

# Investigating the Sustainability of Outcomes in a Chronic Disease Treatment Programme

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## Abstract

This study examines trends in chronic disease outcomes from initiation of a specialised chronic disease treatment programme through to incorporation of programme activities into routine service delivery. We reviewed clinical records of 98 participants with confirmed renal disease or hypertension in a remote indigenous community health centre in Northern Australia. For each participant the review period spanned an initial three years while participating in a specialised cardiovascular and renal disease treatment programme and a subsequent three years following withdrawal of the treatment programme. Responsibility for care was incorporated into the comprehensive primary care service which had been recently redeveloped to implement best practice care plans. The time series analysis included at least six measures prior to handover of the specialised programme and six following handover. Main outcome measures were trends in blood pressure (BP) control, and systolic and diastolic BP. We found an improvement in BP control in the first 6–12 months of the programme, followed by a steady declining trend. There was no significant difference in this trend between the pre- compared to the post-programme withdrawal period. This finding was consistent for control at levels below 130/80 and 140/90, and for trends in mean systolic and diastolic BP. Investigation of the sustainability of programme outcomes presents major challenges for research design. Sustained success in the management of chronic disease through primary care services requires better understanding of the causal mechanisms related to clinical intervention, the basis upon which they can be ‘institutionalised’ in a given context, and the extent to which they require regular revitalisation to maintain their effect.

*Keywords:* Australia; chronic disease; treatment; quality of care; sustainability; indigenous health; outcomes; best practice

## Introduction

The challenges of delivering effective and sustained chronic illness care are widely recognised (Wagner, 1998; Wagner, Austin et al., 2001; World Health Organisation, 2001). These challenges are especially acute in indigenous Australian communities which, like many other indigenous populations that have been subject to colonisation and rapid modernisation, suffer a disproportionate and increasing burden of chronic disease simultaneously with persisting high mortality due to other causes (Powles, 1992). Many of those worst-affected in Australia live in remote regions with under-developed health services. Over the past decade there has been increased attention to developing strategies for primary and secondary prevention. These have included whole-of-community, population-level interventions (Robinson et al., 2001, 2003) and interventions targeting specific conditions or groups of conditions.

The sustainability or maintenance of health benefits after the ‘research’ phase of intervention is over and special purpose funding is withdrawn is an important, yet under-researched subject (Batterham et al., 2001; Beaglehole & Yach, 2003; Bossert, 1990; Greenhalg et al., 2004; Lee et al., 1995; Mak & Straton, 1997). This paper reports a retrospective follow-up study which aimed to assess the sustain-ability of outcomes achieved through a specialised and research-oriented cardiovascular and renal treatment programme from initiation through to handover to the local community health care organisation.

## Methods

### *Study setting*

Until recently, Tiwi Islanders had the highest reported age-adjusted incidence of End Stage Renal Disease (ESRD) in Australia. A community wide screening program in the early nineties identified a high prevalence of risk factors for chronic diseases. This led to the introduction of an intervention programme in the mid- to late nineties (1995–1999) (Buynder et al., 1993; Hoy, 1996). The cardiovascular and renal disease prevention programme (the Renal Treatment Program (RTP)) was based on best practice guidelines, and aimed to reduce the incidence of ESRD by controlling blood pressure using angiotensin converting enzyme inhibitors (ACEi) as the mainstay of treatment (Hoy et al., 2000). The RTP was managed by a specialist physician. Follow-up and treatment were carried out at the community health centres by a specialised team of trained nurses assisted by indigenous community health workers. The team's sole focus was the specific treatment activity of the programme.

It is not clear to what extent the potential withdrawal of funding had been planned for at the commencement of the RTP. However, when RTP funding came to an end in late 1999, the management approach of the program was taken on by the then recently established Tiwi Health Board (THB) which sought to integrate treatment of the RTP's participants into the routine delivery of care in the community health centres. The withdrawal of the RTP occurred within the general timeframe (late 1998–1999) of a broader health reform initiative known as the Coordinated Care Trials (CCTs) which had commenced in 1998 with the formation of the THB. Key elements of these trials, in which the health centres hosting the RTP were participants, were the implementation of 'care coordination' based on best practice guidelines for the prevention and management of a range of common chronic conditions (including renal disease) and an electronic information system designed to support these guidelines (Robinson et al., 2001, 2003).

