Improving Secondary Prophylaxis for Rheumatic Heart Disease in Remote Indigenous Communities: A Stepped Wedge Community Randomised Trial

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Acute Rheumatic Fever (ARF) and its chronic manifestation **Rheumatic heart disease (RHD)** result from an autoimmune reaction to Group A Streptococcal infection. In the Northern Territory (NT) of Australia, Aboriginal communities have 69 times higher ARF incidence & 55 times higher RHD prevalence compared with non-Aboriginal Australians

In Australia, **SECONDARY PROPHYLAXIS** (SP) is a cost-effective treatment to prevent repeated episodes of ARF and reduce cardiac damage. It is a 4-weekly penicillin injection for 10 years after the last ARF episode or until age 21, whichever is longer

LOW ADHERENCE: Proportion of ARF/RHD clients achieving ≥80% of injections in the NT was only 23% in 2009; 45% in 2014. Progress in controlling RHD requires improvements in the delivery of SP

STUDY OBJECTIVE: To improve uptake of SP among people with ARF/RHD by implementing and evaluating a sustainable, transferable, systems-based intervention at NT Health centres

DESIGN: Stepped-wedge, randomised cluster trial with an open cohort design

CLUSTER: Five clusters of paired Aboriginal Health Centres

SAMPLE: People with ARF/RHD who require SP whose health centre is enrolled in the study (N=356)

POWER: >90% to detect a doubling of adherence where pre-intervention rate ≈ 20 %

MEASUREMENT: Repeated measurements: record of every penicillin injection received, as documented in the NT ARF/RHD Register

EVALUATION COMPONENTS

Qualitative data are collected at all stages of implementation to answer *secondary research objectives*:

Process & Fidelity:
- What were the barriers and enablers of implementation?
- What were the barriers and enablers of organisational change?
- What was the acceptability and completeness of implementation of the intervention package, and of individual items?

Performance:
- What were the factors associated with success in achieving organisational and client level improvements in SP for RHD?

Efficiency:
- To what extent did health centres change their delivery of RHD care to align with the systems-based intervention?

Effectiveness:
- To what degree did adopting the systems-based intervention improve processes of RHD care and adherence to SP?
- Which elements of the intervention were most effective in activating change?

Relevance & Impact:
- Did the intervention, (a model of care designed to optimise health systems), improve overall adherence to SP for RHD and minimise 'days at risk'?

Sustainability:
- Which of the activities and streams of the Chronic Care Model were sustained during maintenance phase?

BASELINE (3 months):
2-week site visit, interviews & development of customised action plans

INTENSIVE (15 months):
Monthly site visits, review of action plan progress

MAINTENANCE (up to 15 months):
Monthly follow up, review of action plan progress

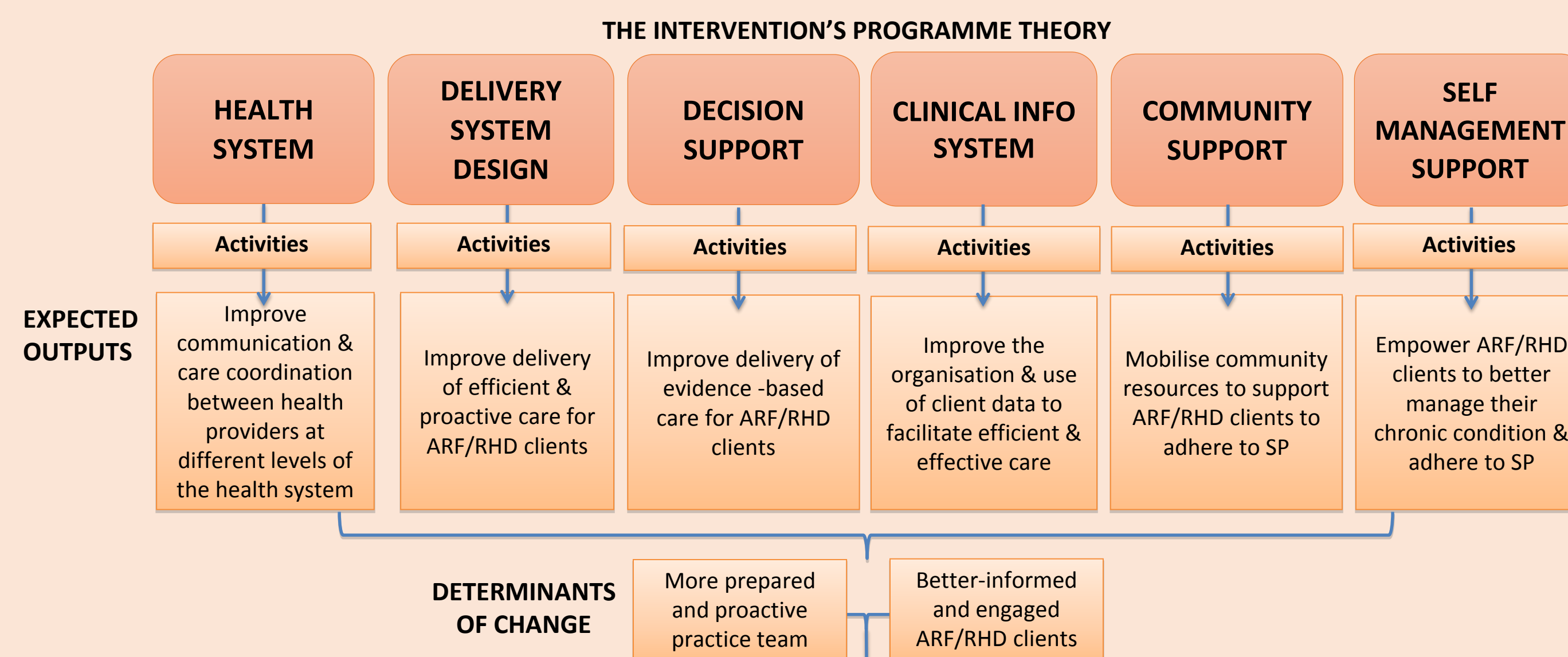**IMPLEMENTATION**: Health centres commence the study at 3-monthly steps in random order

