CRE in Prevention of chronic conditions in rural and remote high risk populations
2012-15

DoH Roundtable,
Canberra December 4 2014
Robyn McDermott

The research reported in this presentation is a project of the Australian Primary Health Care Research Institute, which is supported under the Australian Government’s Primary Health Care Research, Evaluation and Development Strategy. The information and opinions contained in it do not necessarily reflect the views or policy of the Australian Primary Health Care Research Institute or the Department of Health and Ageing.
Today...

- Overview of the APHCRI-funded CRE
- Focus on intervention trials and methodological issues
- Examples from a CRE trial
- Dealing with sudden unpredicted changes in the policy environment
  - Change of government
  - Change of management
Chronic disease in rural and remote areas

• High rates of diabetes, heart and renal disease, preventable complications in remote and Indigenous communities
• Evidence for effectiveness of Primary Health Care based interventions which:
  o Prevent progression of established disease (reduce hospitalisations)
  o Prevent onset of new disease
• Different approaches in different communities (resident outreach, clinical and health promotion staff)

How do these various models of care translate into improved health outcomes for clients?
Research theme 1: Nutrition and physical activity opportunities

Research theme 2: Substance misuse and mental health

Research theme 3: PHC Management of diabetes, renal CVD and Mental Health

Prevention

PHC Model and Implementation Fidelity

Cohort studies

Economic evaluation

Policy analysis

Workforce analysis

Management
Translating research into policy

• Through interventional and observational research demonstrate the impact on health and patient-important outcomes of different models of PHC and community-based prevention on chronic disease risk

• Over time, evaluate place-based interventions on chronic disease risk factors and avoidable hospitalisations in large cohorts utilising record linkage

• Evaluate these models using economic and other mixed methods approaches, including workforce implications
A systems approach to improving health outcomes in individuals with chronic conditions in rural and remote settings: lessons from a “failed” trial

Robyn McDermott
Seminar, Commonwealth DoH Canberra
December 4, 2014
Intervention trials in health services: Pragmatism and serendipity

• What’s special about Health Services Research
• Methodological issues
• Example of “Getting better at chronic care” trial
• What if the trial fails?
  – Theory is wrong
  – Power is insufficient
  – Implementation failure (type 3 error)
What’s special about health services (and much public health) research?

• Interventions are complex
• Settings are complex
• Standard control groups may not be feasible/ethical/acceptable to services and/or communities
• “Contamination” is a problem
• Unmeasured bias/confounding
• Secular behaviour and policy change over time can be strong, sudden and unpredictable
• Context is very important but often poorly described
• Example of the DCP
“Improving reporting quality”
checklists

• CONSORT: RCTs with updates for cluster RCTs
• TREND: Transparent Reporting of Evaluations with Non-randomised Designs (focused on HIV studies initially)
• PRISMA: Reporting systematic reviews of RCTs
• STROBE: Reporting of observational studies
• MOOSE: Reporting systematic reviews of observational studies
Complex interventions

• Review of RCTs reported over a decade
• Less than 50% had sufficient detail of the intervention to enable replication (*Glasziou, 2008*)
• Even fewer had a theoretical framework or logic model
• Systematic reviews of complex interventions often find small if any effects, or contradictory findings. This may be due to conflating studies without taking account of the underlying theory for the intervention (eg Segal, 2012: Early childhood interventions)
Getting Better at Chronic Care (GBACC) in North Queensland: a cluster RCT of community health worker care coordination in remote FNQ settings

Robyn McDermott, Barbara Schmidt, Cilla Preece, Vickie Owens, Sean Taylor, Adrian Esterman, Ashim Sinha, Mark Wenitong
Problem

• >60% life expectancy gap due to chronic diseases
• High burden of obesity, T2DM, incidence of complications especially renal, vascular disease: (T2DM Prevalence 43% adults, incidence 3% per year)
• Glycemia, albuminuria driving CVD incidence and mortality *
• Better PHC based secondary prevention is key in those with established disease

*(McDermott et al, MJA, 2011)*
Study hypotheses

That individualised care of adults with complex poorly controlled T2DM by *community-based IHWs* will improve:

• Care Processes (GPMP, TCA, ACC),
• Clinical control (HbA1c, BP, Lipids);
• And reduce diabetes-related complications (hospitalisations) over 18 months
Does having IHW-led case management lead to an improvement in care processes, appropriate therapeutic action and clinical outcomes for Indigenous adults with poorly controlled diabetes over 18 months?

