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Tailored health care for chronic disease in primary care: minimising the risks and maximising the benefits

An application of policy simulation

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Introduction

In 2010, Australia's first National Primary Care Strategy (NPCS) was released by the Commonwealth Department of Health and Aging (DoHA).¹ It was one of a series of strategies released as part of the National Health Reform 2010.²

The NPCS identified the need to address the growing problem of chronic disease generally, and diabetes specifically, by improving the coordination, quality and delivery of primary care. The research report that informed the strategy identified four main factors:

... contributing to the gap between optimal and current practice ... (i) the method of financing, (ii) the availability of other disciplines to participate in team care, (iii) limited engagement with self-management education, and (iv) lack of information and decision support systems.³ (page 68)

The primary mechanism the NPCS identified to achieve this objective of reducing the gap between optimal and current practice was to improve incentives for general practitioners (GPs) to "become responsible for managing (patient) care" by developing, organising and implementing personalised care plans, including organising access to additional services such as those provided by Credentialed Diabetes Educators (CDEs), exercise physiologists, dietitians and psychologists.

A specific initiative was proposed to capture these incentives: the Diabetes Coordinated Care Initiative (DCCI). The proposed program included:

... a performance framework under which practices will be rewarded if their patients' health improves. GPs will be paid to help patients manage their condition over time, and ensure they can access the kind of care they need.¹ (page 32)

Patients voluntarily enrolling in this program were expected to benefit from having access to the services they needed, coordination of their care across multiple providers and support for their GP to manage their condition "rather than just treating the presenting conditions". There was also an expectation that this initiative would reduce hospitalisations due to complications from diabetes.

The DCCI, proposed by DoHA in June 2010, comprised a fixed capitated payment (\$1,200) per patient with diabetes per year that was intended to cover both GP services (including those not related to diabetes) and AHSs. The payment of either the entire or partial amount of the capitation was expected to be made directly to the GP. The GP would then have the responsibility of allocating these funds to finance the care provided by that general practice, including AHSs provided by that practice.

The proposed payment was a capitation rate, not a capped patient budget, hence there was also a possibility that GPs could redistribute the funds across patients who had differential needs. For example, if the GP could differentiate between patients with above and below average needs, then expenditure on patients with above average needs could be higher than that for lower than average needs. Care could be optimized for individual patients while total costs remained within the overall budget.

There was an expectation that AHS use would increase as patient access to and compliance with best practice improved. This payment of \$1,200 probably represented a premium over the average costs of primary care services and AHSs provided to a sample of patients with diabetes.^{4,a} Therefore, for a GP with a very large and representative sample of diabetes patients, the total pool of funds could be expected to cover the costs of care for the overall patient group.

^a Derived from DiabCo\$t⁴ The report indicates that 12% of the average total direct health care costs are due to primary health care costs. The estimated average total cost from all services is \$4260 in 2003 dollars and 12% of this is \$511.

Additional payments for GPs enrolling patients and for achieving performance benchmarks were proposed. The performance benchmarks were not detailed but were expected to include the proportion of patients whose HbA1c was controlled and the proportion of patients who were hospitalised.

Despite the extensive evidence base for this policy, the initiative met with significant criticism by the GP community. The main criticism was that GPs were unwilling to be fund holders for not only the diabetes related MBS services, but those relating to the “broken leg” or, more likely, comorbidities such as respiratory disease.

A survey by the Medical Observer found that only 5% of respondents (GPs) would take up the initiative.⁵ A range of criticisms was made in both the public and private domain.⁶ These criticisms included:

- > The capacity for a GP or general practice to cream skim, that is, enrol only those patients whose expected service costs are less than the single fixed capitation.
- > The financial dis-incentive to enrol a patient whose care was complex and also less likely to have their key clinical indicators controlled.
- > The requirement for a GP fund holder to be risk bearing, that is, to be able to accommodate the risks that some patients’ care costs will be higher than expected.
- > The performance indicator “hospitalisation rate” is subject to small number problems; a higher or lower than average hospitalisation rate could be due to chance, not performance.
- > If enrolled patients have increased access to AHSs, then patients who were not enrolled could have less access to the services provided by this constrained workforce. If these unenrolled are also more likely to have complex care needs, then there are equity implications also.
- > The use of financial rewards to GPs attributes improved patient outcomes to GPs rather than other team members, or patients themselves.

Our original research proposal was to develop a computer simulation of the proposed DCCI for a range of scenarios around patient-GP combinations, and identify strategies to minimise the risks and maximise the benefits of the policy. However, just after the funding for this research grant was announced, the Health Minister announced that the DCCI would be delayed until a Diabetes Coordinated Care Pilot (Diabetes Pilot) was completed and evaluated.⁷ This curtailed the interaction between the research team and decision makers .

The DCC Pilot was put out to Tender in Early 2011 and started in the first quarter of 2012. The detailed parameters of this Pilot are not in the public domain; there is no website detailing the initiative at the date of this report, January 2012, for example.

The expected share of the estimated \$30M in total funds for the pilot that are allocated to services for patients is not in the public domain. The remainder is expected to be allocated to the evaluation, the IT structure, training, care coordinators and other overheads. It is unclear whether type 1 diabetes patients will be included and whether there will be services specifically designed for Aboriginal and Torres Strait Islanders.

A number of other characteristics of the pilot are discussed in the “grey domain”. (They are subject of discussion within the health community, particularly in Adelaide, Melbourne and Brisbane where the pilot will be implemented.) This discussion generally suggests that the pilot will include the following elements:

- > The DCCI had only one classification of patients and one capitation rate, whereas the DCC Pilot has at least four classifications with detailed “bundles” of service needs for each patient group.

- > Payments for GPs and practice nurses will be made to the GPs but GPs will not hold the funds for allied health service (AHS) providers.
- > There will be centrally employed care coordinators.
- > There will be less reliance on financial incentives in the pay for performance genre, compared to the original DCCI.

The first challenge in this research project was how it could be redesigned given that the policy it was intended to research was delayed and the form of its implementation as a Pilot was not in the public domain. There was no data to populate the computer simulation. The research team's response to these changing circumstances was to generalise the policy intervention and the associated research.

REVISED RESEARCH QUESTIONS

First, the key policy issue was generalised from the specific policy initiative of DDC to: ^a

- > How should the needs of a specific group of patients be addressed within a universal health care scheme such as the MBS?

The term "Tailored Health Care" (THC) is used to describe any initiative that is an alternative to expansion of MBS items as a strategy for addressing the needs of patients whose care needs are not necessarily met optimally within mainstream primary care. (This issue is discussed in more detail in a following section: Policy narrative and policy initiatives)

Then, the research questions were redefined as:^b

1. How can a policy simulation be used to inform any THC style initiative, prospectively?
2. What are the critical elements of an overarching policy framework for THC initiatives for Chronic Disease Management (CDM)?

The rationale for the **first research question** is that existing methods of policy simulation need to be adapted for the primary care policy setting. Methods of policy simulation that explicitly accommodate both the "known unknowns" and the available evidence are ubiquitous in health technology assessment (HTA). However, computer simulations of health technologies are less complex structurally than those of primary care interventions. One example of this complexity, and what it means for simulation tools, is the need to simulate the interaction between both the patient and GP and a given intervention, not just between the patient and the new technology.

The **second question** addresses the overarching regulation of a scheme that requires a patient to either voluntarily or compulsorily change his or her access to the universal MBS. The specific parameters of the DCC Pilot, including the structure of referral processes and the exact incentives for GPs, are being developed by a range of stakeholders. The issue of interest in this research is whether an overarching regulatory structure is necessary for such a scheme and whether the features of such a structure can be specified without access to information about the details of the scheme.

An additional item on the MBS is accommodated within existing regulatory structures. Existing THCs, such as injury compensation schemes, cover certain aspects of care for eligible patients and are covered by specific regulatory structures. Given that the proposed DCCI generates different incentive structures for GPs, including pay for performance, the possibility that additional risks that require additional regulation will also result from this changed structure cannot be dismissed.

The overall focus of the research, the development of a policy simulation tool for a chronic disease initiative, remains the same. And, as shown in the Conclusion to this report, the

^b For details of the original research questions, see Appendix 1 "Changes to Research Questions"

original research questions were answered using the results of the research on the generic policy and methods.

REPORT STRUCTURE

The report structure reflects the two imperatives of the research: methodological and policy. The eight sections of the report are:

1. **Policy simulation:** an introduction to the application of policy simulation using an example of an informal application of the methods to the original DCCI policy.

Method development

2. **Identification of structural uncertainty:** a review of the policy narrative and other aspects of THC to identify the “known unknowns”.
3. **Model specification:** using typologies developed from the policy narrative and focus groups to specify the structure of the computer model.
4. **Analysis of the “known unknowns”:** a formal analysis of the structural parameters: what is the implicit value, what is a plausible alternative value, and does it matter what we assume.