The THB expressed concern that it was not sufficiently funded to sustain the RTP at the same level as had been possible with the specialised resources previously available. Some time after the handover, the Director of the RTP drew attention to declining levels of BP control among clients of the programme. In response, the Board supported an investigation of trends in chronic disease out-comes. Findings of the evaluation of the CCT had indicated that the translation of best practice care plans into effective and sustainable improvements in health care delivery, and in turn into measurable health gains is not a straightforward process (Robinson et al., 2001, 2002). This investigation of trends in chronic disease outcomes was based on the assumption that changes in organisational structures and systems might have impacted on health benefit for clients with high levels of need within the service framework provided by the CCT.

As managed by the Board, participant follow-up was done by health centre staff responsible for general health care, including the high demands of acute care to participants of all ages, with one chronic disease nurse who worked with AHWs to promote active follow-up of cases in three community health centres. Advice on medical management decisions and monitoring of outcomes and performance were largely left to two resident GPs. Although advice was provided by personnel of the RTP during a transition period, there was no systematic redesign of work practice protocols for the Health Board's personnel. Numerous models for designating responsibilities were tried by the Board and abandoned or modified in the months after handover. There was some resistance among staff to adoption of the specific responsibilities for the targeted programme. There was moderate turnover of health centre staff during the period of the follow-up study, until later in 2002 when the position of the chronic disease nurse was terminated. There were no other major changes in the health centre specific to the management of renal disease which coincided with the withdrawal of the RTP. A summary of similarities and differences between management strategies before and after the handover is presented in Table 1.

### *Study sample*

The RTP database included 266 patients who met the RTP eligibility criteria for systematic treatment and follow-up (systolic blood pressure (SBP)  $\geq 140$  and/or diastolic blood pressure (DBP)  $\geq 90$ ; OR diabetes with urinary albumin/creatinine ratio (ACR)  $\geq 3.4$ ; OR progressive overt-albuminuria (ACR  $\geq 34$ ). Enrolment into the RTP occurred from the programme commencement in November 1995 until the programme handover in late 1999 as patients were

identified as meeting the eligibility criteria. Of these 266, 98 participants were identified as having had at least 78 months of medical follow-up at the health centre, commencing during the RTP and extending to 31 December 2002. This sample of 98 excluded participants who required renal dialysis, who were lost to follow-up, or who had died prior to the study cutoff date of 31 December 2002.

TABLE 1. Comparison of management pre- and post-RTP handover

	Pre-handover	Post-handover
Management method	<p>Systematic recall and active follow-up by programme staff</p> <p>Monthly review of medication first six months; three monthly 6–12 months; six monthly after 12 months</p> <p>Rapid feedback to RN/AHW by physician enabling adjustment of medication in cases of high/uncontrolled BP</p>	<p>Assignment of chronic disease care plan(s)</p> <p>Opportunistic follow-up by health center staff, supported by electronic reminder system</p> <p>Review every three–six months depending on the type of care plan</p>
Major differences	<p>Focus on selected chronic diseases by a dedicated clinical team including specialist physician and research resources. No provision of acute care</p> <p>No competition for resources such as vehicle, practitioner time, etc.</p> <p>Clear determination of clinical priorities; stringent application of protocols; systematic medical oversight by physician</p> <p>High level research capacity to monitor and analyse services and health outcomes; prompt feedback to practitioners and participants</p>	<p>Service provided within the context of a comprehensive system of primary care; limited or no dedicated resources for management of specific conditions; continuous pressure to provide acute care</p> <p>Competition for resources between health centre units and priorities</p> <p>Limited ability to identify clinical priorities; limited, less systematic medical oversight by GPs</p> <p>Limited or no capacity to monitor and analyse service levels and participant outcomes to support care coordination and medical oversight</p>

#### *Process and outcome measures, data collection and interpretation of trends*

Outcomes for the sample were measured in terms of BP control (proportion of participants with SBPp140 and DBPp90; proportion with SBPp130 and DBPp80; mean SBP; mean DBP) and, as an intermediate indicator reflecting service activity, proportion of participants with recorded BP measurements. During the period of operation of the RTP, participant medical data were recorded in an RTP database in addition to paper-based medical records. With the advent of the CCTs an electronic client information system was introduced. While the CCT information system (CCTIS) was designed to hold clinical information such as BP measures, health centre staff were also expected to continue to use the paper-based medical records. To ensure completeness of data, the records of the study sample of 98 participants in all three information systems (the RTP database, CCTIS, and the paper-based medical records) were audited. For each defined six month interval over the study period it was determined whether a BP measure had been recorded in any of the information systems, and if so, the BP measure closest to the end date of the six month interval was used as an indicator of BP control for that period.

