CRE Theme 3: Improving primary level chronic care

Economic evaluation alongside a cluster-randomised-controlled trial of intensive management by Indigenous Health Workers of Indigenous people with poorly controlled type 2 diabetes in remote Australia

Was “Getting Better at Chronic Care” cost effective?

Robyn McDermott, Emily Callander, Leonie Segal, Ha Nguyen, Mark Wenitong

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Professor Robyn McDermott

James Cook University

Cairns Qld 4870 Australia

T +61 7 4232 1604

E robyn.mcdermott@jcu.edu.au

http://www.ccdp.jcu.edu.au

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Background

Diabetes and its related complications create significant burden to the health system in Australia. Between 2000/01 and 2008/09, total health expenditure on diabetes increased by 86% to $1,507 million or 2.3% of total health expenditure in 2008/09.1 This increase was 26% more than the increase in total health expenditure.[1]

Indigenous Australians experience a disproportionally high burden of diabetes, responsible for 12% of the large gap in disability-adjusted life years between Indigenous and non-Indigenous people.[2] Indigenous Australians also have higher rates of hospitalisation for diabetes (3.4-5.0 times higher) and higher mortality rates (7.0 times higher) than non-Indigenous Australians.[3] Indigenous Australians are also more likely to develop type 2 diabetes at an earlier age.[4] It is well-established that persistent high blood glucose levels result in organ damage, resulting in renal complications, circulatory and ophthalmic conditions. Indigenous Australians experience exceptionally high rates of complications, including 11.2 times the rate of hospitalisation for renal failure[4] and less effective care partnerships with their clinicians.[5] It is therefore important to develop clinical programs to support the better management of diabetes and its complications for Indigenous people.

It was hypothesised that Indigenous Health Workers (IHWs), who are close to the community linguistically and culturally, could play an important role in improving the quality of primary health care for Indigenous Australians and contribute to better health outcomes. A trial of a recall system in remote Indigenous communities managed by local IHWs supported by a diabetes outreach service reported improved diabetes care and lower hospitalisations.[6,7] A 2006 study on the delivery of diabetes care in remote Indigenous communities found that employing more IHWs was independently associated with improved diabetes care, but not better HbA1c control.[8] Further testing of the role of IHW was indicated.

The Getting Better At Chronic Care Project (GBACC) was a cluster-randomised-control trial (cluster-RCT) designed to improve the care of persons with poorly controlled diabetes living in 12 rural and remote Indigenous communities in north Queensland. Participants in the six intervention communities received in addition to standard primary care, intensive chronic condition management for 18 months delivered by IHWs, who had a Certificate level 3 or 4 in Aboriginal and Torres Strait Islander Primary Health Care, which covers a broad spectrum of primary health care work. These IHWs received additional training in diabetes management and intensive support from the clinical support team. The model was family-centred and based on community out-reach. Control (usual care, UC) communities received care as usual from a centre-based primary care team (nurses, GPs, IHWs etc.), but involving less intensive IHW support. Service configurations vary somewhat across the communities.[9] Primary clincial results, which found a modest improvement in glycemic control in the intervention sites compared to controls, have been published elsewhere.[10] A process evaluation concluded that there was significant implementation failure during the 18-month intervention phase, largely as a consequence of unforeseen service disruptions due to major restructure of services provided by Queensland Health in five of the six intervention sites. While this was also an issue in three of six control sites, the IHW model required an effective working relationship between the IHW and other members of the clinical team which was undermined by the service disruptions.[11]

This paper reports on two economic evaluations of the GBACC project. The first evaluation completed a cost-consequence analysis, in which the costs of implementing the model are compared with differential changes in a range of health outcome measures of study participants in the intervention and usual care groups.

The second economic evaluation looked at hospitalisations related to diabetes, especially those which had been shown in previous reports to be excessive among remote Indigenous adults, mostly acute preventable diabetes-related infections and complications.

THE INTERVENTION

Each site allocated to the intervention arm recruited an Indigenous Health Worker resident in the community (selected by the health service) to work as part of the primary care team, and allocated a caseload of between 9 and 26 clients. The health workers with low caseloads worked part-time. All health workers at the commencement of the study received an intensive 3-week training in clinical aspects of diabetes and other chronic condition care, including how to support patients in self-management skills, advice on medications, routine foot care, nutrition, smoking cessation, follow up referrals to other providers, and scheduled tests. The roles of the health workers included helping patients make and keep appointments, understand their medications and nutrition and the effects of smoking and where appropriate, work with the family to help support the patient in self-management. Home visits and out-of-clinic care were a feature of the trial, however visits were conducted according to the patients' preferences.

The curriculum included specific training and practice in:

- Rationale for the chronic care model and evidence-based management and treatment goals in diabetes, hypertension, COPD, renal disease and CHD
- Hands-on case management, supported by the clinical team
- Working in a primary care team, with clear roles and responsibilities of team members
- Engaging with families and using local resources to support effective client self-management.

During the 18-month intervention period, the health workers attended two workshops where they underwent refresher training, including in Good Clinical Practice and reflective practice. During these sessions, they reported on their patients' progress and shared approaches to problem solving with the clinical support team and peers. In addition, the CHWs kept an activity log and prepared monthly activity reports.

IMPLEMENTATION

All planned training (initial three weeks clinical training, 6-monthly in-service training), weekly teleconferences and scheduled outreach visits by the clinical support team were performed. All trial community health workers were employed by the existing health service in the participating intervention sites, as part of the primary care team. During the early phase of the trial, the Queensland Government health services underwent a radical restructure, including the loss of many clinical and service support positions. These changes affected eight of the 12 trial sites, including four in the intervention group. The immediate impact of these changes was a shortfall in clinic staff in many sites, especially the smaller sites, and extensive delays in replacing key staff when they left. This often meant that the health workers in the study were called upon to undertake other clinical work apart from their assigned clients in the trial. Other effects of the restructure were manifest in a shortfall in visiting specialist services, including diabetes-related staff, which potentially impacted on the rate of referrals and uptake of these services during the trial implementation phase.