Policy Implications

5. **Risk management strategies:** any policy that finances primary care for Medicare eligible patients outside the standard Medical Benefits Schedule has structural uncertainty (e.g. How will GPs respond to non-MBS financial incentives?) What are the key elements of such an overarching regulatory framework in the case of the DCCI?
6. **Validation:** a validation of the process of policy simulation in the context of THC policy.
7. **Results:** how does the research inform the two research questions?
8. **Recommendations and conclusions.**

Policy simulation

A policy simulation is simply a formal modelled simulation of the likely impact of a policy, given what we do (and don't) understand or hypothesise about its mechanisms (and likely impact). It can be used prior to the implementation of a policy to identify risks and strategies to minimise them. Policy simulation using micro-simulations of complete data sets on, for example, Centrelink beneficiaries, and hypothesized responses to changes in well specified policies are used in Social Welfare policy formation.⁶ Formal health system policy simulation is not used routinely in Australian health services or system research, however, its use is increasing. It is however used in Health Technology assessment policy.

POLICY SIMULATION IN HEALTH CARE

Formal prospective simulation of reimbursement policy is now used routinely in new technology adoption in Australia. In the case of the Pharmaceutical Benefits Advisory Committee (PBAC), formal simulation of the expected health and cost consequences of the decision to reimburse a new drug is essential. These pharmaco-economic simulations are informed by the results of clinical trials, other research, and expert opinion. However, key strategic decisions can be critically dependent on parameters of unknown value: the “known unknowns”. For example, the expected cost effectiveness of a new drug could be sensitive to the proportion of patients receiving the drug who have had a history of resistance to an older drug; the drug could be more likely to be associated with an adverse event for these patients. However, even if the proportion of these patients is unknown, a strategy to

⁶ Numerous examples of this kind of policy simulation produced by The National Centre for Social and Economic Modelling and the reader is referred to their website: <http://www.canberra.edu.au/centres/natsem/home>

minimise prescribing to this group could be implemented. Policy simulation allows the “what ifs” of policy to be explored and strategies to manage these “what ifs” to be implemented.

In contrast to the limited use of formal policy simulation in health system research, informal policy simulations are ubiquitous. One example is the imperative to detect cases of undiagnosed diabetes in General Practice. Appendix 9 “The ratio of diagnosed to undiagnosed cases of diabetes” “presents an example of possible informal analysis of “known unknown”. The most recent evidence of the ratio of diagnosed to undiagnosed cases of diabetes might not reflect the changes in screening patterns over the last 15 years. While not definitive, the evidence presented in Appendix 9 suggests that assuming this ratio has changed is a plausible alternative to assuming that, in the absence of evidence to the contrary, the ratio has not changed.

POLICY SIMULATION VS EVALUATION

The objective of policy simulation differs from that of program or policy evaluation: the former works within available evidence to identify opportunities to improve policy design before implementation whereas the latter generates additional evidence to assess the selected policy design. For example, policy simulation could identify that, given the current policy design, if a particular situation occurs there is likely to be a poor outcome for a patient. It can then be used to identify strategies to prevent such patients being enrolled or to minimise the risk of poor outcomes should they be enrolled. However, policy simulation cannot provide an estimate of the proportion of patients who could be in this situation.

REPRESENTING POLICY SIMULATION

Figure 1 represents the process of policy simulation, where the focus is on identification of structural uncertainty, the “known unknowns”, in order to develop risk management strategies around policy initiatives. A range of sources are used to identify and characterise the structural parameters of the policy, including a review of the policy narrative and focus groups. The development of the computer model and the resultant risk management strategies are informed at each step by these sources.

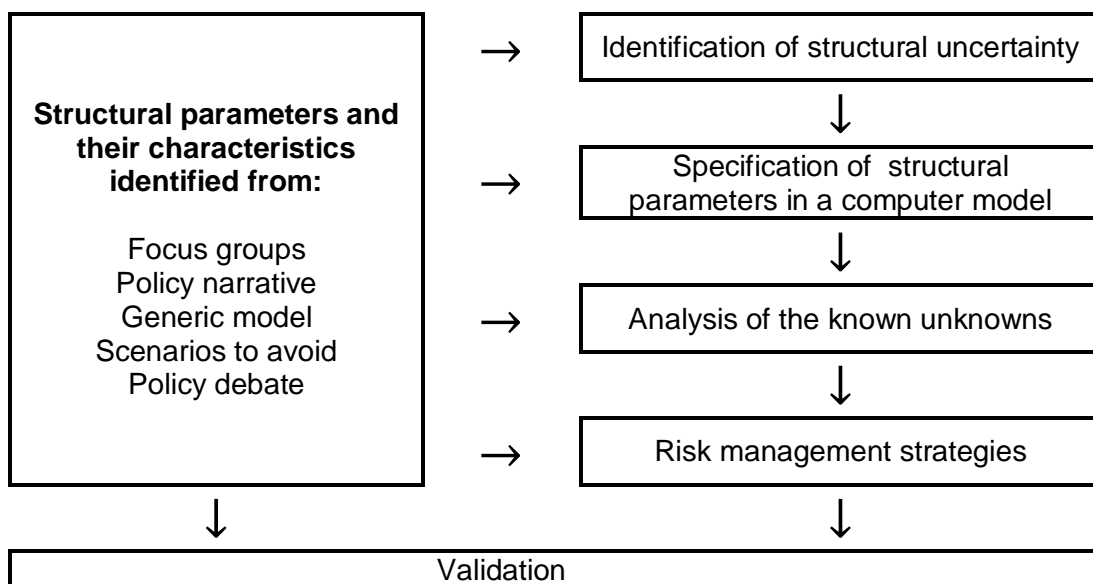


Figure 1 Policy simulation

EXAMPLE OF INFORMAL POLICY SIMULATION

In the case of the proposed original DCCI, it is possible that the decision by the General Practice community to reject the initiative was influenced by GPs’ informal analysis of the “known unknowns” (or “what ifs”) rather than questioning the strength of evidence behind

the single capitation rate of \$1,200 as an estimate of the average cost of care for a person with diabetes.

The policy narrative within which the DCCI was contextualized emphasised the significance of changed financial incentives for GPs in facilitating management of the condition rather than “treating the presenting problem. The use of a capitation rate to promote flexibility in funding was a key mechanism to achieve this outcome. But what should the capitation rate be?

The series of assumptions behind the \$1,200 are not in the public domain. It is reasonable to assume that the results of the DiabCo\$t Study⁴ informed this estimate. At \$1,200 it is also likely that it represents a premium over the mean costs of primary care services in one year for a patient diagnosed with diabetes. However, the majority of GPs rejected this policy. This rejection occurred despite the capacity for a general practice clinic with a large number of representative patients to cover the costs of primary care for these patients, and probably have an additional premium (profit) compared to care under existing financing structures.

An informal policy simulation can be used to explore this issue. The implicit assumptions in this policy include that:

1. GPs would not choose to enrol primarily a group of patients whose expected costs of care were significantly below this capitation rate (cream-skimming); and
2. GPs who enrolled all of their patients would be able to accommodate the risks of variability in patient costs.

Implicit assumption 1 – no cream-skimming by GPs

In relation to the first assumption, GPs’ incentive to cream-skim increases as: i) the gap between the expected costs of care for a low risk patient and the capitation rate increases; and ii) the ability to accurately identify low cost patients increases. Consider two types of low risk patients, both of whom have a capitation fee of \$1,200 paid to the GP. The incentive to cream skim is higher (the expected profit is higher) for the second of the following patient types:

1. Patients with an expected cost of care of \$700 and who can be recognised (distinguished from patients with expected costs of care >\$1,200) with 80% accuracy.
2. Patients with an expected cost of \$250 and can be recognised with near certainty.

There is no evidence Australian GPs cream skim, probably because the opportunities to cream skim within the current MBS structure are limited. In the absence of evidence, it could be reasonable to assume that no GPs will cream-skim under the new system. However, it is plausible that there are clinics that will cream-skim. The incentive to cream-skim is highest when there is a single capitation rate for a group of patients that are heterogeneous in terms of their expected costs and the group with lower than average cost can be identified with some certainty. The proposed DCC Initiative meets these conditions.

Implicit assumption 2 – GPs are willing to be risk bearing

For the GPs who choose to enrol all of their diabetes patients, regardless of whether their expected costs are under or over the capitation rate, there two additional issues. First, there is a question of whether a GP can bear the risk associated with outlier patients. Second, there is the problem that some GPs, particularly those with a special interest in diabetes, could have a higher than average share of more complex patients. In this case the expected mean costs of their patients would be higher than \$1,200. In both cases, a GP choosing not to cream skim (enrol all patients not just profitable patients) might not take on the initiative (unwilling to bear the risks).

In fact a closer review of the DiabCo\$t study suggests that it is plausible that:

1. less complex (lower risk and lower cost) patients can be distinguished from more complex patients prior to enrolment;
2. lower cost patients are likely to have a significantly lower cost of care compared to the average patient;
3. there are outliers that will lead to GPs who enrol less than 100 patients (for example) to bear financial risks; and
4. a GP with a special interest in more complex patients with diabetes could have a higher average cost per patient compared to average costs of diabetes patients overall.

