Academics and clinicians from Germany and Canada have also used the RPHCM for the purpose of educating medical students about practicing in remote contexts.

# **Evaluating clinical guidelines**

Though clinical guidelines add value to the treatment and management of diseases through the promotion of standardized, evidence-based care, the implementation of clinical guidelines is infrequently monitored or evaluated [3]. It is the responsibility of health practitioners in clinical settings to comply with endorsed guidelines. While some authors state adoption of and adherence to clinical guidelines remains low, others have gone further, stating poor practitioner adherence means further guideline development is a waste of resources [8]. There are also questions about the impact of clinical guidelines on clinical practice or health out-

comes and lack of clarity regarding the role that guideline developers should have in both the dissemination and implementation of guidelines [1,2,8,9].

Assessment of guideline uptake and impact is complex. Many scholars suggest that guidelines are not 'self-implementing,' and it is, therefore, important to determine their application in clinical practice through thorough review and assessment of their accessibility and acceptability [1,2,4,10]. This assessment is a key step in ascertaining the level to which these guidelines are used, the first stage in determining their impact.

In this regard, three evaluations of the CARPA STM have been undertaken in the past 20 years to assess user acceptance and compliance. The first was undertaken in 1992, then in 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 some remote clinical practitioners who lacked confidence in using the CARPA STM, and found parts of the manual difficult to understand. It was recommended for organizations using the manual to incorporate training in their use within their usual orientation process.

While there have been three evaluations of CARPA STM, assessment of the entire RPHCM suite has not yet been undertaken. Evaluation of the suite using the objectives relating to acceptance and compliance is necessary to provide insight as to whether remote primary health care staff is compliant with the current manual protocols, as well as determining reasons for compliance or lack thereof. The evaluation results will feed into the editorial review process (being conducted by multi-disciplinary content and context experts) and the publication processes (including changes to layout and format and the creation of easy to use physical attributes). Ultimately, it is hoped that the findings would not only measure the current uptake and impact of the RPHCM but also directly inform their future development.

#### **Methods**

Key aspects of the RPHCM suite directed the evaluation, including the way we tailor our content for end-users, its remote clinical context and the value placed on utilizing user feedback to redesign future editions. Pronovost [8] suggests that guidelines should contain checklists of key practices that are context-appropriate with the greatest empirical evidence base in order to efficiently benefit patients; those guidelines should cater to the management of conditions that coexist (such as diabetes, coronary artery disease and hypertension) and that guideline developers should implement systems and technology to support the use of the guidelines, as opposed to relying on individual actions of practitioners. The RPHCM suite has previously adopted these measures and evaluating these innovations is necessary. To represent the range of clinical, organizational and geographical context in which it is used, the current evaluation of the RPHCM suite will focus its evaluation on selected remote health care centres, both aboriginal community-controlled and government operated, across the northern and central areas of Australia. Because of the need to undertake a comprehensive evaluation, consider the context, gather and analyse complex data, the evaluation utilizes a theory-based evaluation. This focuses on the operating context, devising a programme theory - a tentative explanation of why and how a particular intervention leads to certain outcomes and the conditions in which this takes place [9] – and a mixture of methods to test the programme theory.

#### **Realist evaluation**

In the 1980s, theory-oriented evaluation approaches were developed to address gaps in the evaluation of policies and programmes that remained confined to before—after/input—output evaluation designs [11]. Realist evaluation is a form of theory-oriented evaluation approach [11,12] which offers distinct advantages over non-theoretical evaluation approaches by analysing *how* changes occur, *for whom* and under *which conditions*. Further, by focusing on underlying change processes and the contexts that affect how they work, it offers a different way of assessing whether findings are portable to other situations [11].

Realist evaluation, therefore, has the capacity to elicit the rich information required to meet the current evaluation objective: to assess the acceptability and accessibility of the RPHCM 2014 suite and compliance with the RPHCM protocols in the remote context i.e. amongst remote primary care clinics.

Although the current evaluation will largely follow previous data collection methods to facilitate comparison, realist evaluation will enhance the previous methodological framework through the development of a programme theory. The evaluation method will take into account the isolated context in which remote clinicians practise and the RPHCM used, and aim to identify the mechanisms that lead to, or do not lead to, adoption of standardized, evidence-based care.