MEASURES

The primary outcome measure, glycaemic control (HbA1c) was measured by Queensland Medical Laboratories using standard high-pressure liquid chromatography methods. Secondary outcomes included changes from baseline in blood pressure, height, weight, serum fasting lipids (cholesterol fractions and triglycerides) and urinary albumin creatinine ratio (UACR) and were abstracted from clinic files and electronic records. Taking insulin was defined as having any of long-acting, medium- or short-acting insulin. Albuminuria was defined as urinary ACR≥3.4 (albumin to creatinine ratio or urine microalbumin).

The Test of Functional Health Literacy for Adults (TOFHLA) was administered at study enrolment to all participants to gauge the patients' general understanding of health messages and procedures. In general, TOFHLA was scored highly in both groups, and it was concluded that they would not have major difficulty working with the diabetes care team.

Quality of Life was estimated using the Assessment of Quality of Life (AQoL) instrument, a multi-attribute utility instrument developed using Australian importance weights. Socio-demographic data was by self-report, including years of formal education, household income, employment, food insecurity ("Do you frequently not have enough money to buy food?"), current smoking and medication adherence.

Process measures included guideline-recommended clinical checks, including General Practitioner Management Plans (GPMP) and specialist referrals [13], and were abstracted from primary care records at follow-up for the previous 18 months. For patients with clinical indications, appropriate medication use was recorded, including oral hypoglycaemic agents, insulin, statins, ACEi (angiotensin-converting-enzyme inhibitor), or angiotensin receptor blockers (ARB) or blood pressure control drugs, and vaccination.

The intervention was implemented between March 2011 and September 2012. The participant flow diagram is summarized in Figure 1.

CLINICAL RESULTS OF THE TRIAL

At baseline, there were no significant differences between allocation groups in age (mean age 47.9 years), sex ratio (62% women), employment status, years of schooling, median household income, self-reported food insecurity, household size, median AQoL score on the mental health scale, smoking prevalence, HbA1c (10.7%) and mean BMI (32.5). The intervention group scored lower on the health literacy test.

At follow-up, 45.2% (95% CI, 34.5-56.0%) of patients in the intervention group had a current GP Management Plan (GPMP) for diabetes compared to 35.5% (26.3-44.7) in the waitlist group (OR 1.23, 95%CI, 0.72-2.22). There was no association between having a GPMP at follow-up and HbA1c change from baseline. This may be due to the fact that many GPMPs were done within six months of the follow-up data collection point, so the chance for the GPMP to have an immediate impact would be small. Further follow up may show a stronger relationship between having a GPMP and improved clinical indicators.

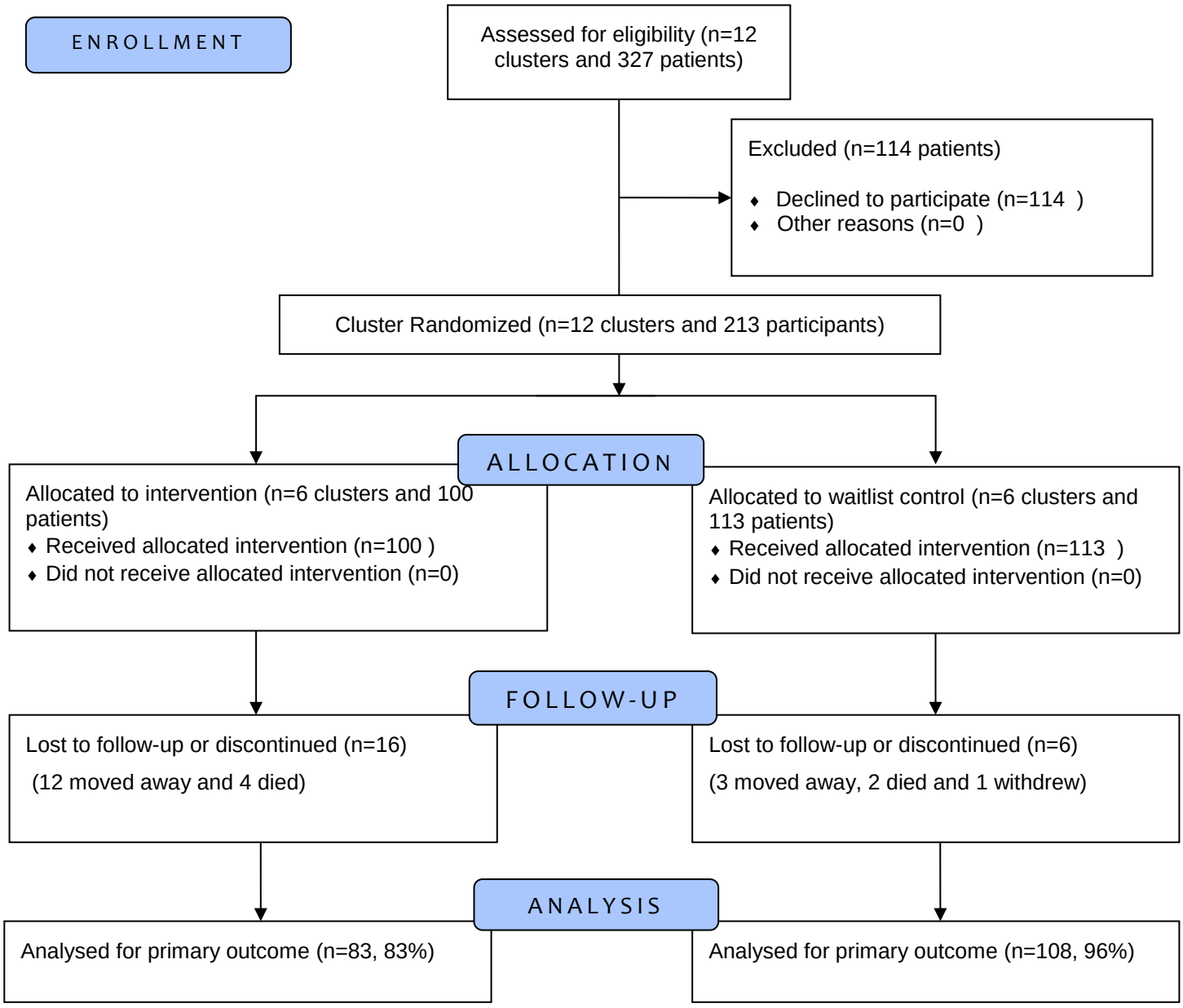
Other clinical care processes, including routine checks and specialist referrals, medications and self-reported smoking and medication adherence were completed at baseline and follow-up. Intervention group patients were significantly more likely to have seen a dietician and dentist and slightly more likely to have seen a diabetes educator, be taking insulin and having influenza vaccination. Waitlist group patients showed greater self-reported adherence to prescribed medicines and were slightly more likely to have had an eye examination and be self-monitoring for glucose. Despite very high rates of dyslipidaemia there was generally very low uptake of lipid lowering treatment in both groups, and the high smoking rates were unchanged. Appropriate management of albuminuria was high in both groups.