The 67% of respondents to the DiabCo\$t Study who reported no complications had a mean of 9.5 GP visits to the surgery, with a standard deviation of 10.2. The corresponding figures for those who reported a complication were 14.4 and 16.7. The high standard deviation suggests the possibility of outliers, and the distinct bi-modal nature of the distribution of costs across patients suggests that there are identifiable groups with different average costs. And finally, a higher average cost for complex patients suggest that GPs currently providing care to more complex patients will be disadvantaged financially relative to those GPs who enrol predominately less complex patients.

Risk management strategies

Two possible risk management strategies are associated with this informal analysis of the implicit assumptions:

1. developing multiple capitation rates by differentiating on the basis of patient characteristics such as previous complication; and
2. removing some of the effect of outliers by removing the non-diabetes related costs.

The DCC Pilot addressed the heterogeneity in the cost of providing best care for patients of varying needs and complexity by proposing multiple capitation rates. It also removed the outlier effect of small high cost events by only covering diabetes related care; what was missing in the original policy proposal was addressed.

CONCLUSION

A formal policy simulation builds on the principles of:

- > reviewing the policy (or policy narrative in this case because the details of the policy were not released) to see what it omits,
- > identification of the “known unknowns”,
- > and an analyses of these known unknowns” to identify the implicit assumptions and plausible alternatives to these assumptions.

Risk management strategies can then be identified.

The important point is that the implicit policy assumptions that were omitted from the policy narrative can be derived by applying reasoning in the absence of evidence. Aspects of this process were performed informally and the pilot included the two changes to manage the risks of cream skimming and risk bearing. In this research we extend this informal approach to a formal approach and hence identify further omissions from the policy narrative and strategies to reduce the associated risks

Identification of structural uncertainty

The policy simulation presented in this research is unusual in that there are almost no parameters of known value, for example, there is no statement on the estimated effect size (capacity for patients to benefit) from the DCCI. Furthermore, there are no formal generic

policy simulations in the Australian primary health care setting to provide a template from which “known unknowns” can be identified. This is in contrast to the state of play in HTA.

Hence, we start with a generic HTA model, with which we identify a set of core parameters for simulating health policies. We use information from the policy narrative, focus groups and informal discussions with stakeholders to identify whether these parameters are “known or unknown knowns”. Then we summarise the information to identify structural parameters and the relationships between these them: known and unknown.

GENERIC HTA MODEL

An example of a generic health policy model can be inferred from an HTA, such as those used by drug companies in their submissions to the PBAC in support of a decision to reimburse their new drug. Effectively, the policy of reimbursement is simulated in a pharmaco-economic model.⁸ The outcome of such a model is the incremental cost and effect of the policy, compared to existing policy (the drug is not reimbursed).

Models used in HTA have the following generic form:

1. **Evidence of cost and effect for each option:** The effect and costs of care under usual care and the proposed alternative (e.g. an existing and an alternative drug).
2. **Evidence of comparative cost and effect:** The incremental effect and cost of changed care (the difference between the effect under each technology, and the cost). The comparative or incremental effect is the capacity for a patient to benefit from the technology compared to usual care.

Comparative effect is a measure of the expected capacity of a patient to benefit from the new drug compared to an existing drug.

3. **Heterogeneity:** Identification of patient groups for whom the incremental cost or effect of the new technology will or is expected to differ. For example, differential analysis of metastatic or adjuvant patients who are currently receiving chemotherapy for breast cancer.
 - a. Factors that influence the incremental cost and effect:
 - b. Factors that influence the variability in incremental cost and effect across patient groups

This step identifies patients with differing capacities to benefit (CtB) from the new technology.

4. **Sensitivity analysis:** A test of the robustness of the model's outputs to assumptions made in the model.
5. **Key metric:** Incremental cost effectiveness ratio (the incremental cost divided by the incremental benefit)

Three structural parameters for DDCI were identified by applying this generic structure to the policy. These guide the broader review:

- > the MBS financing structure provides incentives to treat the presenting problem rather than manage the chronic condition;
- > Heterogeneity across patients in their response to (CtB from) a given intervention where this heterogeneity is the result of different characteristics of patients such as comorbidities, socio-economic characteristics, health literacy and language.
 - o *In other words: different patients will have a different benefit (improved health) from this policy.*
- > Heterogeneity across a given type of patient, in terms of the intervention they receive, where this heterogeneity is a consequence of factors such as variability in type of care provided by GPs, and access to AHSs in a given region.

- *In other words: similar patients will have a different benefit (improved health) from this policy, depending upon where they are located, the availability of AHSs and the type of GP they have.*
- > Opportunity for strategic behaviour by a GP as a consequence of the financial incentive to enrol a patient.
 - *In other words: GPs have an incentive to encourage enrolment by patients for whom there is an additional profit compared to the provision of existing care and discourage enrolment for those for whom there is a loss, regardless of that patient's CtB from enrolment.*
- > The interactions between these three factors

A detailed discussion of the rationale for selecting these three factors is included in Appendix 3.

FOCUS GROUPS

The role of focus groups in this policy simulation is to identify the “players” in the applied economic model (the computer simulation), the range of “types” of each player and the range of contexts in which they will interact. The summary of five patient stories are presented below and the characteristics of these stories that influenced the model structure are highlighted. A summary of participants is presented in Appendix 3 and a summary of the themes raised is presented in Appendix 4.

DH's Story

DH is a male in his 50's. He was diagnosed with diabetes approx. 10 years ago. He stated that it was *difficult to separate issue of diabetes from general men's health* issues acknowledging men do not often take pro-active measures to deal with their health. He indicated there was a *lot of focus of GP's on changing behaviour based on fear, not on wellness*. He said it is a *lonely journey* having diabetes as you live with it constantly and the idea of diabetes being a lifelong disease and maybe incurable is daunting. But at the same time you do not want to hear other people's horror stories. He also noted that there are *no men's health groups dealing with diabetes*.

DH's treatment is primarily by way of *medication* and he has *made attempts to change his lifestyle*. He told the story of making a request for a *dietitian to visit his home and review food cupboard* to advise on sorts of food to avoid and those to have. They would not do this, but instead they *just hand out brochures* and they *just don't have any idea of your life*. He noted that while diabetes is about lifestyle, dietitians and *GP's stop short of understanding people's lifestyles*.

He indicated that he was seeing a GP but he was referred onto specialist; he washed his hands of him noting his *care factor as "zero"*. He has recently moved from 1 specialist to another – seeing a younger more progressive specialist who has really gotten a *better hold of his condition and treating more effectively*. DH said from his experience *"GP's are not leaders in change of improved management and treatment of diabetes"*.

CG's story

CG is an Aboriginal man in his 30's. He has what he refers to as *"borderline" diabetes*. He was diagnosed 10 years ago and takes medication but he is more concerned about issues he has with his heart. CG noted that the *service from the Aboriginal Clinic is ok* but he is concerned about the financial impact. He said he was supposed to be getting free medication under "Closing the Gap" but noted that the *GP was not wanting to get involved as "there is too much paper work"*. CG said he had to change his GP after 15 years and he didn't want to but couldn't afford not to.

WR's Story

WR is an Aboriginal man in his early 50's. He was diagnosed 20 years ago and found out he had diabetes after drinking a lot of sugary drinks and woke up one morning and couldn't see. *WR sees a CDE regularly.* He noted that until recently he believed that the range of *professionals he sees were not talking to each other* about how best to manage his condition and this has only occurred now because of the *ATSI Primary Health Clinic interventions.* He noted that although he had a family GP for a number of years he was *not doing anything to effectively manage his condition*; he was just increasing medication levels and since moving to the *Aboriginal clinic they pay much more attention to his care.*

WR felt the focus is now more on *measures to deal with achieving "wellness"* but in some instances *GP's use fear eg don't drink alcohol with these drugs* otherwise there will be serious outcomes. WR said he would *love to be involved in a pilot program to know about the future of his condition.* He expressed concern that there is not a lot of empathy for people with diabetes – you feel alone – and people (not professionals) have the attitude you should "build a bridge and get over it".

LB's Story

LB is a female in her 30's. She was diagnosed with type 1 diabetes 3 years ago. She said *GP provides good treatment* – they regularly check diet, feet, HbA1c levels and refers her to an endocrinologist. She said she has had a rough 2 years with fluctuating sugar levels, however only she has seen a specialist only once at a public hospital, noting it is *hard to get an appointment* and even though she has private health insurance, living on the fringe of the city it is impossible to see a private specialist, as her suburb is regarded as being in the country.

LB indicated there is *no communication between professionals* she is seeing and only the only contact is the referral letter. She said there is a disconnect between the public and private sectors. She suggested that *public endocrinologists are under huge pressure and don't have time.* She noted that on the last 2 appointments she saw students and not the specialist. LB also said *GPs struggle with providing comprehensive care*, she said her GP did not know about operation of her new insulin pump.