Months	2013 Sept-Nov	2013 Dec-Feb	2014 Mar-May	2014 Jun-Aug	2014 Sept-Nov	2014 Dec-Feb	2015 Mar-May	2015 Jun-Aug	2015 Sept-Nov	2015 Dec-Feb	2016 Mar-May
Sites 1 & 2											
Sites 3 & 4											
Sites 5 & 6											
Sites 7 & 8											
Sites 9 & 10											

Months 1 - 3	Months 4 - 18	Months 19 - 33*
Baseline data collection Planning session	Intensive support phase	Maintenance phase

IMPLEMENTATION (Input)

THE INTERVENTION PACKAGE:
- Project Officers support health centres to develop and implement a customised set of *activities* aimed at improving penicillin delivery
- Activities are aligned under the elements of the Chronic Care Model (CCM)
- The intervention's Programme Theory is organised under the streams of the CCM & aim to activate "determinants" allowing for achievement of outcomes

THE INTERVENTION'S PROGRAMME THEORY

	HEALTH SYSTEM	DELIVERY SYSTEM DESIGN	DECISION SUPPORT	CLINICAL INFO SYSTEM	COMMUNITY SUPPORT	SELF MANAGEMENT SUPPORT
	Activities	Activities	Activities	Activities	Activities	Activities
EXPECTED OUTPUTS	Improve communication & care coordination between health providers at different levels of the health system	Improve delivery of efficient & proactive care for ARF/RHD clients	Improve delivery of evidence -based care for ARF/RHD clients	Improve the organisation & use of client data to facilitate efficient & effective care	Mobilise community resources to support ARF/RHD clients to adhere to SP	Empower ARF/RHD clients to better manage their chronic condition & adhere to SP

DETERMINANTS OF CHANGE
- More prepared and proactive practice team
- Better-informed and engaged ARF/RHD clients

INTERVENTION (Activities & outputs)

DETERMINANTS

MODERATORS (factors that condition the intervention's effect on outcome)

OUTCOMES:
- Measured with generalised linear mixed models; Primary outcome with a logit link
- Outcomes measured at community level: McNemar's test for binary outcomes or a paired t test for normally distributed continuous outcomes

OUTCOME MEASURES
- **Proportion of clients receiving 80% or more of scheduled BPG injections over a minimum 12 month period**
- The proportion of scheduled injections that a client receives over a minimum 12 month period
- The average number of days at risk
- Proportion of clients receiving at least 90% of scheduled BPG injections over a minimum 12 month period
- Proportion of clients receiving 50-79% and <50% of scheduled BPG injections over a minimum 12 month period
- Recurrence rate and proportion of acute rheumatic fever (ARF) episodes that are recurrences, compared to non-participating communities and to the whole jurisdiction
- Improvement in delivery of other services for RHD clients
- Effect of the programme on delivery of other routine services
- Impact of the intervention on RHD clients' experience of care including their perception and understanding of the disease and its management

OUTCOMES
Improved delivery and uptake of SP by ARF/RHD clients

IMPACT
Reduction in ARF recurrence

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