There was a significant decrease in HbA1c of 1% from baseline in the intervention group, from 10.8% (95mmol/mol) to 9.8% (84mmol/mol) compared to the waitlist group, which showed a less marked decrease of 0.2% from 10.6% (92mmol/mol) to 10.3% (89mmol/mol), (p=0.018) and based on the GEE model. More people in the intervention group achieved at least a 0.5% interval reduction in HbA1c (67.5%, 57.3-77.7) than in the waitlist group (48.6%, 38.9-58.2). There were small improvements in both groups for total cholesterol, LDL cholesterol, cholesterol:HDL ratio, with slightly better results in the intervention group. Blood pressure and weight decreased in the waitlist group and increased slightly in the intervention group. None of these effects were statistically significant at the 5% level.

The impact of Health Service Model (community controlled (CC) versus not CC) on the likelihood of a participant having a GPMP was explored independently of whether the trial site was in the intervention or the control group allocation. The percentage of GPMPs completed in sites with a community-controlled service was 71.0% compared to 23.5% among the non-CC sites (OR = 3.0, 95% confidence interval, 1.2-7.5 after adjustment for clustering) (Table 5). However there were no differences in clinical measures between CC and non-CC sites at follow-up.

In summary, the trial suffered from implementation failure in many of the intervention sites, and overall achieved a modest improvement in glycaemic control in the HW-led model compared to usual care.

Figure 1: CONSORT Flow Diagram: Getting Better at Chronic Care Cluster RCT



Methods: First economic evaluation

The first evaluation conducted an economic analysis alongside a cluster-RCT. Details of the trial design, participants, sample size, outcomes and ethics approvals are described elsewhere.[9] Briefly, study participants were Aboriginal and Torres Strait Islander (TSI) adults with poorly controlled T2DM (HbA1c≥ 8.5%) and at least one other chronic condition. The primary clinical goal was a differential mean reduction in HbA1c of 1.0% over the trial (IHW compared to UC).

MEASUREMENT OF COSTS

We calculated the per-person cost to implement the intervention, drawing on project costing records. The primary task was to allocate costs between i) service delivery/support and ii) management and evaluation activities related to the task of running a trial. Costs were separately analysed for the central team and the IHWs.

Costs for the central team

Costs for the central team included,

- Expenses relating to the trial manager and the clinical support team who were responsible for IHW training (developing training materials, training delivery)
- Enhancing the quality of clinical practice through mentoring, advocacy and reflective practice with IHWs, convening IHW meetings, clinical reference group meetings and team meetings
- Evaluation as an embedded component (data collection, data entry, conference presentations, workshops), and
- Coordination of project activities including chief investigator and management group meetings.

Costs were extracted from project financial reports between 01/01/2011 (commencement of the project with trial set up) and 30/09/2013 (trial endpoint). The percentage of time the manager and the clinical support team allocated to the trial *versus* the evaluation were determined by the trial manager (BS), after detailed discussion with LS and HN about the type of activities to be classed as intervention or non-intervention, (evaluation and trial coordination activities).

IHW Salaries (including wage on-costs)

Salaries in the six intervention communities were identified from project records. The percentage of IHW time allocated to intervention participants and non-intervention activities was determined from detailed time logs kept by the IHWs. The IHW cost was the sum of the product of total wage costs and percentage of time allocated to the project by each IHW.

MEASUREMENT OF OUTCOMES

The primary outcome for the clinical trial was the differential change in HbA1c comparing IHW and UC after 18 months of trial delivery. HbA1c measurements were extracted from participants' clinical files. The baseline value was the HbA1c measure closest to the participants' recruitment date and the endpoint was the one closest to the trial endpoint. For the economic evaluation, we also explored the distribution of HbA1c, given the limitations of using the mean to describe a distribution. Thus we also estimated HbA1c outcomes in terms of shift in number with 'moderate', 'poor' and 'extremely poor' control (as described below), given a relationship between level of control and health consequences.

Secondary study outcomes included differential change in quality of life score, disease progression and rates of hospitalisation. Quality of life was measured by the Assessment of Quality of Life 4D (AQoL-4D), which has four dimensions (independent living, relationships, mental health and senses), each with three items and four levels. The AQoL was developed in Australia and the algorithm to estimate the utility score was derived from an Australian population.[12] Its use in an Australian Indigenous population has not been validated.

Disease progression was assessed by allocating a disease stage to each participant using a diabetes severity staging instrument developed by Gibson et al.[13]

The instrument classifies diabetes into four stages,

1) T2DM with no evidence of microvascular or macrovascular risk factors
2) T2DM with screen-detected microvascular comorbidities and/or risk factors for macrovascular disease
3) T2DM with moderate microvascular or macrovascular complications, and
4) Late stage T2DM microvascular or macrovascular complications.

The instrument uses clinical markers and hospitalisation data to allocate each study participant to a disease stage. For *baseline* disease stage, we drew on baseline clinical data and hospitalisations between 01/07/2010 and 01/03/2012 and for *endpoint* disease stage clinical data and hospitalisations between 01/03/2012 and 05/09/2013. The disease stages are defined to be monotonic. Once allocated to a stage, there is no possibility of reverting to a less severe disease stage.