**GBACC Program logic:** IHWs will facilitate GPMP (1) which should generate a further set of activities (checks) in the annual cycle of care (ACC) (2), followed by appropriate therapeutic action (3), which should lead to improvement in clinical outcomes (4) and reduced avoidable hospitalisations (5).

*(1), (2) and (3) are brokered by the IHW, indicating better client engagement.*
GBACC: mixed methods evaluation in 3 phases

Phase 1 (Intervention period: March 2012 – Sept 2013)
- Randomised controlled trial of intensive case management by IHWs
- Process evaluation of model of care

Phase 2 (Nov 2013 – Feb 2014)
- Review of lessons learned
- Implementation plan

Phase 3 (May 2014 – June 2015)
- Economic analysis
- Rollout of model
12 Participating Communities
*Intervention sites in phase 1 (randomly allocated)

Torres and NPA HHS
- Badu*
- Bamaga
- Injinoo*
- New Mapoon
- Seisia
- Umagico*

Cape York HHS
- Kowanyama*
- Mapoon*
- Mareeba (Mulungu)

Cairns and Hinterland HHS
- Mossman Gorge (ACYHC)*
- Napranum
- Yarrabah (GYHS)
Enrolment: 12 sites recruited and 327 patients assessed as eligible

Baseline data collected, n=213

Excluded: 114 patients declined to participate

Group randomisation: 12 sites

Allocation

Intervention: 6 sites (n=100 patients)
Received intervention, n=100

Lost to follow-up (n=16)
• Moved away (12)
• Died (4)

Analysed for primary outcome, n= 84 (84%)

Analysis

Allocated to waitlist group: 6 sites (n=113 patients)

Follow up

Lost to follow up (n=6)
• Moved away (3)
• Died (2)
• Withdrew from study (1)

Analysed for primary outcome, n=108 (96%)
## Baseline socio-demographic characteristics of study participants (SD or %)

<table>
<thead>
<tr>
<th></th>
<th>Control (95% CI)</th>
<th>Intervention (95% CI)</th>
<th>All (95%CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of participants</td>
<td>113</td>
<td>100</td>
<td>213</td>
<td></td>
</tr>
<tr>
<td>Mean age (years)</td>
<td>47.8 (46.2-49.5)</td>
<td>47.9 (45.8-50.0)</td>
<td>47.9 (46.6-49.2)</td>
<td>0.948</td>
</tr>
<tr>
<td>Number (%) women</td>
<td>66.4 (57.6-75.2)</td>
<td>58.0 (48.2-67.8)</td>
<td>62.4 (55.9-69.0)</td>
<td>0.208</td>
</tr>
<tr>
<td>Unemployed (%)</td>
<td>52.2 (42.9-61.5)</td>
<td>40.0 (30.3-49.7)</td>
<td>46.5 (39.7-53.2)</td>
<td>0.204</td>
</tr>
<tr>
<td>Did not complete 12 years</td>
<td>61.9 (52.9-71.0)</td>
<td>73.0 (64.2-81.8)</td>
<td>67.1 (60.8-73.5)</td>
<td>0.344</td>
</tr>
<tr>
<td>education (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (IQR) household income</td>
<td>17420 (12480-33800)</td>
<td>20215 (13585-31200)</td>
<td>18200 (13000-32500)</td>
<td>0.598</td>
</tr>
<tr>
<td>“Not enough money for food” (%)</td>
<td>40.7 (31.6-49.9)</td>
<td>37.0 (27.4-46.6)</td>
<td>39.0 (32.4-45.6)</td>
<td>0.580</td>
</tr>
<tr>
<td>Median score (IQR) TOFLA</td>
<td>90.0 (81.1-94.1)</td>
<td>80.6 (64.9-89.0)</td>
<td>86.1 (71.5-92.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>No of people per household median (IQR)</td>
<td>5 (3-7)</td>
<td>4 (3-7)</td>
<td>4 (3-7)</td>
<td>0.608</td>
</tr>
<tr>
<td>Median AQoL mental health score (IQR) max=1</td>
<td>0.93 (0.89-0.98)</td>
<td>0.93 (0.91-0.94)</td>
<td>0.93 (0.89-0.95)</td>
<td>0.688</td>
</tr>
<tr>
<td>Current smoker (%)</td>
<td>37.6 (28.4-46.8)</td>
<td>40.2 (30.3-50.1)</td>
<td>38.8 (32.1-45.5)</td>
<td>0.231</td>
</tr>
<tr>
<td>Mean BMI (kg/m2)*</td>
<td>33.0 (31.2-34.9)</td>
<td>31.9 (29.9-33.9)</td>
<td>32.5 (31.1-33.8)</td>
<td>0.434</td>
</tr>
</tbody>
</table>
Did GBACC improve diabetes care processes?