Interpretation of trends in outcome measures in terms of changes in organisational structures and systems is based on data collected through observations and interviews conducted as part of the CCT evaluations (Robinson et al., 2001, 2003) and from discussions with health centre staff during feedback of the study findings.

#### *Statistical analysis and study power*

Baseline characteristics of the study sample were compared with RTP participants who did not meet the eligibility criteria for the study. Differences were assessed using t-tests for continuous measures and  $\chi^2$  tests for categorical measures.

The primary outcome measure was the proportion of patients whose BP was below 130/80 for each six month interval. Secondary outcome measures included the proportion of patients whose BP was below 140/90, mean SBP and mean DBP for each six month interval. The initial impact of participation on BP control was assessed by examining the difference in these measures between entry to the programme and 12 months, using McNemar's test for proportions and paired t-tests for means.

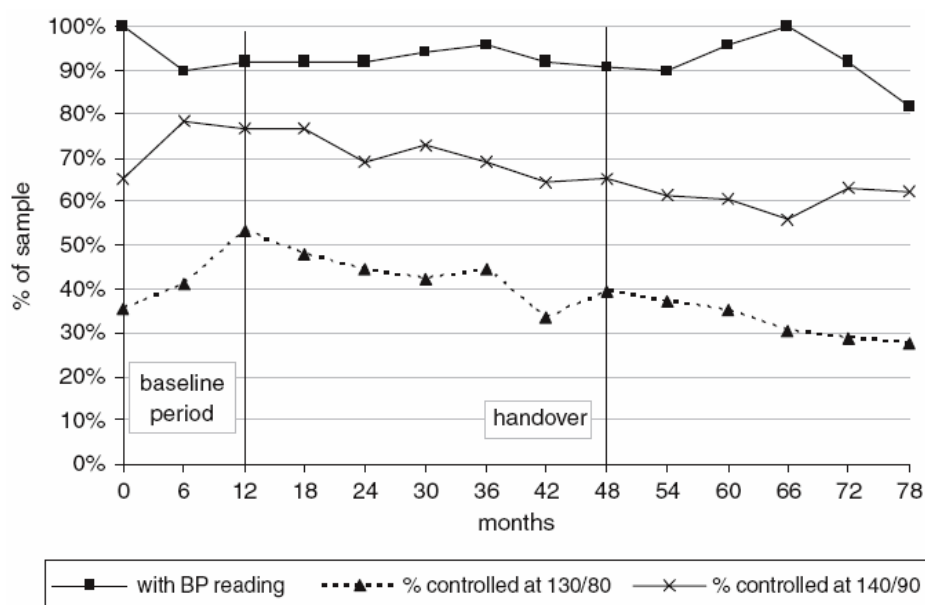
Trends in BP control during pre- (12–42 months inclusive) and post-handover (48–78 months inclusive) periods were estimated and compared using cross-sectional time-series models that take account of the repeated measures nature of the data. The cross-sectional means and proportions were based on eligible patients with non-missing BP data only, so patients with missing data for individual periods were excluded for that period only and not for the time-series models. Logistic models (Stata command *xlogit*) were used for the proportion below 130/80 and 140/90 and linear models (Stata command *xtreg*) used for mean SBP and DBP. Interaction terms (pre- /post-withdrawal by six month interval) were included to determine whether trends in BP control were different for the pre- and post-program withdrawal periods. Similar time-series models were used to compare trends in BP control between diabetic and non-diabetic patients, hypertensive and non-hypertensive patients and between males and females. All analyses were performed using Stata version 8.2 (StataCorp, 2003).

The scientific protocol for this follow-up study was approved by the formally constituted institutional ethics committees responsible for overseeing health and medical research in the region. The study funders had no role in the study design, collection, analysis or interpretation of data.

## Results

### *RTP participants and study sample characteristics*

There were significantly fewer hypertensive patients in the study cohort (25%) compared to other RTP patients (40%). No differences were found with respect to other key parameters (age, sex, diabetic status, mean SBP, DBP, GFR and serum creatinine).