Hospitalisation data were derived from the Queensland Hospital Admitted Patients Data Collection which covers all patient separations (discharges, deaths and transfers) from all recognised public and licensed private hospitals in Queensland.[14] Data were obtained for all inpatient episodes for study participants discharged between 01/07/2010 and 05/09/2013. This covered all inpatient discharges during a 19-20 month pre-intervention period and 18 months concurrent with the intervention. Hospitalisations were categorised into four groups based on ICD 10 codes,

- All hospitalisations
- Hospitalisations with principal or other diagnoses related to T2DM ("E11" code in the principal or other diagnoses)
- Ambulatory Care Sensitive (ACS) hospitalisations related to chronic disease (used by the AIHW to estimate ACS hospitalisations for Aboriginal and Torres Strait Islander people[15], and
- The top three ACS condition categories (T2DM principal diagnosis, Cardiovascular diseases (CVD) and Infections).[16] Hospital costs were taken from the same records, and were length of stay adjusted DRG costs.[17]

STATISTICAL ANALYSES

The statistical analysis was conducted on an intention-to-treat basis and in accordance with current guidelines for clinical and economic analysis alongside a cluster-RCT to measure differential costs and consequences.[18] We adopted methods that take into account the clustering (within community) and correlation of cost and outcome data. Among available methods for economic analysis of cluster-RCT[19], we applied the linear multilevel models (MLMs). MLMs acknowledge clustering by including additional random terms, which represent the differences in the cluster mean (costs and outcomes) from the overall means in each intervention group. MLMs are efficient, provide good coverage for confidence interval of estimates and are applicable to RCTs with less than 10 clusters in each trial arm.[18] Analyses were undertaken using Stata 12.0.

We used a Markov model to describe disease progression for the IHW and UC group. The probability of staying in the current state or moving to a more severe disease stage between baseline and endpoint is estimated and presented in a transition matrix. This is a simple way of presenting rate of disease progression and testing for any effect of the intervention.[20]

Results: First economic evaluation

There were 100 participants enrolled in the IHW group and 113 in the UC group. Of these, 87 in the IHW and 106 in the UC group met the study inclusion criteria of HbA1c equal or greater than 8.5%. Table 1 shows some demographic characteristics and risk factors at baseline for participants who met the inclusion criteria. There were no statistically significant differences between the two groups at baseline in terms of age, BMI, smoking or alcohol use.

Table 1. Baseline characteristics of study participants

	Usual care (N=106)		**IHW (N=87)**		**p-value**
	n	**% or mean** (SD)	**n**	**% or mean** (SD)	
Age in years (mean)	106	47.6 (8.7)	87	47.5 (10.6)	0.958*
BMI (mean)	43	32.6 (6.2)	44	31.2 (6.3)	0.522*
Female (%)	70	66.0	53	60.1	0.533^
Daily smoker (%)	38	37.3	34	40.5	0.654^
Current drinker (%)	39	40.7	36	45.6	0.511^
Obesity – BMI ≥ 30 (%)	28	65.1	23	52.3	0.280^

*Notes: * p-values of t-test for equal means in IHW and usual care groups taking into account clustering*

^ p-values of chi-square test of equal proportions in IHW and usual care groups taking into account clustering

COSTS OF THE INTERVENTION

All expenditure from the commencement of the project to the trial endpoint is summarised in Table 2. Total expenditure was $1,991,904, of which $1,006,027 was attributed to intervention delivery. The remaining costs were allocated to research and other non-intervention activities. Total salaries (including wage on-costs) for the IHWs were $690,989. Three IHWs were employed full-time and three part-time. After adjusting for IHW involvement in other activities (between 6% and 56% of their time); the cost for the IHWs attributed to the intervention was $522,421. To this is added the attributed costs of the trial manager and clinical support team of $483,606.

With 100 persons receiving the intervention, the average per-person cost of delivering the intervention was $10,060 ($1,006,027 ÷ 100). This represents the best estimate of the costs of rolling out the model incorporating the same elements as the GBACC. Based on an 18-month service delivery period, this is equivalent to $6,707 per-person per year.

Table 2. Total cost estimates – Getting Better at Chronic Care Project

	Total Trial Expenditure	**Time and Cost allocated to GBACC intervention**	
	$	**%^**	**$**
Central (control) team Clinical Support Team	626,091	57	357,353
Management	234,624	10	23,462
Operation	440,200	23	102,791
Sub-Total	**1,300,915**	**37**	**483,606**
Indigenous Health Workers Community A	151,551	78	118,210
Community B	151,551	64	96,993
Community C	75,775	44	33,341
Community D	78,028	89	69,445
Community E	156,056	84	131,087
Community F	78,028	94	73,346
Sub-Total	**690,989**	**76**	**522,421**
Grand total	**1,991,904**	**51**	**1,006,027**

Source: project financial reports

Notes: ^ The allocation of the project team time between research and service delivery was determined by the program manager, reflecting her knowledge of tasks and roles.

Allocation of Indigenous Health Worker (IHW) time to GBACC was based on time records.

EFFECTIVENESS OF THE INTERVENTION

Results of the incremental effectiveness analyses are reported in Table 3. This includes change in mean HbA1c between the IHW and the UC groups between baseline and endpoint and the differential change between the two groups adjusting for clustering. The mean reduction in HbA1c of -0.93% in the IHW group was non-significantly (*p-value=0.17*) greater than that in the UC group of -0.49%. Both groups experienced a slight fall in quality of life with no significant difference (*p-value=0.62*). This is slightly different to the result reported in McDermott *et al.*[10] due to the exclusion of participants who failed to meet the study inclusion criteria in the current analysis.

