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-week penicillin injection for 10 years after the last ARF episode or until age 21, whichever is longer

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

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

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

<table>
<thead>
<tr>
<th>Month</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
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</thead>
<tbody>
<tr>
<td>Site 1</td>
<td>May</td>
<td>Apr</td>
<td>May</td>
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<td>Site 2</td>
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<tr>
<td>Site 6</td>
<td>May</td>
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**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

**THE INTERVENTIONS’ PROGRAMME THEORY**

<table>
<thead>
<tr>
<th>DELIVERY SYSTEM DESIGN</th>
<th>DECISION SUPPORT</th>
<th>CLINICAL INFO SYSTEM</th>
<th>COMMUNITY SUPPORT</th>
<th>SELF MANAGEMENT SUPPORT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activities</td>
<td>Activities</td>
<td>Activities</td>
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<tr>
<td>Improve effective &amp; proactive care for ARF/RHD clients</td>
<td>Improve the organisation &amp; care of clients to facilitate effective care</td>
<td>Mobilise community members to support ARF/RHD clients to adhere to SP</td>
<td>Empower ARF/RHD clients to become management champions</td>
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**DETERMINANTS:**

- 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

**OUTCOMES:**

- Improved delivery and uptake of SP by ARF/RHD clients
- Reduction in ARF recurrence

**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?

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

**THE INTERVENTION’S PROGRAMME THEORY**

<table>
<thead>
<tr>
<th>ELEMENT</th>
<th>OUTCOMES</th>
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<tbody>
<tr>
<td>Expected Outputs</td>
<td>IMPACT</td>
</tr>
<tr>
<td>Informed &amp; engaged ARF/RHD clients</td>
<td>Reducing in RHD recurrence</td>
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<tr>
<td>More prepared and proactive practice teams</td>
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**OUTCOMES MEASUREMENT:**

- 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% <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

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