LB has to purchase boxes of insulin for her pump and pump parts need replacing every 3 months - cost \$50 to \$80 per month all up at least – "if you can't afford it you can't afford it". She said without assistance people take short cuts which in turn affects treatment. Also once people turn 18 assistance cuts out as though people no longer require treatment beyond 18. LB said she could make an *informed decision to join a pilot program* as she knows more than her GP about her condition.

MC's Story

MC is a female in her late 30's. She was diagnosed 20 years ago after she had a virus, which developed into measles and then pneumonia. She lost a lot of weight and her diagnosis was confirmed. She *did not believe the "professionals" she sees talk to each other* and plan things together about her diabetes. This was confirmed when she was pregnant noting *no obvious consultation between professionals.* Through her pregnancy MC stated she did not receive good advice; she knew more about her condition and diabetes generally than the professionals in hospital. She said they "*had no idea!*"

MC said the *only conversation she had with her GP was about the length of time it takes to get an appointment with the specialist.* She indicated that she does *not have a conversation on the bigger picture with her GP as they are focussed only on the issue at hand.* She thought one reason for this is they probably don't have the time. Another reason is they probably don't know what questions to ask or advice to give! But MC also noted that she has *more understanding of her condition* as she has studied and researched it for 20 years.

MC said there is a *need for a lot more focus on exercise* – even though it can be “scary” but regard it as very important to keep and stay healthy. She said a lot of it is guessing and making it up as you go along. MC made the comment that providing *extra funding to GPs may not be the answer – it may be preferable to have Diabetes centres of excellence*.

Summary

The focus groups informed the structure of the applied economic model (computer model) by identifying the sources of variability of patients’ care needs and in their types of GPs. Issues included:

- > Some patients benefit from GPs having referral networks whereas other patients develop their own networks.
- > Some patients have specific needs regarding the broader qualities of AHS providers, for example education for patients with a number of comorbidities or language barriers.
- > Patients perceived GPs as variable in quality of the care they provide.
- > Patients preferred longer consultations with their GPs to shorter consultations, when revising their care needs.

POLICY NARRATIVE

The policy narrative is the story that surround, supports and justifies the proposed policy. In many cases it reveals the omissions from the policy development process (the implicit assumptions).

The use of the policy narrative to critique economic development models was first proposed by Roe⁸. Roe argued that the policy narrative simplifies the relationship between cause and effect and, if it is sufficiently persuasive it can lead to evidence being ignored or critical parameters that determine outcomes being ignored. The review of the policy narrative for this research was targeted to the literature and media releases by DoHA, however, some references are made to published critiques of these policies. The main objective was to understand the simplified cause and effect inherent in this narrative and the implications for omitted parameters.

The Australian policy narrative around diabetes and primary care from 1999 to 2011 was reviewed for this project. The key themes, and any changes in these themes, were noted, as were omissions relating to the issues around heterogeneity of patients and GPs.

The main ongoing theme was the limitation of the MBS fee for service as way of financing CDM and that this was the primary causal factor for poor patient outcomes. While there are a number of references to gaps between optimal and current care (the extent of poor outcomes), there is no evidence provided about the quantification of this gap, for example, does this relate to 10%, 20% or 60% of all patients.

In the following three sections, the analysis of the policy narrative is presented in three parts:

- > Identifying the main triggers for the choice of a scheme external to the MBS by reviewing the attempts to improve chronic disease management (CDM) by changing the MBS items.
- > Reviewing how other schemes that are used to finance primary care outside the MBS address risks associated with these schemes.
- > Combining the previous sections on the focus groups and structural parameters (e.g. patient heterogeneity) with the discussion on the policy narrative to identify omissions in the policy narrative.

The rationale of this approach is that the omissions in the policy narrative represent possible risks in the policy; if parameters are not identified, they cannot be managed.

Changes to the MBS to accommodate CDM

In 1999, the Commonwealth introduced items onto the MBS to encourage: i) care planning by GPs; and ii) GPs to work with multidisciplinary teams (MDTs) to provide care for people with chronic disease. This initiative, the Enhanced Primary Care Package¹⁰, was a response to the concern that the MBS did not generate the incentives necessary for CDM.¹¹ One commentary on the early initiatives to encourage more GPs to provide intense management to diabetes patients raised the question of what would GPs need to give up in terms of patient care; coughs and colds or more serious chronic conditions for which there was no additional incentive. (See Appendix 2 “MBS Diabetes Initiatives”)

In the following years, further initiatives were introduced. By 2011, a number of MBS Items that had been introduced to the MBS in 1999 and the early 2000s had been replaced or removed. The imperative to continue changing these items probably contributed to the complexity of the process of claiming the relevant items; “the red tape”.¹²

There was a ten year period over which changes were made to the MBS to increase its capacity to accommodate CDM. However, at the end of 2010 decision makers appear to have come to the same conclusions as they had when the 1997 Coordinated Care Trials commenced: the only solution is to have a financing system that is outside the MBS. Hence, the DCC Initiative was designed to be financed using a scheme external to the MBS.

However, the MBS changed in some fundamental ways as a consequence of this decade of reforms. First, GPs could be paid for being involved in the care planning process, with the expectation that some of these activities could be performed by practice nurses. Second, GPs would be paid to perform services without the patient being present. These services were specifically related to case conferences with other team members. And third, GPs could refer patients to AHS providers who would be able to provide up to five consultations for which reimbursement could be claimed by the patient from the MBS. (These AHS providers had their services subsidised by the MBS for the first time.) Other changes include additional Practice Incentive Payments (PIP) and financing of Divisions of General Practice to train and educate GPs and practices on the initiatives.

In summary, the view that the MBS fee for service cannot adequately support best practice care for patients with chronic disease has not changed since 1999. If the policy reforms since 1999 have not had the anticipated benefits, then it is possible that the major finding from 10 years of reform is that a universal health care scheme cannot provide incentives for CDM, even if specific changes are made. If the MBS cannot be adapted to accommodate CDM, then alternative financing structures for primary care are necessary.

Other schemes that work outside the MBS

THC solutions is a term used to describe a health care financing solution that finances primary care provided to specific patient groups, but uses funding and fee schedules other than the MBS. Examples of such solutions include care provided to veterans (DVA), injured workers (e.g. WorkCover) and persons injured in vehicle accidents, (motor accident schemes). Private health insurance also covers some aspects of primary care in certain circumstances. The key message from reviewing other schemes is that they all have a higher degree of structure around GP - scheme relationship, compared to the MBS. For example, they might require GPs provide report directly to the scheme about patients. Or they might require GP to undergo special training to be able to provide services within that scheme.

THC solutions were first explored as a response to the complexities of managing chronic conditions within the MBS fee structure in the 1997 to 2000 Australian Coordinated Care Trials. These trials were premised on significant reductions in MBS, PBS and hospital

admissions achieved by increased up front spending on improved coordination, care plans and improved access to AHS. However, the reality was that these gains did not eventuate.¹³

THC solutions for patients whose services are currently reimbursed through the MBS could take any one of a number of forms but have two key characteristics in common:

- > The success of any THC is defined in terms of patient outcomes relative to the outcomes for these patients under their options in existing care, including options outside mainstream primary care; and
- > Critical to this success is a different set of incentives, particularly financial incentives, for providers, particularly GPs, compared to what they would otherwise have.

The DCCI and the Diabetes Pilot are examples of THCs. In addition to the elements above, there is an opportunity to finance positions such as a care coordinator that can be used by a practice but not financed by that practice. This element not only provides smaller clinics with the efficiencies possible from the economies of scale available to larger clinics, but it also provides a directed infrastructure subsidy. This contrasts to the undirected subsidies of the Practice Incentive Payments (PIP) initiatives.

In summary, there are a number of primary care financing schemes outside the MBS, most of which operate under different legislation to the MBS, often State based. One difference between these schemes and the MBS is the relationship between the GP and the financier.

Omissions in the policy narrative

One set of omissions from the policy narrative is a discussion of the implications for the policy design of the lower than anticipated uptake of the CDM MBS initiatives. For example, will taking the financing structure outside the MBS resolve the structural issues that could have prevented uptake of the MBS items. For example: i) exactly what types of guidelines are useful to aide clinical decision making; ii) is it useful to treat complex patients as series of chronic diseases; and iii) how significantly do care models need to change within a general practice to accommodate changes in the MBS?^{14,15}

A major omission is the parameters that HTA identifies as essential in health technology policy decisions: heterogeneity in capacity for patients to benefit from the policy and evidence that there will be a benefit to patients provided with the new technology. Specifically, there is no discussion of:

- > heterogeneity in the patient CtB from enrolment into this model,
- > GP heterogeneity in quality of care currently and response to interventions.

Furthermore, there is no estimate of the proportion of patients who receive suboptimal care currently. There is some discussion about the variability in access to AHSs.