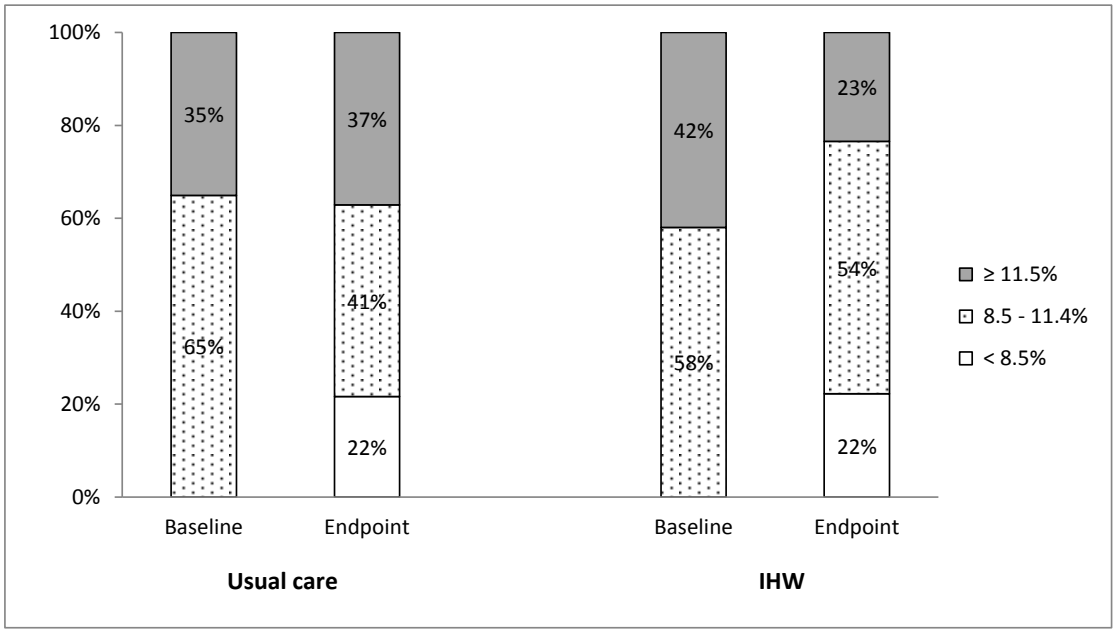
In terms of distribution of HbA1c, there was a statistically significantly reduction in the proportion of participants with extremely poor control HbA1c (≥ 11.5) in the IHW group, (42.0% to 23.5%), compared to a slight increase in the UC group (35.1% to 37.1%) (*p-value=0.002*) (Figure 2). If the change observed in the IHW group had been achieved by the UC group, the expected number of persons with HbA1c ≥11.5% would have been 17 less $(17 = 97 \times 37.1\% - (97 \times 35.1\%) \times \left[\frac{42.0\% - 23.5\%}{42.0\%}\right])$

Table 3. Summary of the incremental effectiveness analyses (change between baseline and trial end)

	Usual care (*n* = 106)			Indigenous health worker-supported (*n* = 87)			Difference of differences† (95% CI)	*P*
	Baseline	Endpoint	Change*	Baseline	Endpoint	Change*		
HbA_{1c} level (SD), mmol/mol	94.7 (19.0)	89.3 (24.1)	–5.4 (*n* = 97)	99.0 (17.4)	88.8 (25.7)	–10.1 (*n* = 81)	–4.7 (–11.6 to 2.1)	0.174
AQoL-4D, mean utility score (SD)	0.80 (0.18)	0.79 (0.21)	–0.01	0.75 (0.18)	0.72 (0.28)	–0.03	–0.02 (–0.08 to 0.05)	0.623
Rate of hospitalisation (per person per year; total number of admissions in parentheses)								
All causes, excluding dialysis‡	1.02 (172)	1.24 (176)	0.22	0.98 (135)	1.07 (124)	0.09	–0.13 (–0.68 to 0.41)	0.633
Type 2 diabetes, any diagnosis§	0.53 (88)	0.92 (128)	0.39	0.47 (64)	0.78 (88)	0.31	–0.08 (–0.20 to 0.03)	0.150
Ambulatory care sensitive								
All¶	0.33 (58)	0.44 (60)	0.11	0.31 (45)	0.30 (36)	–0.01	–0.11 (–1.04 to 0.81)	0.811
Type 2 diabetes as principal diagnosis**	0.15 (26)	0.18 (23)	0.03	0.17 (23)	0.11 (13)	–0.06	–0.09 (–0.18 to 0.00)	0.063
Cardiovascular disease††	0.01 (1)	0.08 (12)	0.07	0.02 (3)	0.04 (5)	0.02	–0.05 (–0.13 to 0.02)	0.149
Infections‡‡	0.13 (21)	0.14 (20)	0.02	0.10 (14)	0.09 (11)	–0.01	–0.03 (–0.10 to 0.04)	0.362
Mean hospitalisation cost (per person per year)								
All causes	$5438	$7421	$1982	$8010	$9866	$1856	–126 (–5024 to 4771)	0.960
Type 2 diabetes, any diagnosis§	$4248	$6582	$2335	$4921	$8595	$3674	1340 (–2724 to 5404)	0.518
Ambulatory care sensitive								
All¶	$1665	$2132	$467	$2967	$2677	–$290	–757 (–2130 to 616)	0.280
Type 2 diabetes as principal diagnosis**	$907	$1245	$338	$1553	$1245	–$308	–646 (–1348 to 56)	0.071
Cardiovascular disease††	$23	$163	$140	$239	$383	$144	4 (–749 to 757)	0.992
Infections‡‡	$623	$609	–$14	$1040	$451	–$589	–574 (–1490 to 342)	0.219

*AQoL-4D = Assessment of Quality of Life 4D score. * Only participants for whom baseline HbA1c levels were measured after 1 January 2009 and endpoint levels after 1 March 2012 were included. † Estimates for incremental difference in outcomes between usual care and IHW groups using linear multi-level models adjusted for within-community clustering. ‡ Two people in the IHW group had dialysis after the intervention commenced (starting July 2012 and March 2013); their dialysis records were excluded. § International Classification of Diseases, revision 10 (ICD-10) code in principal or any other diagnoses starting with E11. ¶ All potentially preventable hospitalisations (ICD code in principal diagnosis: D501, D508, D509, E101–E108, E110–E118, E130–E138, E140–E148, E40–E43, E550, E643, E86, G40, G41, H66, H67, I10, I119, I110, I20, I240, I248, I249, I50, J02, J03, J06, J20, J312, J41–J44, J45, J46, J47, J81, K02–K06, K08, K098, K099, K12, K13, K250–K252, K254, K255, K256, K260–K262, K264–K266, K270–K272, K274–K276, K35–K37, K522, K528, K529, L03, L04, L08, L88, L980, L983, N10–N12, N136, N390, N70, N73, N74, O15, R02 or R56).16 ** ICD-10 code in principal diagnosis starts with E11. †† ICD-10 code in principal diagnosis: I10, I110, I119, I20, I240, I248, I249, J81 or I50. ‡‡ ICD-10 code in principal diagnosis: H66, H67, J02, J03, J06, J312, L03, L04, L08, L980, L88, L983, N10–N12, N136, N390, N70, N73, N74, or R02.*

Figure 2. Distribution of HbA1c categories at baseline and endpoint



Notes: Only participants with baseline HbA1c measured after 01/01/2009 and endpoint HbA1c measured after 01/03/2012 were included (nUC = 97, nIHW=81).

