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TITLE PAGE**a) Title**

Approaches to improving adherence to secondary prophylaxis for rheumatic fever and rheumatic heart disease: a literature review with a global perspective

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Conflicts of Interest

None

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ABSTRACT

Acute rheumatic fever (ARF) and rheumatic heart disease (RHD) are auto-immune conditions resulting from infection with group A streptococcus. Current management of these conditions includes secondary antibiotic prevention. This comprises regular 3 to 4 weekly long-acting intramuscular benzathine penicillin injections.

Secondary antibiotic prevention aims to protect individuals against reinfection with group A streptococcus thereby preventing recurrent ARF and the risk of further damage to the heart valves. However, uptake of benzathine penicillin can be poor leaving patients at risk of avoidable and progressive heart damage.

This review utilizes the Chronic Care Model as a framework to discuss initiatives to enhance the delivery of secondary antibiotic prophylaxis for ARF and RHD. Results from the search strategy utilized revealed that there is limited pertinent published evidence. The evidence that is available suggests that register/recall systems, dedicated health teams for delivery of secondary antibiotic prophylaxis, education about ARF and RHD, linkages with the community (particularly between health services and schools) and strong staff-patient relationships may be important. However, it is difficult to generalize findings from individual studies to other settings and high quality studies are lacking.

While secondary antibiotic prophylaxis is an effective treatment for those with ARF or RHD, the difficulties in implementing effective programs that reduce the burden of ARF and RHD demonstrates the importance of on-going work in developing and evaluating research translation initiatives.

KEY WORDS

Rheumatic fever; Rheumatic heart disease; Prophylaxis; Prevention; Indigenous health

TEXT

INTRODUCTION

Acute rheumatic fever (ARF) is an autoimmune response to infection with group A streptococcus (GAS).¹ It is associated with inflammation of the heart, skin, brain and joints. While episodes of ARF are usually self-limiting the immune response may result in heart valve damage, particularly of the mitral or aortic valve. This chronic condition is called rheumatic heart disease (RHD).¹ RHD is more likely to develop after repeated episodes of ARF.

Owing to the difficulties in identifying and implementing effective primordial and primary prevention strategies, a core component of ARF/RHD management is secondary prevention. Secondary prevention aims to protect individuals who have previously had ARF, or already have RHD, against GAS infection. This in turn protects these individuals against recurrent ARF and development or progression of valve damage associated with RHD.

One aspect of secondary prevention is antibiotic prophylaxis in the form of three to four-weekly long-acting intramuscular benzathine penicillin injections (LAB).¹⁻³ LAB has been demonstrated to be effective in preventing recurrent episodes of ARF and modelling suggests that secondary prophylaxis is the most cost-effective means of controlling RHD (US\$142 per disability-adjusted life year gained and US\$5520 per death averted).^{2, 4-6} While oral penicillin can be used in secondary prevention, it is less effective than LAB in preventing ARF.^{2, 7} Hence LAB remains the recommended treatment for secondary prophylaxis except in cases of demonstrated penicillin hypersensitivity.¹

While the effectiveness of secondary antibiotic prophylaxis has been demonstrated⁸, delivery of LAB can be difficult. ARF/RHD patients not receiving adequate secondary prophylaxis are at risk of avoidable and progressive heart damage. Suboptimal delivery of secondary antibiotic prophylaxis has been highlighted in numerous countries including Australia⁹, Egypt¹⁰, Taiwan¹¹, Brazil¹² and South Africa.¹³ It has been suggested that low uptake may be due to the longevity and inconvenience of treatment (up to 20 years of LAB), the pain of injections, poor community engagement, inadequate patient education, cost and distance from health centres.^{14, 15}

Addressing the issue of low uptake of secondary antibiotic prophylaxis is an ongoing public health priority.¹⁴ The aim of this review is to evaluate the evidence pertaining to improving uptake of ARF/RHD prophylaxis within a framework of the Chronic Care Model (CCM) developed by Ed Wagner and colleagues.¹⁶ Given the longevity of secondary prophylaxis required for ARF/RHD patients, suboptimal uptake of treatment and the reality that delivery of health care in this context is far broader than individual interactions between patients and clinicians, it is timely to examine ARF/RHD secondary prophylaxis within a framework developed to improve chronic disease care.