**Fig. 1.** Trends in monitoring and control of blood pressure.

### *Study sample BP monitoring and control*

Aside from the final six months, at each period less than 10% of the sample had missing BP readings (Fig. 1). The proportion of patients with control of BP at the target level of less than 130/80 increased significantly in the first year of follow-up from 36% to 53% ( $w^2 = 9.85$ ,  $p = 0:0017$ ). There was also a significant increase in control at the 140/90 level from 66% to 77% ( $w^2 = 3.85$ ,  $p = 0:0499$ ) (Fig. 1). Average SBP decreased significantly from 131 to 122 mmHg ( $t = 4:29$ ,  $po0.0001$ ) and DBP declined from 79 to 77 mmHg although this difference was not statistically significant ( $t = 1:55$ ,  $p = 0:1252$ ) (Fig. 2).

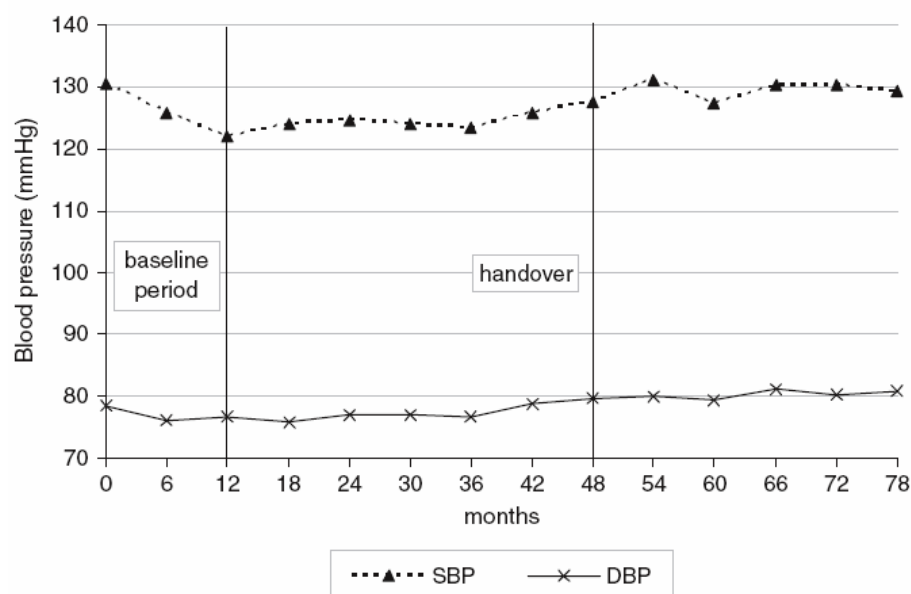


Fig. 2. Trends in mean SBP and DBP.

There was a significant decline in the proportion of the sample below the 130/80 target (OR = 0.89, 95% CI = 0.85, 0.93) over the remainder of the study period (Fig. 1). This means that for any given six month interval, the odds of having BP under control compared to the previous interval are reduced by 11%. The interval by period interaction term was not significant (OR = 1.00, 95% CI = 0.85, 1.19), which indicates that the decline in BP control was similar for the two periods. There was a similar significant decline in the proportion below 140/90 at each interval (OR = 0.92, 95% CI = 0.88, 0.96), but again the interval by period term was not significant (OR = 1.11, 95% CI = 0.93, 1.32). A significant increase was found in both SBP (b = 0.72, 95% CI = 0.42, 1.02) and DBP (b = 0.42, 95% CI = 0.23, 0.62) over the study period, but again the interval by period interaction terms were not significant for either measure indicating no difference in the rate of BP increase between the periods (Table 2).

TABLE 2. Odds ratios (OR) and slope parameters from the time-series regressions of BP control<130/80, BP control<140/90, mean SBP and DBP