There was no significant difference in the change in any of the hospitalisation categories. Rates of all-cause hospitalisations (excluding dialysis) and T2DM related-any diagnosis increased in both groups; with a small observed difference in favour of the IHW not significant. Ambulatory care sensitive hospitalisations increased slightly in the UC group with rates unchanged in the IHW group. The difference was not statistically significant (*p-value=0.81*). Where diabetes was the primary diagnosis there was a differential net reduction in the admission rate of 0.09/person-year, the only category to approach statistical significance (*p-value*=0*.06*). But the size of effect is small at eight fewer hospitalisations per year across the 87 IHW participants (relative to total admissions of 18 per year). Still, the data suggest a possible small improvement in morbidity.

Annualised hospital costs are also reported in Table 3. Across most categories, a small relative reduction is observed in the IHW group, which only approaches significance for T2DM as primary diagnosis. If this observed reduction in hospitalisations for T2DM were a true result, this would indicate a cost saving of $646 per person per year, a small offset against the intervention cost of $6,700 per person year.

The probability of transitioning into later disease stages (e.g. from stage 2 to stage 3/4, or stage 3 to stage 4) between the baseline and follow-up disease stage allocation (a mean period of 28.5 months) was considerable for both the IHW and UC groups. The observed differences between the IHW and UC group were not statistically significant (*p-value*=0*.73*).

COST-EFFECTIVENESS OF THE INTERVENTION

At an additional cost of just over $6,700 per participant per year with no significant improvement in mean HbA1c, rate of disease progression or QoL; but a significant reduction in hospitalisation for T2DM primary diagnosis yielding an estimated saving of $646, which if true gives a net intervention cost of just over $6,000 per person per year or $9,000 for the 18 month trial. Taking the other significant finding of a reduction in the number of persons with very poorly controlled diabetes this gives a cost of $42,880 per person whose HbA1c moves out of the critically high level of ≥11.5% ($\frac{\$9,000 \times 81}{17}$).

Methods: Second economic evaluation

The main outcome measures for this evaluation were hospitalizations by principle diagnosis (ICD-10), length of stay, hospitalizations for acute infections and acute severe diabetes-related events. Eleven main categories of hospitalizations were generated according to the likelihood of them being affected by the CHW model of care (Table 4).

Table 4. Categories of hospitalisation events for trial participants, 01/07/2010 to 05/09/2013

Group	Group name	ICD-10 codes from Principal Diagnosis field only
1	DM as principal disease	E1173, E1165, E1164, E1169, E1064, E1122, E1172, E1065, E1073, E1135, E1161, E119, E872, I2511 (14)
2	Heart disease, stroke, and hypertension	R074, I214, I500, I200, R073, I209, J81, I210, I64, G459, I208, I211, I10, I212, I238, I259, I269, I440, I489, I501, I629, I634, I639, I802, I841, R001, T828 (27)
3	CKD, other renal disease	N185, Z490, E877, N059, N131, N139, N183, N359 (8)
4	Infections	L0311, N390, J189, M8697, A419, J22, N12, J440, M8667, L024, R509, T8141, A241, B86, J180, K358, L0310, N10, N61, N764, A099, H663, K613, L022, L023, L0302, M0096, M8698, A083, A090, A244, A4151, B349, H664, H700, J100, J853, K750, L028, L033, L088, L732, L989, M0094, M8668, M8688, N730, N750, R508, , T827, T835 (51)
5	Injury, arthritis, myalgia	L97, F100, S6230, T874, F101, M546, S099, T813, G728, H160, H720, H728, M1316, M542, M545, M6096, M6286, M6289, M6787, M751, M7912, S0602, S298, S499, S6188, S6252, S6300, S798, S826, S921, S930, T383, T612, T793, J90, S010, S0269 (37)
6	Cancer, neoplasm	C349, C519, C509, C518, C64, D125, D231, D236, D251, D259, D27, D350, D410, E042, N63 (15)
7	Elective surgery or admission, not diabetes related	H269, R104, Z509, G560, H110, K430, N132, R02, R101, R33, Z488, Z492, E875, H001, H359, H409, H904, K102, K130, M203, M204, N823, S0005, T172, T810, Z433, Z466, Z508, Z598, Z7511 (30)
8	Anaemia, GI symptoms, pancreatitis, gall bladder and liver disease	K2970, K859, D509, K2920, K529, D649, I881, K590, K729, K8050, K810, K811,K852, K922, D508, E611, E780, K219, K2990, K37, K429, K439, K460, K621, K701, K8010, K830, K851 (28)
9	Mental health, neurological problems	R410, R55, F3290, F430, R42, R51, R568, F3220, F432, G518, I951 (11)
10	Obstetric & gynaecological conditions	O2412, O82, N832, N871, N920, N946, O039, O11, O13, O998, Z301 (11)
11	COPD/asthma/other respiratory (non-infections)	J459, J449, R042 (3)

STATISTICAL ANALYSIS

Hospital admissions

This analysis used a baseline “Before” period of 1 July 2010 – 1 March 2012 (20 months) and an intervention “After” follow up period of 2 March 2012 – 1 September 2013.

For this analysis, renal dialysis admissions were excluded as were admissions with ICD code Z763 (Healthy person accompanying sick person). For analysis of the prevalence of admissions (i.e., admitted one or more times), each participant had a single record in the file. For incident admissions, each participant had either a single record showing no admission, or a separate record for each admission, hence each subject could have none, or multiple admissions. In the intervention period, the number of admissions per person ranged from 0 – 24. In the follow up period, the number of admissions ranged from 0 – 26.