CHRONIC CARE MODEL FOR ARF/RHD

There are a broad range of models of care that have been developed and utilized in chronic disease management.¹⁷⁻¹⁹ Many of these focus on specific chronic diseases^{20, 21}, particular elements of treatment or the health care system²², defined providers²³ or the client themselves.^{21, 24} Others are based on Wagner's CCM and encompass a broader whole-of-system approach that incorporates patient, provider and system-level interventions. The CCM has been utilized in this review as it provides a generic framework that is recognized and

utilized internationally and for a broad range of communicable and non-communicable chronic diseases.²⁵⁻²⁸

The CCM highlights that effective chronic disease care results from positive relationships between empowered patients and proactive care teams. Wagner argues that delivering effective chronic disease care is best achieved through redesigning delivery systems within the context of three core domains: community resources, health care organization, and clinical practice (see Figure 1).

While the CCM has been associated with improvements in chronic disease care^{16, 27, 28} it has not been utilized specifically in relation to ARF/RHD. Furthermore, the model has limitations including the fact that there are few data relating to its cost-effectiveness and the potential difficulties in applying such a model of system redesign to regional and remote settings where many individuals with ARF/RHD live. Nonetheless, given the broad nature of the CCM framework it was considered the most suitable framework to use when examining potential strategies to improve the delivery of secondary antibiotic prophylaxis for ARF/RHD.

SEARCH STRATEGY

A PubMed search of English language articles was undertaken to identify literature relating to activities undertaken to improve uptake of secondary antibiotic prophylaxis for ARF/RHD. Published conference abstracts were included. The reference lists of retrieved articles were also searched. The search strategy included a combination of the following search terms: “secondary prophylaxis OR antibiotic prophylaxis OR benzathine penicillin OR preventive therapy”, “rheumatic fever OR rheumatic heart disease” and “adherence OR compliance”. A grey literature search was also undertaken examining the first ten pages of

Google and Google Scholar for the following search terms "secondary", "antibiotic", "prophylaxis", "penicillin", "rheumatic", "adherence" and "compliance". The criteria for the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) were applied.

In total 104 articles were reviewed. Articles which did not report adherence data for secondary prophylaxis or which did not describe interventions to improve uptake were excluded. Sixteen articles satisfied all selection criteria and were included. Given this low number, other potential strategies for improving uptake of secondary prophylaxis were discussed based on evidence from studies in other areas of health care.

REVIEW OF INTERVENTIONS TO IMPROVE UPTAKE OF SECONDARY ANTIBIOTIC PROPHYLAXIS WITHIN A CCM FRAMEWORK

1. Community Resources

The CCM recognizes that the health care system is embedded within the wider community. It suggests that better patient outcomes may be expected if “community resources” are mobilized to meet the needs of patients.¹⁶

Mobilizing community resources to improve delivery of ARF/RHD secondary prophylaxis may involve a broad range of initiatives. For example, health access may be improved through community-control, clinical outreach or developing linkages between health services and community-based agencies such as schools, sports bodies, stores, churches and welfare agencies. It may also be possible to promote secondary prophylaxis through community events and cultural activities. A thorough understanding of local community dynamics is likely to be integral to identifying potential community partners for such activities.

Within an indigenous context, research focused on Canada's First Nations peoples has shown that community control of health services, self-governance, control of traditional lands and community-controlled schooling can improve health outcomes.^{29, 30} Nonetheless, this research was specifically related to youth suicide and may not be generalizable to chronic disease care in general and ARF/RHD specifically.