	BP<130/80 OR (95% CI)	BP<140/90 OR (95% CI)	SBP slope (95% CI)	DBP slope (95% CI)
Overall trend	0.89 (0.85, 0.93) <i>p</i> <0.001	0.92 (0.88, 0.96) <i>p</i> <0.001	0.72 (0.42, 1.02) <i>p</i> <0.001	0.42 (0.23, 0.62) <i>p</i> <0.001
Interval by period interaction	1.00 (0.85, 1.19) <i>p</i> = 0.970	1.11 (0.93, 1.32) <i>p</i> = 0.233	-0.08 (-1.29, 1.14) <i>p</i> = 0.903	-0.09 (-0.89, 0.70) <i>p</i> = 0.822
Interval by diabetes-status interaction	1.03 (0.95, 1.12) <i>p</i> = 0.475	1.10 (1.01, 1.20) <i>p</i> = 0.033	-0.45 (-1.05, 0.15) <i>p</i> = 0.141	-0.49 (-0.88, -0.09) <i>p</i> = 0.015
Interval by hypertensive-status interaction	1.02 (0.92, 1.14) <i>p</i> = 0.650	1.02 (0.92, 1.12) <i>p</i> = 0.744	-0.09 (-0.80, 0.62) <i>p</i> = 0.804	0.04 (-0.42, 0.51) <i>p</i> = 0.862
Interval by gender interaction	1.01 (0.93, 1.10) <i>p</i> = 0.787	1.03 (0.95, 1.12) <i>p</i> = 0.487	-0.66 (-1.25, -0.06) <i>p</i> = 0.031	-0.43 (-0.82, -0.03) <i>p</i> = 0.034

As no significant difference was found to exist between periods, these were combined in the models used to assess the difference between various types of patients. The interval by diabetes-status interaction term was not significant for the proportion less than 130/80 (OR = 1.03, 95% CI = 0.95, 1.12, *p* = 0.475) or mean SBP (b = -0.45, 95%

This indicates that patients with diabetes showed a slower decline in the proportion with BP control below 140/90 and less of an increase in DBP compared to non-diabetics (Fig. 3). There was no significant interaction for interval by hypertensive-status or for any of the BP control variables, indicating that there is no difference in the rate of change between hypertensive and non-hypertensive patients. There was a significant interval by gender was less than that for females. The interaction term was not significant for BP below 130/80 or 140/90.