# **Programme theory**

Realist evaluation typically begins by eliciting and formalizing a programme theory [13–15]: 'a theory that lies between the minor but necessary working hypothesis, and the all-inclusive systematic efforts to develop a unified theory that will explain the observed uniformities of social behaviour, social organisation and social change' [16]. A programme theory can either be formulated by an existing theory and experience, or through on-site research to identify implicit models used to make sense of the intervention [12,13]. The programme theory explains why and how a particular intervention leads to certain outcomes and the conditions in which this takes place [12]. In realist evaluation, the programme theory outlines mechanisms triggered by the intervention in its context(s) to which the generation of outcomes can be attributed [11]. A definition of mechanisms commonly used in realist evaluation is 'the interaction between resources programs provide and the reasoning of participants'. Mechanisms at different stages of a programme may result in participation (or not) - which in this instance might be defined as use (or not) of the manuals [12,13,17,18].

In realist evaluation, an initial programme theory is formulated based on previous research findings or conversations with stakeholders. The programme theory is then laid out in the form of Context-(C) Mechanism-(M) Outcome-(O) pattern configurations. CMOs are actually descriptions of causal pathways: how programmes activate mechanisms in specific conditions to cause changes in behaviours or events or regularities.

A preliminary programme theory was developed for this evaluation based on previous evaluation findings, and feedback from users and other stakeholders of the RPHCM. The theory is as follows:

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 the content less suits their needs and daily practice.

This theory, at a high level, can be visualized in the form of a flow chart (Fig. 1):

#### **Evaluation sites**

The evaluation is taking place in over 30 aboriginal community-controlled and government-operated remote primary health care centres across the northern territory and cross-border areas of South Australia and Western Australia. While the centres will be selected by their location (representative of different regional areas), sizes (large and small remote health centres), the willingness of organizations and history of being involved in manual evaluations, logistics plays an important role in the centres selected. The geographical area being considered is spread over 1.3 million square kilometres with enormous distances between clinics [19,20]. To allow for timely completion of the evaluation and within existing resources, select clinics have been chosen for face-to-face interviews.

#### **Approvals**

As the evaluation covers 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.

The RPHCM are specifically designed for practise in aboriginal and Torres Strait Islander health. The evaluation will include aboriginal and Torres Strait Islander remote practitioners, and interviews will be conducted in clinics in remote aboriginal communities. All ethics committees, therefore, required clear indications of the project's recognition of and respect for diversity within the culture and languages of aboriginal and Torres Strait Islander peoples, along with a capacity to address the six core

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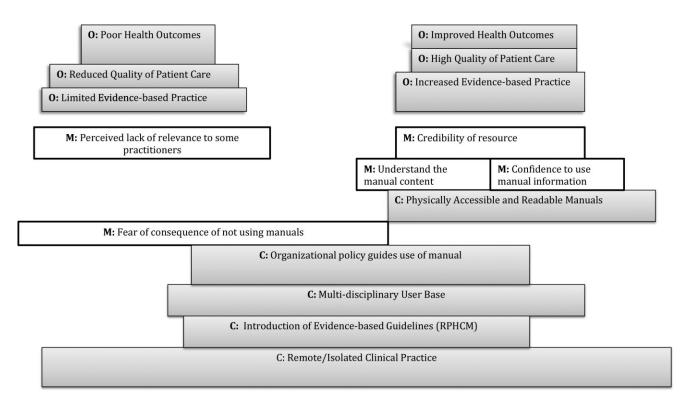


Figure 1Preliminary Programme Theory

values of Reciprocity, Respect, Equality, Responsibility, Survival and protection, and Spirit and integrity [21]. The project ensured cultural representation on our reference group, consulted with the peak Aboriginal Medical Services body in Central Australia, and will adopt relevant local cultural protocols [22] while conducting the evaluation. Examples of cultural protocol that will be considered include avoidance of naming deceased people when interviewing aboriginal health practitioners and respecting ceremonies in aboriginal communities by not travelling to the communities during this period.

# Data collection

As this is a theory-based evaluation assessing a complex scenario, a variety of methods will be employed to collect data: face-to-face interviews, telephone interviews, online survey and clinical audits. The mixed method approach aligns with the realist evaluation, which favours a combination of methods to test the programme theory [11–13]. In this case, the interviews and survey will help to identify and probe mechanisms that enable adoption of standardized practice (or not). The audits will contribute to the assessment of compliance of clinicians with manual protocols. Use of a mix of methods will also enable triangulation of data.