Local events such as concerts and cultural gatherings may provide a useful forum for engaging young populations at particular risk of ARF. There is evidence that health promotion activities at such events can influence health-related behaviour including reducing tobacco consumption.³¹ However, no studies have been published regarding the possible role of community events in encouraging the uptake of ARF/RHD prophylaxis.

The development of linkages between health care and education systems can be particularly effective in improving uptake of secondary prophylaxis by children and adolescents. One secondary prophylaxis program in Auckland, New Zealand, focused on community nurses delivering LAB injections at schools.³² Within a year of implementing this program significant improvements in uptake were reported. The proportion of clients receiving all scheduled injections ranging across nine sites ranged from 80% to 100%.

There is some evidence that a 'whole of community' response to ARF/RHD prevention can be effective.³³⁻³⁵ Such an approach was implemented in the Cuban province of Pinar del Rio between 1986 and 1996.³⁵ Five years after the program commenced the occurrence of ARF and RHD had declined by up to 90% and a progressive increase in uptake of secondary prophylaxis was reported. Community involvement and the utilization of public media were key components of this program. Similar success with 'whole of community' interventions has been reported in Costa Rica³³ and the Caribbean³⁴. Unfortunately it is

difficult to identify the exact elements which contribute to the success of such broad-scale programs.

2. Health Care Organization

The CCM highlights that to improve chronic disease care it is necessary to improve the quality and safety of the culture, systems and practices of health care organizations.¹⁶ To effect such change requires clinician leadership and advocacy from service providers, patients, community leaders and clinical and consumer organizations.

One mechanism that is often used to refine health systems is continual quality improvement (CQI). CQI refers to a structured organizational process to plan and implement a continuous suite of interventions to improve the quality of health care provided by an organization.³⁶ It involves examining and reworking existing health care processes in light of best-practice, evidence-based knowledge and scientific methodologies.³⁶ While systematic reviews have demonstrated that CQI can be effective in improving health care, the evidence is limited and improvements are generally small to moderate.^{37, 38} Moreover, positive results tend to be seen when baseline adherence to recommended practice is low and intensity of audit and feedback is high.³⁹ CQI programs may be difficult to implement if they are complex, time-consuming and resource-intensive. These problems may be exacerbated in low resource, indigenous and remote settings⁴⁰ where ARF/RHD are most prevalent.

There are currently only limited published data reporting on the efficacy of CQI initiatives in ARF/RHD care. One study from the Northern Territory in Australia suggested that CQI activities did improve some aspects of ARF/RHD care but had no impact on the proportion of patients receiving $\geq 80\%$ of their scheduled LAB injections.⁴¹ Thus, it remains unclear whether formal CQI initiatives are superior to other organizational strategies to

improve service delivery such as those that encourage reflective and responsive health care at an individual provider level.

Providing incentives to health care providers may be another potential mechanism to improve patient care. In the context of ARF/RHD, secondary prophylaxis providers could be rewarded for each dose delivered or when uptake targets are met. While there is no published literature in relation to such ‘pay-for-performance’ (P4P) strategies for secondary prophylaxis there is evidence relating to other elements of health care. Systematic reviews by de Bruin *et al.*⁴² and Scott *et al.*⁴³ revealed that P4P strategies can result in small improvements in the quality of care provided to patients but that most P4P studies included significant methodological limitations and no assessment of cost effectiveness. In contrast, a systematic review by Witter *et al.* of interventions in low to middle income countries found little to support the use of P4P in such settings.⁴⁴ Furthermore, it has been argued that the complexity and design of P4P initiatives can make it difficult to generalize apparently successful initiatives to other settings.⁴⁵ Despite these limitations, the success of some P4P schemes suggests that well designed incentive systems with clear evaluation strategies are worthy of further investigation as a mechanism to enhance ARF/RHD secondary prevention.