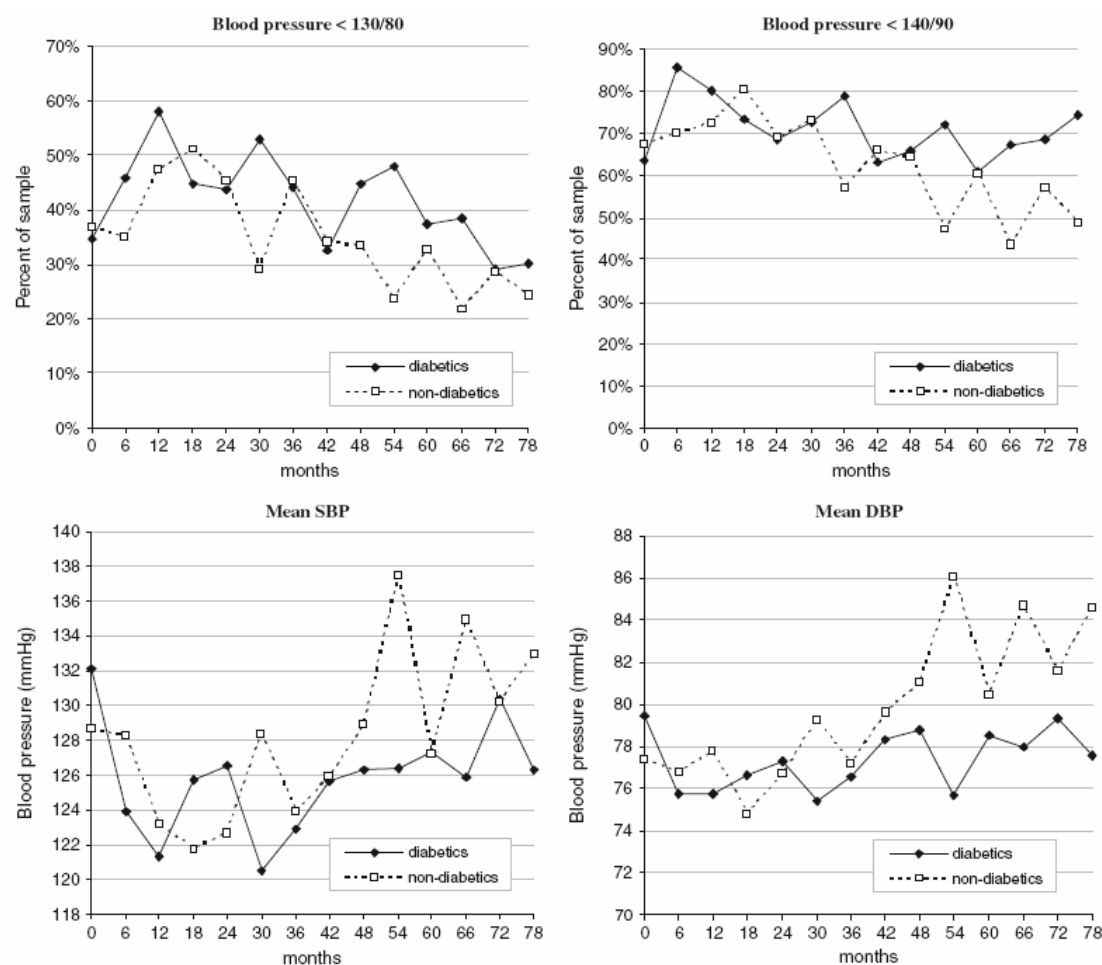


Fig. 3. Trends in BP control for diabetic and non-diabetic patients.

## Discussion

This study shows that an initial positive impact on BP control associated with the implementation of the RTP was followed by a steady decline in BP control. After 42–48 months following entry to the programme levels of control were similar to levels at entry for all outcome measures. There is no evidence of a change in the rate of decline of control following withdrawal of the RTP at about 48 months after entry for the study cohort. Changes in BP control between baseline and 12 months are probably attributable in part to regression to the mean and in part to treatment effect. Whatever underlay the initial improvements, they were followed by a decline that commenced well before the changes in service delivery associated with the handover. The findings clearly challenge the assumptions of the researchers, the Health Board and others concerning the impact of the handover of the RTP on treatment outcomes, assumptions recently restated by the Director of the RTP and co-investigators (Hoy et al., 2005). They must give rise to new questions regarding the failure to sustain initial improvements in BP control.

It has been argued that the ‘incorporation’ (Bracht et al., 1994) or ‘integration’ (Bossert, 1990) of evidence-based practice requires that it be ‘institutionalised’ (Steckler & Goodman, 1989), or ‘routinised’ within general health care (Shedid-Rizkallah & Bone, 1998). Such routinisation arguably rests on capacity building at a number of levels, from individual staff members, to teams, organisations, links between organisations, and to the community itself (Hawe et al., 1998). Interventions that have built primarily on local community capacity in similar settings to the RTP appear to have shown improvements to be sustained over three years (McDermott et al., 2003). However, the findings of our study suggest that generalised capacity building linked to the implementation of evidence-supported clinical protocols is not necessarily sufficient to ensure sustainability of a health benefit—even when service levels appear to be maintained at target. Perhaps particularly for clients in receipt of relatively high levels of service, better



differentiation of effects may be needed. Some determinants of effectiveness may need to be more closely specified for effective implementation within routine care.

The concept of ‘programme fidelity’ is relevant to both the sustainability and the transferability of an intervention. Programme fidelity assumes that all causally active elements within an intervention can be delivered in constant fashion in order that outcomes can be sustained over time. The contributions of these elements to measured outcomes need to be identified in order that the total intervention can be institutionalised in new service contexts and, if necessary, be ‘reinvented’ in altered circumstances (Baumann et al., 1991). In the case of the RTP, it appears that the causal mechanisms underpinning the initial gains of the RTP were not effective in preventing a subsequent declining trend in BP control, either during the RTP or after handover. It is not clear if this was a failure to maintain programme fidelity or a natural progression of BP trends with ageing of the cohort. In relation to programme fidelity, the translation of clinical protocols into effective practice requires the development of key elements of *process*. These may include the nature of engagement of clients by practitioners and the approaches and systems to promote appropriate lifestyle and medical management. With the handover of the RTP, there was a loss of continuity in high level management support, in information system management and analysis enabling feedback to practitioners, and in direct medical oversight of the caseload by senior clinicians.

While the monitoring of BP after handover appeared to be at the same high levels achieved by the RTP (Fig. 1), our evaluation revealed a lack of certainty about appropriate action among health centre staff, a lack of clear delineation of staff roles and of processes of referral to senior clinicians, and more generally inadequate protection of chronic disease care functions within health centre practice (Robinson et al., 2001, 2003). All of these factors could have been expected to contribute to a decline in BP control and thus to deteriorating programme effectiveness after programme handover. However, this expectation is clearly contradicted by the observation that the steady decline in BP control commenced from as early as 12 months after initial treatment—that is well before the handover period—continuing at the same rate of decline after handover.