SCENARIOS TO AVOID

The review of the policy narrative, in terms of the inclusions and omissions, and the results of the focus group were used to identify three scenarios that could arise because the “known unknowns” were not appropriately accommodated in the policy design. These are sources of risk and opportunities for risk management.

The questions that were asked to identify the risks are:

- > What if patients whose care and outcomes are currently optimal would prefer not to be part of a pilot of a THC scheme?
- > If all GPs have a CtB financially from the patients they choose to enrol, is this a sufficient reason to enrol a patient with no CtB from changed care?
- > Will researchers, initially, and GPs, subsequently, have an incentive to convey the message that all patients have the potential to benefit from the initiative?

These three scenarios are summarized below and detailed in Appendix 4 “Scenarios to avoid (detailed)”.

1. Patients:
 - a. whose current outcomes are good
 - b. have no CtB from enrolling into an alternative scheme
 - c. but whose GPs have a financial incentive to enrol them,
2. Patients:
 - a. whose current outcomes are poor
 - b. for whom improved outcomes are likely to be conditional on the GP changing clinical practice, from currently suboptimal to optimal
 - c. for whom there is a high probability that the GP will not change their practice.
3. Patients:
 - a. whose current outcomes are poor and
 - b. who are likely to benefit from options other than either current care or THC, for example a multidisciplinary team at a Tertiary Diabetes Centre (TDC), a nurse led clinic, an IHS or a migrant health centre.

SUMMARY

The key “known unknowns” identified in this step are:

- > heterogeneity across patients in CtB from the policy,
- > heterogeneity in GPs in capacity to respond to the policy by improving the quality of their care, and
- > heterogeneity in the service models patients have access to.

The interactions between these parameters are also structural parameters of uncertain values. The next step is to specify these in a spreadsheet simulation as an applied economic model and explore these parameters and the relationship between them.

Specification of structural parameters

The computer simulation (an applied economic model) was specified using the information presented in the previous chapter. A generic structure for a primary health care model was identified. Some of the technical details are provided in Appendix 10 “Policy simulation in primary care – some issues for modellers” and the spreadsheet model is available on request. Then the specifics of the policy were modeled.

MODEL STRUCTURE: PLAYERS AND SETTINGS

There are two steps in developing a typology for a policy simulation. First, the elements of the computer model are identified; in this case GPs, patients and the service model within which the GP and patient interact. Second, classifications are developed for each element allowing the heterogeneity to be specified in the model. In this case: two types of GPs; seven types of patients; and four GP-centric service models. Additionally, there is a range of non-GP-centric service models. Summaries of each of these types are presented below.

General Practitioners

Two possible typologies were identified for GPs: i) Just Dr. Average (only one type) and ii) Mixed (two types). The distinguishing feature of these typologies is length of consultation. Essentially, the first typology assumes that a distribution of GPs by mean length of their consultations is unimodal and has a small standard deviation. The second typology assumes that this distribution is bi-modal: GPs can be classified as either short or long style.

Appendix 11 “Do All Australian GPs practice 14 minute medicine (on average)” sets out the rationale for these two typologies. Also, Appendix 8 sets out an example from the literature that raises the potential for, but does not explicitly consider, GP heterogeneity.

In the spreadsheet model, by specifying 100% of GPs as belonging to either all Dr. Comprehensive or all Dr. Six Minute, then the assumption of Dr. Average as being typical of all GPs could be specified.

Typology 1: Just Dr. Average

This is the typology implicit in the policy narrative. If each GP in Australia were represented as a distribution of the length of their consultations, they would all have the same proportion of long and short consultations and hence the same average duration of consultations. Variations in income would be due to the proportion of consultations that are bulk billed or the hours worked each week, rather than the mix of consultations. All GPs would respond similarly to the changed incentives of THC, for example they could all change the proportion of longer consultations from 10% to 20%.

Typology 2: Mixed

The two types of GPs are: Dr. Comprehensive and Dr. Six Minute.

- > Dr. Comprehensive types plan their days with 15 minute consultations and 2 to 3 minutes between each patient. They regularly have half hour consultations during the week. The average practice revenue from consultations by this type of doctor is around \$140 an hour: \$35 from each of two 15 minute Level Bs and \$69 from a 30 minute Level C. They bulk bill their patients, who are mainly older.
- > Dr. Six Minute types plan for 8 level B consultations an hour, which bring in \$280 in MBS revenue an hour.¹⁶ This type of GP will rarely do more than one problem in each consultation and will ask the patient to come back the following week if the consultation is about to go over 6 minutes.

Dr. Comprehensive types may or may not provide better quality of care to their patients compared to Dr. Six Minute. If Dr. Six Minute is in an area with a low ratio of GPs to patients, then their strategy could be the best option for both practice income and population health. Dr. Comprehensive might refer to other providers such as diabetes educators, or could take on the task of diabetes education. Dr. Comprehensive is likely to provide better quality of care to complex patients for whom longer consultations are necessary. However Dr. Comprehensive’s consultations could be longer simply because they converse socially with patients.

This typology illustrates how if GPs have different practice styles, the MBS schedule generates variability across GPs in the MBS revenue per GP per hour. It also shows how a GP will make a financial loss compared to their maximum possible income if he or she adopts the style of Dr. Comprehensive rather than Dr. Six Minute. It illustrates that, to the extent that complex patient CDM necessitates longer consultations, then Dr. Six Minute is less likely compared to Dr. Comprehensive to change practice to provide more of such care. In other words, the financial loss of changed practice could dominate his or her choices. However, if improved CDM is driven by increased referrals and increased delegation to practice nurses then, then this could be accommodated by both types of GPs.

Patients

The computer model has seven types of patients differentiated by four different characteristics:

- > complexity (complex and less complex);
- > and sensitivity or otherwise to each of
 - o quality of GP care,

- quantity of AHS; and
- both quality and quantity of AHS.

The way in which these four characteristics combine to form seven patient types is illustrated in the top half of Table 1. Patients can have three current health outcomes: good, moderate or poor. Each type's health outcome is a function of that type's own characteristics and care context (GP type plus service setting). In this model, the patients are not characterised by the factors that influence their current outcomes, for example the presence of comorbidities such as depression and heart failure or socio-economic determinants. Instead, they are characterised by their CtB from (respond to) a range of care or treatment situations, or, in other words, the context being impacted by the initiative. This approach (classify patients by their CtB) is analogous to the way that capitation systems with multiple payments classify patients by what determines heterogeneity in total costs of care, for example, initial year of diagnosis or subsequent year.

Table 1 Seven patient types defined by four characteristics and linked to outcomes

Patient types by complexity and sensitivity to service model and GP care quality		1	2	3	4	5	6	7
	Complex	✓	✓	✓	✓	✓	✓	
Sensitivity to care and service model	Sensitive to GP care	✓	✓	✓				
	Sensitive to quantity	✓	✓		✓	✓		
	Sensitive to quantity & quality	✓			✓			
Patient outcomes by patient type and context (GP care and service model)		1	2	3	4	5	6	7
GP care optimal	Quality and quantity	G	M	M	M	M	P	G
	Quantity	M	M	M	P	M	P	G
	Limited	M	P	M	P	P	P	G
GP care suboptimal	Quality and quantity	M	M	P	P	M	P	G
	Quantity	P	M	P	M	M	P	G
	limited	P	P	P	P	P	P	G

Legend: G = Good outcomes; M = Moderate Outcomes; P = Poor outcomes

An example of a patient who is complex and is sensitive to GP quality is one who requires longer consultations and if he or she has these, the source of their complexity can be addressed and outcomes improved. An example of a patient who is sensitive to quality as well as quantity of AHS is a recently arrived refugee who is not fluent in English and needs an interpreter to assist them with the complexities of diabetes education. Some patients are complex and have high level of service use but their outcomes remain poor, regardless of the quality and quantity of their care. Less complex patients might have good outcomes, with short consultations only and education provided by a practice nurse.

Service models

There are four types of GP-centric service models: Solo GPs; GP plus practice nurse; GP plus primary care referrals (not team based); and multi-disciplinary team in primary care setting. The outcomes of each of these service model in terms of the quality and quantity of access to AHSs, for example diabetes education, is assumed to vary across these models. For example, some but not all GPs who work in solo practices will have the skills and experience to provide up-to-date diabetes education. Some, not all, solo GPs will refer to AHS providers if they do not have the time or experience for diabetes education. Patients

who see GPs who work in multidisciplinary teams are more likely to have access to quantity and quality of AHS.

There are also non GP-centric service models available to patients; different GP-centric primary care is not the only option available to patients. Indigenous Health Services (IHSs) provide services in a culturally appropriate setting and with culturally aware staff. An important example in Brisbane is the Inala Health Service, which has recently demonstrated improvements in care and outcomes for Indigenous Australians with chronic disease including diabetes.¹⁷ Tertiary Diabetes Centres (TDCs) provide care to patients in an outpatient setting. Patients have access to multidisciplinary teams that include: endocrinologists, diabetes educators, podiatrists, dieticians, psychologists and exercise physiologists. Such centres will often provide care to more complex patients, including people with type 1 diabetes and gestational diabetes. TDCs also see patients who are referred by GPs for a range of reasons, including starting on insulin.¹⁸

And finally, Diabetes Educator led clinics, operating outside a general practice are not yet a permanently funded part of the Australian health care system. There are opportunities to expand these models of service delivery, however, the lack of additional funding outside the community health sector will constrain this growth. For example, a nurse led clinic in Canberra is funded entirely outside the MBS.¹⁹

INTERVENTION: HOW WILL IT THIS WORK?