Time on trial was estimated as 20 months for the intervention period, less days in hospital, and 18 months in the follow up period less days in hospital. Where the person died (all deaths were in the follow up period), deaths were assumed to have occurred mid-way through the period and the time on trial was halved. Although there were 6 deaths of participants, two occurred after the end of the trial.

Time on trial was summed for all participants including those not admitted to hospital. Although a number of participants were lost to follow up, we were still able to obtain their hospital records as long as any admissions occurred in Queensland. It is likely that this was the case in the majority of those lost to follow up. Analysis was by intention to treat for all participants enrolled.

Prevalence data (admitted at least once) were analysed using a logistic regression model, adjusting for clustering by individual and community and using time on trial as the exposure variable. The model included as independent variables: group, period, and a group-period interaction term, the latter being the formal test of an intervention effect. Incidence data were analysed similarly but using log binomial generalized linear models.

Length of stay (LOS) was analysed for all those admitted to hospital with exclusions as above. Although length of stay is highly skewed, means and SEMs are provided for descriptive statistics to allow for economic modelling. LOS was modelled using a gamma identity generalized linear model, adjusting for clustering by individual and community. The model included as independent variables: group, period, and a group-period interaction term, the latter being the formal test of an intervention effect.

Economic analysis

The time frame for the economic evaluation was the duration of the intervention period, with analysis conducted from a health provider perspective. The number of diabetes acute complications or acute severe infections hospitalisations prevented was chosen as the focal outcome because this is an area of health system performance that could be improved by the trial. Therefore, costs incurred during hospitalisation were not taken into account, rather only the costs of implementing the intervention were considered.

The number of patients needed to be treated (NNT) to prevent one diabetes acute complications or acute severe infections hospitalisation was calculated based upon the Actual Control Rate (ACR) of diabetes acute complications or acute severe infections hospitalisations for patients who underwent usual care; and the adjusted-relative risk (RR) of diabetes acute complications or acute severe infections hospitalisation for the intervention group compared to the control group. The formula used to calculate NNT was:

NNT = (1/(100 x ACR x (1 – RR)))

The incremental cost-effectiveness ratio (ICER) was estimated from the difference between the total cost of the intervention multiplied by the number of patients that needed to be

treated (NNT) to prevent one hospitalization for diabetes acute complication or acute severe infection, where ACR = 81 per 113 = 0.72 and RR = 0.59

Results: Second economic evaluation

Hospital separations were captured for the 20 months prior and the 18 months following commencement of the trial, a total of 370 separations (excluding dialysis) in the control group and 292 separations in the intervention group.

Overall 50.7% of participants were admitted to hospital at least once in the before period, compared to 43.1% in the after period. The intervention group had a 42% increased odds of being admitted one or more times to hospital after allowing for baseline admission prevalence, however, this was not statistically significant (p=0.254).

Compared to baseline, hospital separations at 18 months for all causes per person per year increased in both groups, but with a slightly smaller rise in the intervention group. The intervention group had a 3% increased rate of being admitted for any condition after allowing for baseline admission incidence, however, this was not statistically significant (p=0.696) (Table 5).

For Diabetes as the Principal Diagnosis, at baseline, rates were similar in both groups and remained unchanged in the control group. There was a significant reduction in rates per person year in the intervention group compared to controls (OR 0.20 95% CI: 0.08-0.51). For groups 1 and 4 combined, which represent both diabetes acute complications and acute severe infections, intervention groups were 41% less likely to be admitted (RR 0.59 (95% confidence interval 0.38-0.91), p=0.09) (Table 6). For the four conditions which are directly related to diabetes (groups 1-4 inclusive) the intervention groups were 35% less likely to be admitted (RR 0.64 (0.49-0.85), p=0.002) (Table 6).

For those hospitalisations which were not directly related to diabetes care (groups 5-11) the intervention group had a 226% increased rate of being admitted after allowing for baseline admission incidence, and this was statistically significant (p=0.001) (Table 6). The biggest differences accounting for this observed increase in the intervention group were for elective surgery, cancer, gastro-intestinal complaints and mental health problems.

Cost comparison between intervention and control groups to prevent unnecessary hospitalizations. Based on the above reported RR of 0.59 (95% CI: 0.38 – 0.91) for being admitted to hospital for diabetes acute complications and acute severe infections for the intervention group relative to the control group, the number needed to treat (NNT) was 3 patients treated to prevent 1 hospital admission. The overall intervention cost was AUS$10,060 more per patient than routine care. The incremental healthcare cost to prevent one diabetes acute complication and acute severe infection complication using this intervention was AUS$30,180 (Table 7).

Table 5. Hospitalization episodes by condition group, intervention and control groups (N=617)

	Control group n=351		**Treatment group n=266**		**Total n=617**	
Diagnosis groups	**Before**	**After**	**Before**	**After**	**Before**	**After**
1. Diabetes	28	24	29	13	57	37
2. CVD	9	20	19	27	28	47
3. Renal	4	19	0	7	4	26
4. Infections	50	57	45	30	95	87
5. Injury, arthritis	17	17	13	11	30	28
6. Cancer	8	0	2	7	10	7
7. Elective surgery	30	15	9	15	39	30
8. GI conditions	16	14	8	14	24	28

9. Mental, neurological	4	2	7	7	11	9
10. Obs & Gynecology	7	4	1	1	8	5
11. Respiratory	4	2	1	0	5	2

Table 6. Incident hospital admissions by condition groupings

	Control group		**Intervention group**	
	Before	**After**	**Before**	**After**
Episodes (All)	177	174	134	132
Person days	137990	128717	111715	95825
Incidence Rate (All) / 100,000 person days (95% CI)	128.27 (110.07 – 148.62)	135.18 (115.84 – 156.83)	119.95 (100.50 – 142.06)	137.75 (115.26 – 163.36)
Episodes (Groups 1-4)	91	120	93	77
Incidence Rate (Groups 1-4) / 100,000 person days (95% CI)	65.95 (53.10 – 80.97)	93.23 (77.30-111.48)	83.25 (67.19-101.98)	80.35 (63.42-100.43)
Episodes (Groups 5-11)	86	54	41	55
Incidence Rate (Groups 5-11) / 100,000 person days (95% CI)	62.32 (49.85-76.97)	41.95 (31.52-54.74)	36.70 (26.34-49.80)	57.40 (43.24-74.71)
Episodes (Groups 1 and 4 only)	78	81	74	43
Incidence Rate (Groups 1 and 4 only) / 100,000 person days (95% CI)	56.5	62.9	66.2	44.9