How can the decline observed in this study be explained, and what factors might be amenable to intervention by health services to achieve sustained improvements in BP control in the future? Some lines of inquiry suggest themselves. To what extent were the intensity or quality of the non-pharmacological treatment components of the RTP responsible for the initial treatment effect and to what extent did these change after the screening and induction conducted during the first months of treatment? These changes might include lessening frequency and intensity of counselling and follow-up after initial screening, diagnosis and recall, and generally less championship of the programme in the community after its key components had been routinised for delivery by RTP staff. On the other hand, the routine repetition of the service may have led to deterioration of the effect without decline in intensity or frequency of contact. While routinisation of services is necessary for their successful integration in health care, it may well be deleterious for those motivational components of client response which are also presumed to have some bearing on the outcomes of treatment.

In other contexts (for example in ‘substance use programs’ in schools) there is evidence of a ‘decaying effect’ over time that limits the ‘durability’ of the intervention effect (Resnicow & Botvin, 1993). Is the decaying effect found here a simple reflection of declining intensity or frequency of service contacts from early in the RTP? The evidence is ambiguous at best. A lower rate of decline in BP control was found for study participants with diabetes and for males. In the case of diabetics, this may be the result of more intensive medical attention and higher levels of self-care among these patients. However, males are typically less frequently in contact with health services than females, contradicting the supposition that more frequent treatment is the key influence. The findings rather appear to support the view that strategies for reinforcement of behaviour change can be beneficial both during and after intensive intervention (Prasad & Costello, 1995). This may include significant ‘reinvention’ or reinvigoration of strategies to counteract the psychological impacts of long-term disability. The pattern of decline in BP control observed within the RTP study cohort may in part derive from processes that might be expected with introduction of best practice guidelines in the absence of such a ‘reinvention’ of its strategies for engagement with clients.

Research into the sustainability of a complex intervention of this kind presents major challenges for evaluative research design (Medical Research Council, 2000). Follow-up studies

of the extent to which the natural progression of disease (including associated comorbidity combined with ageing) is responsible for the continuing decline in BP control would be ethically problematic. Long-term randomised controlled trials of interventions present similar ethical challenges and, moreover, may be unfeasible because of sample size and cost. They would also not necessarily provide the required insight into process factors including the significance of quality (rather than just quantity or timeliness) of care. Interrupted time-series analysis is regarded as one of the strongest feasible study designs for this type of intervention (Cochrane Effective Practice and Organisation of Care Group, 1998). However, study participants who survive and for whom data are available over a prolonged period are inevitably a select group. The extent to which their experience is generalisable to the broader population of people with chronic illness is uncertain. Measures of their clinical outcomes, such as BP, depend on data collected by service providers, with limited potential to ensure standardisation over the study duration. Furthermore, there may have been unmeasured influences that varied over the duration of the study. These are recognised limitations of this study. Collection of adequate data on process factors during prolonged follow-up should ideally be done over the duration of the study. From a pure research perspective, this would be resource intensive and ethical practice would require that the data be used to refine service delivery. This would in turn constitute an ongoing intervention which might render attribution of outcomes difficult.

The extent to which research can adequately address programme sustainability within ethical and resource constraints is perhaps more limited here than in many other areas, and may go some way to explaining the dearth of research on this subject (Greenhalg et al., 2004).

## Conclusion

The challenge in reorienting health services (Beaglehole & Yach, 2003) to address the epidemic of chronic disease arguably lies in ‘institutionalisation’ of the key features of successful interventions while taking account of contextual factors relevant to the delivery of comprehensive primary health care services to populations. Chronic disease care will need to be established as a long-term strategic priority for primary care services, and as such will require ongoing management attention, regular revitalisation and appropriate resourcing of the approach. Attention needs to be paid to all causal mechanisms, including the specific contribution of *implementation processes* underpinning service programmes if the development of models for chronic illness care (Wagner, Glasgow et al., 2001) are to lead to continuous improvement in routine service delivery, and in turn to sustained health benefits for patients. Pressure on staff and their organisations to perform to a high standard in the expectation that this will lead to improved outcomes for their clients needs to be backed by good evidence on what needs to be sustained—or reinvented—and how it can be done.

## Acknowledgements

The authors acknowledge the assistance of the then Tiwi Health Board, the staff of the health centres where the study was conducted and staff of the RTP. The project was made possible by grants from the Cooperative Research Centre for Aboriginal and Tropical Health (HS0123), and the Office for Aboriginal and Torres Strait Islander Health, Commonwealth Department of Health and Ageing.

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