For the purpose of the policy simulation, the intervention was characterised as having three components, which are generalisable to any CDM intervention within THC:

1. Increased financial payment for GPs to provide the set of care planning services plus the possibility of "pay for performance" or for compliance with guidelines for referrals.
2. Three elements of the strategy to improve information systems:
 - a. Transfer of electronic information between providers in different organizations.
 - b. Improved patient records and improved data extraction to review these records, including software that prompts the more straight forward aspects of the care guidelines. For example: Was a foot check performed? What was the result?
 - c. Clinical decision support software that supports a GP through complex clinical decision making. For example, if a patient has a number of co-morbidities, how does this influence initiation and ongoing prescribing of insulin and the decision to treat within a General Practice rather than within a Multi-Disciplinary Team.
3. Improved access to AHSs via either improved referral networks or MDTs.

The policy simulation did not explicitly consider the effect of financial incentives for pay for performance because insufficient detail on these was available. Instead it assumed that GPs will enrol a patient only if there is no financial loss relative to the MBS revenue received if they did not enrol that patient. This net effect on financial revenue is determined by both the opportunity cost of spending more time with this patient and less time on other work and the increase in the revenue paid for care for that patient.

However, the simulation was structured to allow for the possibility that heterogeneity in GP characteristics could result in differential uptake of one or more of the components of the intervention, or differential incentive to enrol a given patient. Specifically, the model accommodates the following scenarios.

- > Dr. Comprehensive is providing a bundle of services for a given patient and currently receives \$450 in revenue for 5 hours of care over one year; an average hourly rate of \$90, which is consistent with his or her average hourly rate. If the payment for the bundle of services that was expected to be provided to that patient under changed care were \$600, and the hours were increased from 5 to 6 per year; this would represent an hourly rate of \$100. This would equate to a premium compared to his or

her existing average hourly rate for care generally of \$90. Hence there would be a financial incentive for Dr. Comprehensive to enrol his or her patient.

- > In contrast, Dr. Six Minute could be providing care for an average hourly fee of \$120 across his or her patients. This GP could also be providing care for 5 hours a year for this patient, but be receiving \$600 a year. Differences could include a patient copayment for each item 23 and only one problem is addressed in each consultation, which is shorter on average compared to Dr. Comprehensive. There is no financial incentive for Dr. Six Minute to enrol his or her patient in the new scheme, regardless of the patient's CtB and regardless to the financial advantage to Dr. Comprehensive.

SCENARIOS: HOW THE TYPES INTERACT WITH EACH OTHER AND THE INTERVENTION TO PRODUCE OUTCOMES

The typology, the intervention, and the outcomes for patients are brought together in an input table on the simulation spreadsheet that identifies, in this case, 37 scenarios about how these elements interact. Table 1 summarises how a patient of a given type (1 to 7) interacts with a given context (GP care quality and service model outcome (access to quality and quantity) to produce a health outcome (good (G), moderate (M), poor (P)). The tool allows the user to select the health outcomes for a given combination.

In the version presented in this report, the user has specified that if the patient is not complex, then, regardless of the health service model and GP quality, the health outcomes will be "good". Patient 7 is complex, and sensitive to service model quality and quantity and clinical quality. As this patient's access to service models that have both quality and quantity improves, and GP quality improves, so does his or her outcomes. In the computer model, the function of this table is to specify the pre and post health states for seven types of patients in six possible contexts; a total of 37 possible scenarios.

The intervention acts to move some, but not all, patients to better health service models and better GP care. This specification allows a given patient's CtB from the changed policy to be predicted based on heterogeneity in the patient, the GPs care and service model. What is a good, moderate or poor outcome? In this case it is HbA1c control. This model can be adapted for other conditions by changing the indicators under good, moderate or poor outcomes.

SUMMARY

The five "known unknowns" identified in the review of the generic HTA model and the policy narrative and the types identified in the focus groups informed a formal specification of the applied economic model as a spreadsheet model. The full set of input models is presented in Appendix 7 "Model input tables".

Typically, the next step would be to address the following question: What quantitative values should the parameters take? This model is unusual because all the parameters in the model are "known unknowns"; there are no values in the public domain. If this model were based only on EBM, the process would stop here; we cannot assume values for these parameters (e.g. heterogeneity of GPs) because there is no evidence. The advantage of policy simulation compared to EBM as a way of informing policy is that it requires decision makers to identify the default or implicit assumptions in policies. Policy simulation recognises that even though estimates are not available, assumptions still need to be made in order to assess a policy prospectively. Then alternative assumptions that are at least equally plausible are identified. The sensitivity of outcomes to equally or more plausible assumptions can then be tested.

Analysis of “known unknowns”

The process of selecting inputs for the policy simulation is described in Appendix 7 “Model input tables”. However, the advantage of this approach is difficult to demonstrate with the input tables alone. Furthermore, the output tables are difficult to present without the interactive process, mainly because there are multiple parameters and any output table requires a range of parameters and their relationship to be identified. We used an alternative to displaying output tables that can be thought of as translating a multi-dimensional model into a series of simple 2D models. These can then be used to illustrate the difference between the default and possible alternative values of a range of structural parameters and relationships between parameters.

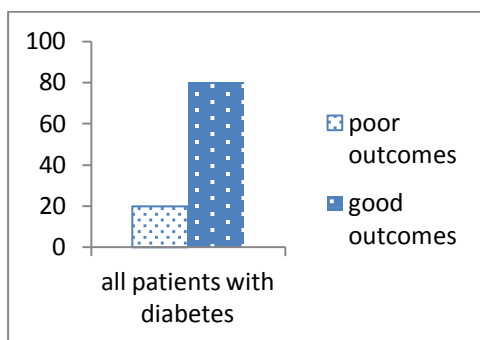
In the following series of charts, each of the “known unknowns” are analysed using the following questions:

- > What is the implicit assumption in the policy narrative?
- > What is a plausible alternative to this assumption?
- > How is this specified in the computer simulation?
- > Does it matter what value this parameter has?

We start with GP heterogeneity and then introduce heterogeneity of patient CtB. The specific structural parameters reviewed in this section relate to the idea of the existence of different types of GPs, where type may or may not be a determinant of patient outcomes under current care or THC. The questions that will be considered include:

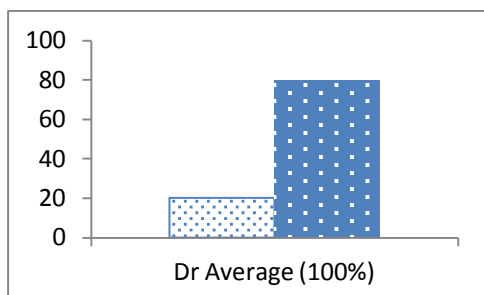
1. Is there a uni- or multi-modal distribution of GPs by average duration of consultation?
2. Is type of GP associated with:
 - a. patient outcome under current care?
 - b. patient CtB from intervention?
 - c. any potential selection bias in enrolment?

The first five diagrams explore the question of GP type and relationship to current outcomes.



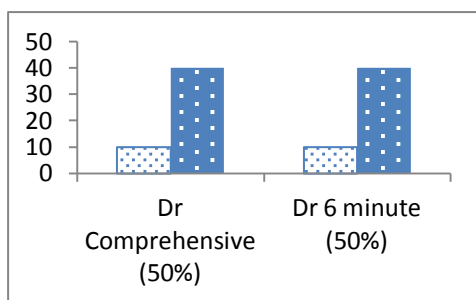
Evidence we have:

We start with a cohort of 10,000 diabetes patients who have either good outcomes under the current system or poor outcomes, however poor and good are defined. In this example, 20% have poor outcomes. The policy narrative attributes this gap to a range of factors including the MBS financing structure. However, it does not quantify this gap.



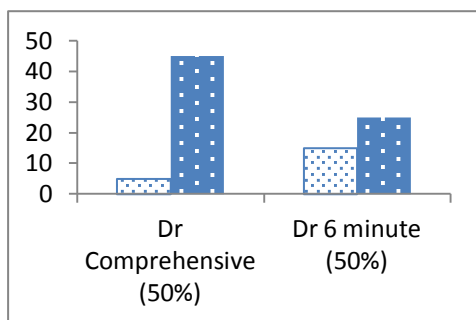
Scenario 1

The implicit assumption in the policy narrative is that, because we have no evidence to assume otherwise, we should assume that there is no characteristic of a GP that would result in variability in patient outcomes – all GPs are Dr. Average. (In the terms of this policy simulation.) Hence, all GPs have 20% of patients with poor outcomes.