### Interviews

The evaluation will utilize convenience sampling to identify clinic staff across disciplines, who are interested and available for interview during the study period. Ideally, a purposive sampling will have better suited this evaluation but the busy nature of clinics and

logistics has led to the choice of convenience sampling. The interviews will be used to gain a general understanding of if and why remote practitioners use the manuals frequently, which protocols are used most often and which protocols are most useful. A semi-structured interview format, constituting a series of open-ended questions will allow for minimum control of the respondent's answers while permitting accurate comparison across respondents. The interviews will further be used to assess how and why the manuals are accessible, applicable or credible to remote practitioners. The interviews will assess all the manuals in the RPHCM suite and both the hard copy and online versions.

Access to staff and the period during which the evaluation will be organized will be negotiated with individual clinic managers or relevant staff within participating organizations. To enable timely and practical data collection, specific team members will travel to each region and conduct the interviews. Logistics and safety of four-wheel drive travel across the considerable distances involved will be managed from within the project team. An option of telephone interviews for those who are unavailable during the team members' visit, or to clinics that cannot be accessed by project staff, will be offered.

# Survey

An online survey replicating the interview questions will be made available for those who have expressed interest in participating but cannot be present for the face-to-face or telephone interviews. The surveys will help to increase coverage and also capture those with particular motivation to participate because our assumption is that they will have particular views to contribute.

#### **Clinical audits**

An important component of this evaluation is the clinical audits, undertaken to assess compliance with RPHCM protocols and triangulate the interview findings. The audits will assess whether patient records, obtained from organization electronic patient information systems, demonstrate adherence to clinical protocols in the CARPA STM and WBM. Selected clinical protocols unique to the context and relevant to stakeholders and will be audited. Several conditions (anaemia in children, urine problems in children and gonorrhoea and chlamydia in women) were used as tracer conditions in the evaluation of the first edition of the CARPA STM, and will thus be used as a 'yardstick' to measure any changes in compliance with CARPA STM protocols. The other protocols (anaemia in pregnancy, anaemia in adults, high blood pressure in pregnancy, combined checks for chronic disease) were either used in the last evaluation or have been identified by participating organizations as important to assess within the remote aboriginal and Torres Strait Islander health context. Use of these selected protocols will both simplify the audit process and provide a general indication of compliance with the RPHCM.

Tailored audit tools were developed for this evaluation, as previous audit tools did not align with updated manual content. The clinical audit tools were piloted on electronic patient care information systems of participating organizations. We will work closely with the organizations for access to their patient care information systems remotely or from specified venues, and relevant researchers will undergo orientation to and training for the specific systems.

# **Analysis**

Unlike other programme evaluations, realist evaluation analyses data in the form of CMO configuration patterns [12,13]. The patterns are reflective of causal pathways postulated to lead to the outcomes being studied. Realist evaluation does not attempt to capture every individual causal pathway or answer all stakeholder queries; instead, it positions itself to test and refine the specific programme theory developed in consultation with the stakeholders [11,18]. A fundamental tenet of realist evaluation is that programmes work differently in different contexts. This is because mechanisms (M) required to achieve the intended outcomes (O) fire only in certain contexts [12]. Context (C) is, therefore, an important consideration in realist analysis, underlying the exploration of the 'why, when and for whom' questions key to this evaluation, and operationalized in the CMO configuration pattern.

Accordingly, the evaluation will analyse collected data largely through CMO elements and configurations, based on our initial programme theory. To frame the analysis, the initial programme theory has been broken down into specific CMO patterns as seen in Table 1.<sup>2</sup>

The CMO elements will be entered into the NVIVO software package to enable coding of interview transcripts or survey results and application to the programme theory. Consistent with the iterative nature of realist evaluation, an initial sample of 20 interview transcripts (spread across various regions and professions) will be analysed. Based on this analysis, the preliminary programme theory will be refined and new mechanisms and patterns identified. The remainder of the interview data will then be analysed against the refined CMO configurations. At the end of the second phase of analysis, the programme theory will be revisited to refine it further.

Another important consideration during the analysis will be the recognition of patterns by clinician profession. Previous evaluations and anecdotal feedback have indicated the lower use of the RPHCM suite amongst medical practitioners and high use by nurses and aboriginal and Torres Strait Islander health practitioners. The current evaluation will test, firstly, whether and to what extent this is still the case and secondly, what might explain the pattern of use across professions.