3. Clinical Practice

3(i) Self-management support

The CCM recognizes that a central component to improving chronic disease care is to provide patients with the knowledge, skills, motivation and support to manage their own health.¹⁶

An uncontrolled evaluation of a secondary prophylaxis program in Barbados demonstrated that supporting ARF/RHD patients to self-manage through the use of patient-

carried cards to record injection dates may be effective.^{46, 47} This program was associated with an uptake of 97% of possible doses of therapy by patients. However, the specific impact of the patient cards could not be separated from other confounding factors including the fact that their introduction coincided with the establishment of an ARF/RHD clinic at the local hospital. While a system of hand-held records may prove particularly useful for patients who are mobile and access health care at various sites there is little published evidence to support this.

Another mechanism that may support self-management is the use of mobile telephone-based short message service (SMS) reminders. One review of SMS reminders found that they substantially increased the likelihood of patients attending clinic appointments.⁴⁸ The increasing use of mobile telephones in low resource and remote settings suggests that the use of SMS-based reminders may be a viable option to enhance ARF/RHD care across a broad range of settings.^{49, 50} Nonetheless, at present there is no published evidence to support this.

When considering the concept of self-management in health care it is important to reflect on the extent to which individuals and communities may wish to take on such a role. An Australian study investigating ARF/RHD prophylaxis in a remote Aboriginal community found that a patient's sense of taking responsibility for their own health was not clearly related to uptake.⁵¹ Rather, patients felt that the role of the health service was not only to provide medical care but also to perform a pastoral role in terms of home visits, engaging families, encouraging patients and caring for them emotionally. Another Australian study reported that the uptake of secondary prophylaxis was closely linked with positive patient–staff interactions.⁵² These studies imply that in a remote Aboriginal context self-management for ARF/RHD may play a secondary role to the quality of relationships between health staff

and patients/families. Nonetheless, these findings may be specific to their contexts and not generalizable to other cultural situations.

A key component of chronic disease self-management is patient, family and community education. ARF/RHD education has been associated with an improvement in the uptake of secondary prophylaxis in Costa Rica³³ and the Caribbean.³⁴ Furthermore, an Egyptian study showed that inadequate education of parents regarding ARF/RHD and secondary prophylaxis was the main factor jeopardising quality of care for their children.¹⁰ Nonetheless, the Costa Rican and Caribbean studies were uncontrolled multi-dimensional interventions and so the isolated effects of education initiatives remain difficult to determine.

It has been suggested that patient/carer incentives may be a useful tool to improve uptake of ARF/RHD secondary prophylaxis.¹⁴ Two recent Cochrane reviews of the effectiveness of incentives in limiting tobacco consumption^{53, 54} and a systematic review investigating the use of financial incentives for the treatment for obesity⁵⁵ found that such schemes were not generally successful. Nonetheless, a review of eleven randomized controlled trials investigating the effect of financial incentives on compliance with medication, medical advice, or medical appointments did find a positive association.⁵⁶ Given the lack of conclusive evidence supporting the effectiveness of patient incentives, and that there is no evidence relating to their use in the context of ARF/RHD prophylaxis, further research is required before recommendations can be made.

3(ii) Delivery system design

The CCM highlights that improvement in chronic disease outcomes requires the delivery of clinical care that is effective and efficient.¹⁶

It is often suggested that a key element in the successful delivery of secondary prophylaxis is having systems of patient registration and recall that are up-to-date, accessible and clear.³⁴ Such systems are thought to be particularly useful in following up patients who miss LAB injections.^{1, 57} Nonetheless, the evidence supporting their effectiveness in enhancing secondary antibiotic prophylaxis is limited to uncontrolled audits.^{8, 35, 58} Under such conditions it is not possible to determine whether changes in prophylaxis uptake are due to the register/recall systems or other undefined factors.

Successful delivery of secondary prophylaxis requires clarity regarding roles and responsibilities of clinical and non-clinical health staff. High uptake rates were reported for a New Zealand secondary prophylaxis program that involved community-based nurses working with ethnically appropriate health workers who provided education, support and transport.⁵⁹ Other studies have confirmed that uptake of secondary prophylaxis improves where clear responsibility is placed upon a particular staff member to actively follow-up clients who miss injections.⁵²

One study in central Australia investigated the novel concept of delivering secondary prophylaxis at times of the full moon.⁶⁰ While uptake increased significantly it did not occur at the time of the full moon. Such findings reinforce the need to critically evaluate claims that any specific initiative has enhanced ARF/RHD secondary prophylaxis uptake when often confounders and other uncontrolled factors may not have been adequately addressed or controlled for in the study.