Care processes (n and % with GPMP, TCA done) at T3 for intervention vs control sites in GBACC among all the participants (N=213) at T3

<table>
<thead>
<tr>
<th>Care process done</th>
<th>Control group n=113</th>
<th>Intervention group n=100</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>% (95% CI)</td>
</tr>
<tr>
<td>GPMP</td>
<td>39</td>
<td>34.8 (25.9-43.7)</td>
</tr>
<tr>
<td>TCA</td>
<td>39</td>
<td>34.8 (25.9-43.7)</td>
</tr>
</tbody>
</table>

Intervention sites were 26% more likely to have implemented a GPMP at T3, however this did not reach statistical significance (Odds Ratio = 1.26, 95% confidence interval 0.72-2.22):
### Clinical care processes at baseline and follow up (%)

<table>
<thead>
<tr>
<th>Process</th>
<th>Baseline Control n=113</th>
<th>Baseline Intervention n=100</th>
<th>Endpoint Control n=107</th>
<th>Endpoint Intervention n=84</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Foot check %</td>
<td>50 (44.2 (35.0-53.5)</td>
<td>31 (31.0 (21.8-40.2)</td>
<td>38 (35.5 (26.3-44.7)</td>
<td>26 (31.0 (20.9-41.0)</td>
</tr>
<tr>
<td>Seen by DM educator %</td>
<td>46 (40.7 (31.6-49.9)</td>
<td>52 (52.0 (42.1-61.9)</td>
<td>41 (38.3 (29.0-47.6)</td>
<td>44 (52.4 (41.6-63.2)</td>
</tr>
<tr>
<td>Seen by dietician %</td>
<td>22 (19.5 (12.1-26.8)</td>
<td>30 (30.0 (20.9-39.1)</td>
<td>21 (19.6 (12.0-27.2)</td>
<td>37 (44.0 (33.3-54.8)</td>
</tr>
<tr>
<td>Dentist check %</td>
<td>20 (17.7 (10.6-24.8)</td>
<td>13 (13.0 (6.3-19.7)</td>
<td>9 (8.4 (3.1-13.7)</td>
<td>15 (17.9 (9.6-26.5)</td>
</tr>
<tr>
<td>ECG check %</td>
<td>37 (32.7 (24.0-41.5)</td>
<td>42 (42.0 (32.2-51.8)</td>
<td>34 (43.9 (34.4-53.4)</td>
<td>35 (40.5 (29.8-51.1)</td>
</tr>
<tr>
<td>Eye check %</td>
<td>54 (47.8 (38.5-57.1)</td>
<td>42 (42.0 (32.2-51.8)</td>
<td>56 (52.3 (42.8-61.9)</td>
<td>37 (44.0 (33.3-54.8)</td>
</tr>
<tr>
<td>Smoker %</td>
<td>38 (34.5 (25.6-43.5)</td>
<td>34 (35.1 (25.5-44.7)</td>
<td>33 (31.2 (22.4-40.4)</td>
<td>34 (41.5 (30.7-52.2)</td>
</tr>
<tr>
<td>Blood sugar self-monitor %</td>
<td>45 (40.9 (31.6-50.2)</td>
<td>46 (46.0 (36.1-55.9)</td>
<td>63 (59.4 (50.0-68.9)</td>
<td>44 (52.4 (41.6-63.2)</td>
</tr>
<tr>
<td>Taking insulin %</td>
<td>55 (48.7 (39.4-58.0)</td>
<td>40 (40.0 (30.3-49.7)</td>
<td>47 (43.9 (34.4-53.4)</td>
<td>40 (47.6 (36.8-58.4)</td>
</tr>
<tr>
<td>Dyslipidemia %</td>
<td>83 (73.5 (65.2-81.7)</td>
<td>84 (84.0 (76.7-91.3)</td>
<td>91 (85.0 (78.2-91.9)</td>
<td>76 (90.5 (84.1-96.8)</td>
</tr>
<tr>
<td>Taking lipid lowering medicines %</td>
<td>5 (4.4 (0.6-8.3)</td>
<td>3 (3.0 (-0.4-6.4)</td>
<td>3 (2.8 (-0.4-6.0)</td>
<td>5 (6.0 (0.8-11.1)</td>
</tr>
<tr>
<td>Albuminuría and taking ACEi or ARB drugs</td>
<td>46 (88.5 (79.6-97.3)</td>
<td>47 (88.7 (80.0-97.4)</td>
<td>58 (82.9 (73.9-91.8)</td>
<td>51 (89.5 (81.4-97.6)</td>
</tr>
<tr>
<td>Adherent to all medicines</td>
<td>53 (46.9 (37.6-56.2)</td>
<td>55 (55.0 (45.1-64.9)</td>
<td>57 (53.3 (43.7-62.8)</td>
<td>41 (48.8 (38.0-59.6)</td>
</tr>
<tr>
<td>Had Fluvax %</td>
<td>50 (44.2 (35.0-53.5)</td>
<td>66 (66.0 (56.6-75.4)</td>
<td>51 (47.7 (38.1-57.2)</td>
<td>50 (59.5 (48.9-70.2)</td>
</tr>
</tbody>
</table>
Clinical measures: 212 Indigenous adults with poorly controlled T2DM, baseline and follow-up at 18 months