Analysis of clinical audit data will be undertaken at two levels. Abstracted data will be obtained from electronic medical records of patients with relevant conditions to examine staff compliance with CARPA STM and WBM protocols. Percentage of compliance and non-compliance by protocol (and its sub-elements) and the clinic will be compiled. The next level will be to present these data in realist evaluation format (i.e. identifying patterns of compliance). For example, nurses in a certain clinic may comply with the protocols more than the aboriginal health practitioners in the same clinic. This way, the clinical audit data can be used to corroborate or challenge findings from the interview data set.

As previously stated, the main outcome of interest from the analysis is to not only identify if people use the manuals, but *how*, *when*, *why*, *with whom*, and *in what circumstances*, and also if varying use of the manuals contributes to different outcomes. A realist evaluation framework allows exploration of these issues compared across professions and clinical protocols.

# **Discussion**

The RPHCM are clinical protocols and procedures developed for health practitioners working in isolated primary care centres in remote aboriginal and Torres Strait Islander communities. While each manual covers different clinical areas, they are essentially designed to support evidence-based best practice in primary health care centres servicing remote communities. By examining the accessibility, acceptability and compliance to the RPHCM suite in remote health care centres, this evaluation assesses whether RPHCM protocols are in fact widely used in remote practice in Australia, and whether they have contributed to evidence-based care. The fundamental tenet of the RPHCM is development by practitioners, for practitioners. This underscores the importance of context experts as well as content experts. Assessing manual content and receiving feedback through evaluation is expected to contribute to tailoring content for practitioners.

Incorporation of evaluation findings will potentially lead to improved quality in the development of the future editions of the RPHCM, which in turn may lead to improved acceptance, more frequent use and increased availability and accessibility of the manuals to remote health care practitioners. The other potential

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<sup>&</sup>lt;sup>2</sup> For this evaluation, to recognize the importance of intervention in a causal pathway, we separated out the intervention sub-element within the context for some configurations. The intervention sub-elements are noted in italics.

Table 1 Context-mechanism-outcome configuration pattern

Context	Mechanism	Outcome	
Organizational policy guides use of CARPA STM and WBM	Fear of consequences of not using manual content	Use the content as de facto guideline	Adherence to standardized practice
Busy clinical practitioners	Understanding the information provides confidence to use the information	Regular use of RPHCM content	
Low English literacy/English as a second language			
Readable manual content			
Wide distribution of RPHCM content			
Busy clinical practitioners	Reliance on manual content	Regular use of	
Isolated clinical practice		RPHCM content	
Inexperienced staff			
Wide distribution of RPHCM content			
Accessible content			
Expert and end-user input into development of RPHCM content	Manuals are perceived to be significant for clinical practice	Frequent reference to RPHCM content	
Need for orientation and training guides for			
remote clinical practice			
Manuals included as part of organisation orientation and training			
Availability of RPHCM in all clinics			
Lack of access to alternate guidelines	Compelled to refer to RPHCM because of	Relevant use of	
Organizational policy guides use of CARPA STM and WBM	lack of options or because of organizational policy	manual protocols	
Availability of RPHCM in all clinics	organizational policy		
RPHCM does not cover all information	Perceived lack of relevance to certain	Lower use of	Lesser adherence to
relevant to remote clinical practice	practitioner needs	manuals	standardized practice
RPHCM content less relevant for some	practitioner riceas	manaas	Standardized practice
practitioners			
High Staff Turnover	Less compulsion to adhere to organization	Lower use of	Lesser adherence to
Short Term Staffing	policies to use manuals	manuals	standardized practice

outcome is increased compliance with the RPHCM protocols by remote primary health care staff, not only due to increased quality but also because of increased credibility of the manuals due to consideration of the 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 as that experienced by aboriginal and Torres Strait Islander peoples living remotely [5,6].

Realist evaluation makes some quite different assumptions to other types of evaluation. For example, it assumes that nothing works for everyone or every time. What is being identified through realist evaluation is why it works when it does, and why it does not work when it does not work. The analytical framework embedded in the realist methodology will elucidate the causal pathways leading to the adoption of standardized evidence-based clinical practice following the introduction of the RPHCM (as illustrated in the form of CMO configuration patterns) and contextualize the findings. Importantly, it will also bring forth how and why the manuals are being used. This is very valuable, not only for quality improvement within the RPHCM but also for the clinical guidelines field, in which there is very little research available on how and why clinical guidelines are adopted (or not) amongst their core audience.

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