3(iii) Decision support

The CCM recognizes that clinical care provided to patients with chronic diseases must be based on current evidence while at the same time taking account of patient preferences.¹⁶

In respect of ARF/RHD care evidence-based best-practice guidelines are available for a number of settings including South Africa, Asia, North America, New Zealand, and Australia, and globally via the World Health Organisation.^{1, 8, 61-64} The CCM acknowledges the importance of incorporating such guidelines into existing care and register/recall systems. Nonetheless, these guidelines cite many of the studies already discussed in this review to support specific recommendations regarding secondary antibiotic prophylaxis. As outlined above, much of the evidence in these studies is limited.

To improve decision-support regarding ARF/RHD secondary prophylaxis a number of specific issues need to be addressed. First, there must be clarity and consistency in relation to timing of delivery and period of coverage required. Unfortunately, even in high income countries such as Australia, adherence to national guidelines is variable.⁹ Second, support systems are required for local health providers to deal with more complicated management issues not adequately addressed by local ARF/RHD guidelines. Such systems may include accessing specialist or more experienced primary health care providers through telemedicine or outreach clinics. While there is no published evidence relating specifically to the use of telemedicine in secondary prophylaxis, one report noted that the use telemedicine in the Pacific Islands enabled more efficient and effective evaluation and follow up of RHD patients requiring surgical intervention.⁶⁵ Third, as the severity of RHD dictates the frequency of health care review and the longevity of prophylaxis required¹, routine review of patients and their medical records is needed to ensure that decision support systems are correctly applied. Such review can ensure that secondary prophylaxis is ceased when appropriate which would prevent patient inconvenience and unnecessary consumption of finite health resources.

3(iv) Clinical information systems

Effective clinical information systems provide easy access to up-to-date patient and population data thereby allowing health practitioners to make well-informed decisions about patient care. A preferred system for facilitating the uptake of ARF/RHD prophylaxis is one that integrates patient information, decision support and recall and follow-up.¹ The structure of any such system will be dependent upon available resources. In higher income settings this may include electronic patient medical records which interface with centralized ARF/RHD register/recall systems and electronic decision support. In other settings these may be paper-based records, registers and protocols or hand held records. The effectiveness of such register/recall systems in improving uptake of secondary antibiotic prophylaxis has been discussed above.

CONCLUSION

The CCM provides a framework within which to plan, implement and evaluate initiatives to improve chronic disease services. Evidence suggests that the uptake of secondary antibiotic prophylaxis for ARF/RHD is often inadequate and hence we used the CCM framework to review interventions to improve service delivery.

There is limited published evidence pertinent to improving the delivery of ARF/RHD secondary prophylaxis. That which is available suggests that register/recall systems, dedicated teams to deliver prophylaxis, ARF/RHD education, linkages with the community (particularly schools) and staff-patient relationships may be important. However, it is difficult to generalize findings from individual studies to other settings, and high quality studies are lacking.

The problem of uptake of ARF/RHD secondary prophylaxis remains vexed. The solution to preventing ARF/RHD is likely to lie in understanding and addressing the role of

poverty, developing an effective GAS vaccine and researching new systems of delivery of secondary prophylaxis that do not require monthly injections over decades. In the interim the focus should be on developing and evaluating innovative programs to improve delivery of LAB. A current Australian multicentre community-based clinical trial evaluating a multidimensional primary health care based intervention to enhance secondary prophylaxis delivery may inform this process.⁶⁶

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FIGURE LEGENDS

Figure 1 Diagrammatic representation of the Chronic Care Model.^{16, 19}