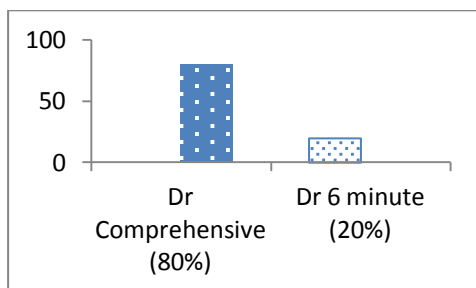
Scenario 2

An alternative assumption is that there are two types of GPs, some of whom practice primarily longer and other shorter consultations. In this example we assume that that 50% of GPs are in each group. We also assume that the type of GP does not influence patient outcome, hence 20% of patients in each type of GP have poor outcomes.



Scenario 3

A third scenario is that GPs are heterogeneous and the type of GP does influence outcomes of patients with chronic disease. In this case we assume that 90% of all Dr. Comprehensive patients have good outcomes whereas 60% of all Dr. Six Minutes patients have good outcomes. In this simple version it is assumed that GP practice style is the only determinant of this variation across GP type.



Scenario 4

A fourth possible scenario is that all patients seen by Dr. Six Minute GPs have poor outcomes whereas all patients seen by Dr. Comprehensive have good outcomes. In this case we need to assume that only 20% of all GPs are of the Dr. Six Minute type. This demonstrates the interrelatedness of the parameters (% of GPs of each type, % of all patients with poor outcomes).

The previous diagrams consider a range of scenarios about the mix of GPs and the relationship of GP type to patient outcomes. The default assumption, in the absence of evidence, is Scenario 1 – all GPs are of the same type and the patients with poor outcomes are distributed uniformly across GPs. The remaining Scenarios explore the possibility that a distribution of GPs by mean consultation duration is bi-modal – there are two broad types. Scenario 2 assumes that there are types but types do not influence patient outcomes (pre-intervention). Scenario 3 assumes that GP type can be one factor that influences current patient outcomes. (The rationale is set out in Appendix 11.) Scenario 4 assumes that GP type is the only factor that influences outcomes. Scenario 4 is considered implausible but Scenarios 2 and 3 are considered plausible.

The critical difference in policy simulation and EMB is this: *An EBM policy researcher could argue that there is no evidence as to the proportion of GPs in each type or that type influences current outcome, therefore we should assume scenario 1. Using policy simulation, we conclude that in the absence of evidence, Scenarios 1, 2 and 3 are all plausible.*

Does it matter whether GPs are of variable type and whether type influences current outcome?

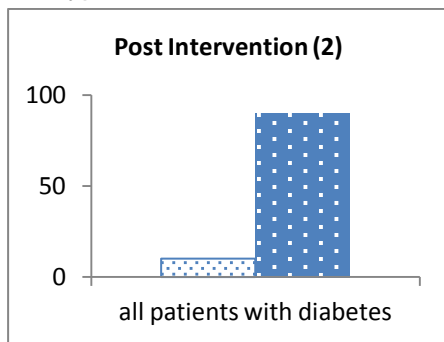
To address this question we first, assume that: i) all enrolled patients will achieve good outcomes post intervention; ii) all GPs have the same incentive to enrol patients; and iii) type, if it exists, does not influence patients outcomes post intervention. In terms of achieving improvement in patient outcomes, GP type is irrelevant in this situation. (It could matter however if there are additional costs associated with this policy and the same outcomes could have been achieved by targeting it only to patients who have poor outcomes.)

Now assume that:

- > type does influence patient’s current outcomes (Scenario 2 or 3 above apply),
- > GP incentive to enrol is influenced by type (due to the different opportunity cost of longer consultations by GP type); and
- > patients with poor outcomes can have a CtB from DCC that is a function of GP type.

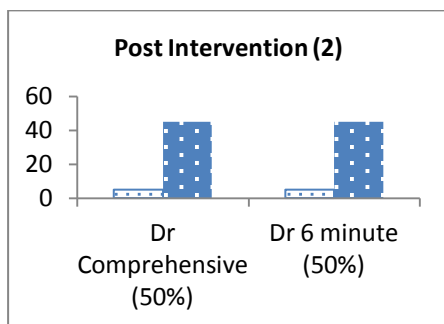
These assumptions are not evidence-based, however, nor are the default (implicit) assumptions (above). The reason why these plausible alternatives to the implicit assumptions matter is because they introduce a range of risks including those identified previous as scenarios to avoid. For example, a scenario that decision makers could wish to avoid is a GP who enrolls a patient with poor outcomes, where GP practice style contributes to this poor outcome and this type of GP is unlikely to respond to the intervention by changing practice. This situation could be the result of a financial incentive to enrol the patient, but a financial disincentive to change practice style. (See Appendix 4 for a detailed discussion of the scenarios to avoid.)

The following three diagrams demonstrate some of the associated risks of not recognising GP types and other “known unknowns”.



Scenario 5:

The diagram on the left is a hypothetical outcome for enrolled patients post intervention – 90% have good outcomes compared to 80% prior to a DCC Initiative. This result could be consistent with all GPs achieving the same share of patients with good outcomes – an extension of Scenarios 1, 2 and 3 above. It could also be consistent with a situation where GPs can be classified by type and type determines response to DCC.



Scenario 6:

This scenario is a post intervention extension of Scenario 2 above. In this case GPs have the same result pre and post (for enrolled patients). However, there could be an additional influence which is that GPs have a preference for enrolling patients whose final results are most likely to be “good” post enrolment. In this case the results for enrolled patients are not generalisable to unenrolled. Alternatively the bias might only be relevant to Dr. Six Minute who could have a financial disincentive to enrol patients who require the GP to change their practice style and which will result in a reduced income.

The objective of the policy simulation is to formally consider the possibility that, in the absence of evidence, the default or implicit assumption is not the only plausible assumption. The structural parameters were reviewed in the simulation and the following risks and associated strategies were identified in cases where it matters what assumption we make in the absence of evidence.

Risk management strategies

All risk management strategies in this report are based on the following assumption:

- > GPs will only enrol a cohort of patients if the expected income is no less than the opportunity cost (foregone income) of providing care.

That is, we assume that GPs will act as “rational economic agents”; they will not make a systematic change to their practice that reduces their expected income. In other words, GPs are assumed to enrol patients only if there is a capacity for GPs to benefit financially, or to make no financial loss.

This explicit assumption could be challenged by another research team.

ENHANCED CONSENT PROCESS

The key risk is that patients with no CtB from THC will be enrolled without a full understanding of their CtB from enrolment. This can occur if:

- > GPs are optimistic (overstate) the potential for a patient to have a CtB from enrolment and will tell a patient they have a CtB, even if this is not the case.
- > GPs currently provide less than optimal care, have a financial incentive to enrol patients but no financial incentive to change their practice, hence the patients have no CtB.
- > Patients and GPs do not have a shared understanding of the reasons why a given patient’s outcomes are poor under current care. In short, if the reason a patient’s current outcomes are poor is due to the quality of the GP’s care, will the GP recognise this, will he or she tell the patient or will the GP attribute poor outcomes to other factors.

This issue of over optimistic estimate of the CtB from changed care is distinct from the issues arising from the need for patients to have a culturally and linguistically appropriate enrolment process. This situation could occur whether or not the patient has a complete understanding of what is communicated. The issue of interest is the explication of patient CtB from enrolment.

The risk management strategy is enhanced enrolment. First, patients enrolling in DCCI should be informed by an objective assessment of their CtB from enrolment. It is assumed that patients will be assessed at enrolment in order to classify them for capitation purposes (complex, recently diagnosed etc.). This assessment does not inform the patient of their CtB from enrolment, only the expected costs of their care and expected services.

Second, to inform a patient of their CtB, additional assessments are necessary. A pre enrolment process should identify factors that influence current health status such as GP care quality, Practice IT and decision support software and access to AHS. It should also assess whether the factors influencing the patient’s current outcomes are likely to change under DCCI, including the care currently provided by the GP. Hence, the patient consent process should be preceded by a peer review of the quality of care provided to each patient.

THIRD OPTION FOR CARE

The risk is that:

- > a patient with poor outcomes under current care is enrolled in THC but their best option is to be referred to another organization that specialises in diabetes care for patients whose care is complex.

The risk management strategy is that, as part of the enrolment strategy is to ensure that GPs and patients are presented with an alternative to both current care and enrolling in a THC. Such care options include: Indigenous Health services; Migrant Health services; specialist diabetes clinics - TDCs. In some cases this could involve patients being referred to specific MDTs rather than referral within a network of providers.

REPORTING ON BOTH ENROLLED AND UNENROLLED PATIENTS

The risks are that:

- > GPs and or practices will be strategic in enrolling patients. They will not enrol patients who are less likely to meet the requirements for pay for performance, to attend all necessary consultations and more likely to have significant comorbidities such as depression, heart disease and respiratory illness.
- > Evaluation of the DCC pilot and initiative will exclude unenrolled patients at participating practices and practices that do not participate and hence there is a risk of a systematic bias in the measurement of the benefit of DCC and a potential to overestimate the performance of the participating GPs.