<table>
<thead>
<tr>
<th>Measure</th>
<th>Baseline</th>
<th></th>
<th>Endpoint (excluding 22 lost to follow-up)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control</td>
<td>Intervention</td>
<td>Control</td>
<td>Intervention</td>
</tr>
<tr>
<td></td>
<td>n=113</td>
<td>n=100</td>
<td>n=107</td>
<td>n=84</td>
</tr>
<tr>
<td></td>
<td>No.</td>
<td>Mean SD</td>
<td>No. Mean SD</td>
<td>No. Mean SD</td>
</tr>
<tr>
<td>HbA1c</td>
<td>113</td>
<td>10.6 1.87</td>
<td>99 10.8 2.0</td>
<td>105 10.3 2.2</td>
</tr>
<tr>
<td>Total Cholesterol</td>
<td>87</td>
<td>4.6 1.3</td>
<td>81 4.5 1.3</td>
<td>100 4.7 1.3</td>
</tr>
<tr>
<td>Trig</td>
<td>86</td>
<td>2.5 1.9</td>
<td>81 2.1 1.4</td>
<td>100 2.7 1.8</td>
</tr>
<tr>
<td>HDL</td>
<td>72</td>
<td>1.1 0.6</td>
<td>79 0.9 0.2</td>
<td>99 0.9 0.2</td>
</tr>
<tr>
<td>LDL</td>
<td>65</td>
<td>2.6 1.0</td>
<td>76 2.7 1.1</td>
<td>95 2.6 1.1</td>
</tr>
<tr>
<td>Weight</td>
<td>89</td>
<td>91.4 19.3</td>
<td>87 89.7 22.6</td>
<td>92 87.4 18.6</td>
</tr>
</tbody>
</table>


HbA1c measures at baseline and follow-up by group, absolute values

Baseline
Control: 10.5
Intervention: 11.0

Endpoint
Control: 11.0
Intervention: 9.5
GBACC hospitalisations per person year for intervention and control sites (2011-2013)
Did GBACC have an impact on acute, diabetes-related hospitalisations?

<table>
<thead>
<tr>
<th>Hosp category</th>
<th>Control T1</th>
<th>Control T3</th>
<th>Intervention T1</th>
<th>Intervention T3</th>
</tr>
</thead>
<tbody>
<tr>
<td>DM complications as principal Dx</td>
<td>162</td>
<td>175</td>
<td>134</td>
<td>129</td>
</tr>
<tr>
<td>Pyelonephritis</td>
<td>9</td>
<td>7</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Cellulitis</td>
<td>10</td>
<td>14</td>
<td>10</td>
<td>6</td>
</tr>
<tr>
<td>Gangrene</td>
<td>3</td>
<td>8</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Subtotal DM complications &amp; acute severe infections</td>
<td>184</td>
<td>204</td>
<td>153</td>
<td>144</td>
</tr>
<tr>
<td>% change from baseline (95% CI)</td>
<td>+11% (6.1 - 18.8)</td>
<td></td>
<td>-6% (-2.5 to -12.7)</td>
<td></td>
</tr>
</tbody>
</table>

Hospitalisations for acute infections and DM complications were decreased by 6% in the intervention group but increased by 11% in the control sites.
Was there evidence of Implementation Failure (type 3 error)?

Implementation fidelity was assessed from HW reports and interviews with staff

- Major issues with Doctors doing GPMPs
- Major issues with IHWs being pulled into mainstream acute work
- Major issues with IHWs getting access to clients’ electronic records
- ACC could have been improved if IHWs could initiate pathology testing
- Around half clients in the intervention group were “difficult to engage” according to IHW reports
Effectiveness will vary by Context

Context elements can include

- Host organization and staff
- System effects (e.g., funding model, use of IT, chronic care model for service delivery)
- Target population
- Policy environment e.g., major perturbations caused by change of government
Acknowledgements

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