Table 7. Cost-effectiveness estimates (95% CI) for the CHW intervention

Additional total cost ($) per patient	AUS $10,060
Control event risk/population expected event risk for admission for diabetes acute complication and acute severe infection complication	0.42
Relative risk of hospital admission for diabetes acute complication and acute severe infection complication (Groups 1 and 4, 95% CI)	0.59 (0.38 – 0.91)
NNT	3
Cost per hospital admission for diabetes acute complication and acute severe infection complication prevented	AUS $30,180

Discussion

We report here the results of two approaches to an economic evaluation of a pragmatic cluster RCT of a health-worker led care model for Aboriginal and TSI adults who have poorly controlled diabetes in remote Queensland communities. Both approaches use the same costing data but look at different outcomes.

The first analysis looked at a range of clinical and QoL outcome measures, including the primary trial outcome of change in HbA1c as a measure of overall glycemic control, quality of life measures, modelling of disease progression, and hospitalisations overall.

The second economic evaluation looked at the effect on those hospitalisations which would be expected to be impacted upon by the care model and which were shown to be reduced in a previous trial.[26]

The conclusions from the first analysis show a disappointing result where the average per-person cost at just over $6,700 per annum for the intensive IHW intervention (which is additional to regular primary care for medical, nursing, allied health services etc.), is high relative to reported costs of primary care in Indigenous communities in Australia. Gibson *et al*. estimated the mean primary care costs in 21 mainly remote Indigenous communities in north Queensland (including some of the same communities in this trial) at $1,825 in 2004-05, equivalent to ~$2,700 in 2012/13.[21] (This covered IHWs, medical, clinic health workers, nursing, managerial, clerical staff.) The AIHW reported total primary care expenditure per Indigenous person at a similar $2,648 in 2012/13.[22]

A reduction in the number of participants with extremely poor control was also observed in the intervention sites, and it is these individuals who are at very high risk of renal disease and severe acute complications. The second economic analysis showed this effect, and the trial demonstrated a “number need to treat” (NNT) to prevent each such admission of only three, generally regarded as worth doing (if it was a drug trial for example). Participants in the intervention group were 40% less likely to be hospitalized for an acute infection or diabetic complication compared to the control group. The high cost of the intervention in this trial meant that each such admission prevented a cost of around $30,000.

Workshops with service providers suggested that good community ‘buy-in’ was achieved through on-going community engagement with the IHW model building on the Apunipima Cape York Health Council (ACYHC) ‘family-centred’ approach, ACYHC as a partner in the trial and MW, Public Health Medical Advisor with ACYHC a CI on the project.

Investment in the training, qualification upgrade and clinical support of the IHW is likely to generate value elsewhere in the health system and over the longer term, a likely benefit not captured in this evaluation.

It is also worth reflecting on whether the presumed theory underpinning the trial was correct. In expanding the capacity of IHWs to provide direct and intensive support for indigenous patients in the community, through outreach as well as centre-based care, it was hoped to achieve more effective chronic disease management through greater cultural awareness and improved patient engagement in self-care mediated through a better trained and clinically supported IHW cohort. While some health gains were identified, given the high psychosocial and economic issues common in very disadvantaged populations, and the strong relationship between these factors and chronic disease, it may be necessary to address these factors more directly.[23] Most of the IHW communities sit in the bottom 2% in terms of socio-economic disadvantage for Queensland, indicating an extreme level of deprivation, likely combined with a range of serious adversities.[24] We did not have data on major life stressors (such as early death of family and friends, involvement with criminal justice or child protection systems) known to affect physical health and likely diabetes control; and these may occur differentially across the intervention and control communities.

Health services need to review their systems of care in order to maximise the value of IHWs as a specialist member of the multidisciplinary team. Case study material from the IHWs who participated in regular clinical review sessions identified examples of improved self-management negotiated by the IHW[25] consistent with better HbA1c results observed in patients with the poorest control, but also considerable patient disengagement.

A more holistic cross-agency approach may be required, seeking to directly address the psychosocial, patho-physiological and environmental issues that are common in highly disadvantaged populations. While the need to address social and economic determinants is well understood, there are still major gaps in service delivery around these issues. And despite the widely observed co-occurrence of poor mental and physical health, which is most apparent in disadvantaged communities given high experiences of trauma, ensuring that psychological health receives priority attention within the primary care system is not necessarily occurring. The challenge is for the public health community to devise and implement interventions based on that broader understanding of the determinants of health and test their effectiveness.

STUDY LIMITATIONS

Limitations to our study include lower than expected patient recruitment, small numbers in two of the intervention sites, a relatively high loss to follow up (10%) which was higher in the intervention group and missing data for some of the secondary clinical endpoints. The latter was due to the pragmatic nature of the trial where clinical data was extracted from patient records. Other key developments which potentially limited the effectiveness of the study were major health system reform occurring in the Queensland government health services generally during the life of the trial, which limited the ability of the service to recruit and retain essential staff. These changes disproportionately affected four of the six intervention sites. Process evaluation found that all six health workers experienced higher workloads as the services expected them to undertake clinical work in addition to their study caseload. This tended to dilute the potential impact of their work on the care of study patients.

The time window for the intervention (18 months) may have been too short to demonstrate a full effect, especially given the service interruptions happening at the time. A longer follow-up period may have seen a greater effect in the communities where the HWs were operating at full capacity.

Conclusion

Our results suggest that the costs of delivering the GBACC model were considerable in absolute terms and that the trial suffered from considerable implementation problems. The standard approach to the economic analysis (first evaluation) showed very modest impact for a relatively high cost intervention. The second analysis, which focused more on what the program would likely achieve in the short term (18 months) based on previous work published in this population (a reduction in acute sever hospitalisations due to infections and complications directly attributable to poor glycemic control) was more positive, with NNT of three.

The training of IHWs and clinical support is generally viewed as positive, but translating that into measurable outcomes for persons with poorly controlled T2DM in highly disadvantaged communities represents a challenge.

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