The risk management strategy is that MBS (and extra MBS) services and, where possible, outcomes such as hospital admissions, should be reported to monitor the ongoing effects of the initiative. This reporting should include:

- > diabetes patients who do and do not enrol from a given practice; and
- > from participating and non-participating practices .

Characteristics of participating GPs can be compared with non-participating GPs using Medicare Australia data, without identifying individual GPs or patients. For example, whether GPs are doing predominately long or shorter consultations, their prescribing of diabetes medications and their historic use of care planning items.

MODELS OF AHS DELIVERY

The risks are:

- > A model designed to increase access to AHSs and MDTs will increase use of these services and that this increase comes at a cost of services available for those who are not enrolled. There are two equity issues:
 - o access to these AHSs for patients whose GPs are not participating vs. patients whose GPs are participating
 - o Access to AHSs for two patients whose GP is participating, but only one of is enrolled.
- > There are equity and effectiveness issues if more complex patients are not enrolled and have less access to AHS compared to patients with less complex needs and who are more likely to be enrolled.

Increased demand for AHSs, a constrained resource, is an inevitable result of a policy responding to poor access to such services. Improved referral process can improve access but improved service models are necessary to improve the efficiency with which constrained resources are able to supply increased demand.

Risk management strategies include improved reporting of service use (see previous recommendation) and methods to improve the efficiency with which AHSs can be provided.

Results

Results against the original research questions are reported in Appendix 1. The results reported against the final research questions are reviewed below.

1. How can a policy simulation be used to inform any THC style initiative?

The first challenge was technical. Policy simulations designed for primary care need to be able to specify interactions between:

- > Intervention;
- > Patient;
- > Health care setting; and
- > Key provider (the GP in this case).

In contrast, HTA simulations, while they have other complexities, essentially assume no strategic behaviour and focus on the interaction between the patient and the intervention. From a technical perspective, this task is challenging. The approach used in this project was to develop a hypothetical individual patient simulation, with the addition of a cohort of GPs that could interact with the individual patient cohort. A scenario table provided possible outcomes for all possible combinations of items ii) to iv) in the above list. The intervention determined the probability that a given individual was in a given scenario, and was analogous to the states in a Markov model or a micro-simulation model. The difference between conventional states in models and the states used in this model was that they were defined by patient characteristics, GP characteristics and setting rather than stage of disease or patient risk factors, for example.

The second challenge was epistemological. Researchers from an EBM paradigm found policy simulation a difficult technique and tended, initially, to be very skeptical of its value. A typical response when a structural parameter was introduced to such a researcher is: “But there is no evidence of its value so how can we assume it has a value of x%?” A number of devices were developed during the research in order to address this issue. For example, the assumption made implicitly by the researcher was elicited, the plausibility that it had a different value was established, and the significance and possibility of managing the risks associated with the uncertainty were demonstrated. A key distinction for EBM researchers was the distinction between: i) assuming a parameter has a value of x%; and ii) using this value to test whether it matters if a parameter has a value apart from that assumed implicitly.

The third issue was how to demonstrate validation. The validation of the method was in its capacity to identify structural uncertainty and risk management strategies not considered in the current policy narrative and policy design. Other researchers could have identified different sources of structural uncertainty and different risk management strategies. This is discussed in more detail in Appendix 12.

2. What are the critical elements of an overarching policy framework for THC initiatives for CDM?

The policy simulation identified five main sources of structural uncertainty – “known unknowns” – that were not part of the policy narrative and hence not explicitly considered in policy design. These sources of uncertainty mattered, in that their values, while uncertain, could impact on patient outcomes. The risk management strategies associated with these “known unknowns” are the critical elements of overarching policy framework.

Recommendations and conclusions

The policy narrative around the DCC Initiative and Pilot omits reference to the following:

- > The possibility that patients with poor outcomes will not necessarily benefit from changed practice, even if there is an incentive for GPs to enrol these patients.
- > The possibility that patients with currently good outcomes will not have a CtB from enrolment.
- > The possibility that GPs are heterogeneous and this heterogeneity influences heterogeneity in patient outcomes and in GP response to the DCC.

The three recommendations are:

1. Any THC developed to improve care for patients should include consideration of the critical elements (risks and risk management strategies) identified in this research. The application of policy simulation in conjunction with decision makers could identify additional sources of structural uncertainty and hence risk management strategies.
2. Data that is in the private domain of Medical Practitioners and DoHA (Medicare) is used more effectively to inform the possible value of “known unknowns”, without compromising the confidentiality of individual GPs or patients. These parameters relate to the relationship between average length of consultation and incentive to take up the existing CDM items.
3. The policy narrative should be realistic rather than optimistic about the potential benefits of enrolment. Not all patients with a given condition have a CtB from THC.

This research also identified that evidence based policy does not address the “known unknowns” rigorously. In the absence of evidence, the assumption that there is no heterogeneity in patient CtB or in GP practice style is not the only option available to decision makers . Furthermore, failure to recognise that other assumptions are more plausible than “default” assumptions, can lead to a failure to recognise the risks of policy change and to identify strategies to minimise these risks.

References for main report

1. Australian Government Department of Health and Ageing. Building a 21st Century Primary Health Care System. Australia's First National Primary Health Care Strategy [Internet]. Commonwealth of Australia; 2010. Available from: [http://www.health.gov.au/internet/yourhealth/publishing.nsf/Content/3EDF5889BEC00D98CA2579540005F0A4/\\$File/6552%20NPHC%201205.pdf](http://www.health.gov.au/internet/yourhealth/publishing.nsf/Content/3EDF5889BEC00D98CA2579540005F0A4/$File/6552%20NPHC%201205.pdf)
2. Australian Government Department of Health and Ageing. National Health Reform Strategies. [Internet]. Commonwealth of Australia; 2010. Available from: <http://www.yourhealth.gov.au/internet/yourhealth/publishing.nsf/content/home>.
3. Australian Government Department of Health and Ageing. Primary Health Care Reform in Australia. Report to Support Australia's First National Primary Health Care Strategy. [Internet]. Commonwealth of Australia; 2009. Available from: [http://www.yourhealth.gov.au/internet/yourhealth/publishing.nsf/Content/nphc-draftreportsupp-toc/\\$FILE/NPHC-supp.pdf](http://www.yourhealth.gov.au/internet/yourhealth/publishing.nsf/Content/nphc-draftreportsupp-toc/$FILE/NPHC-supp.pdf)
4. Colagiuri S, Colagiuri R, Conway B, Grainger D, Davey P. DiabCo\$t Australia: Assessing the burden of Type 2 Diabetes in Australia. Canberra: Diabetes Australia; 2003.
5. Bracey A. Poll: Most GPs will snub diabetes scheme [Internet]. Medical Observer; [Updated 2010 April 23; cited 2011 Nov]; Available from: <http://www.medicalobserver.com.au/news/poll-most-gps-will-snub-diabetes-scheme>.
6. Kidd MR. General practice and the Australian Government's National Health Reform Plan. *Med J Aust.* 2010;193(2):71-74.
7. Australian Government Department of Health and Ageing. Media Release. Early Pilot of Diabetes Coordinated Care to Begin July 2011 [Internet]. Commonwealth of Australia; 2010 [Updated 2010 Nov; cited 2011 Nov]. Available from: <http://www.health.gov.au/internet/ministers/publishing.nsf/Content/mr-yr10-nr-nr169.htm?OpenDocument&yr=2010&mth=11>.
8. PBAC. Guidelines for preparing submission to the Pharmaceutical Benefits Advisory Committee (Version 4.2). Canberra: Commonwealth Department of Health and Ageing; 2008.
9. Roe EM. Development Narratives, or Making the Best of Blueprint Development. *World Development.* 1991;19(4):287-300.
10. Australian Government Department of Health and Ageing. Enhanced Primary Care Program (EPC) [Internet]. Commonwealth of Australia; 2010 [Updated 2010 March 10; cited 2011 Nov]. Available from: <http://www.health.gov.au/epc>.
11. Blakeman TM, Zwar NA, Harris MF. Evaluating general practitioners' views on the enhanced primary care items for care planning and case conferencing. A one year follow up. *Aust Fam Physician.* 2002;31(6):582-5.
12. Australian Medical Association Victoria. Productivity Commission says it again: 'Cut the red tape' [Internet]. AMA Victoria; [Cited 2011 Nov]. Available from: http://amavic.com.au/page/Protect_General_Practice/Media_Releases/Media_stories/Productivity_Commission_says_it_again_Cut_the_red_tape/.
13. Esterman AJ, Ben-Tovim D. The Australian coordinated care trials: success or failure? *Med J Aust.* 2002;177(9):469-470.

14. Dennis S, Zwar N, Griffiths R, Roland M, Hasan I, Powell Davies G, et al. Chronic disease management in primary care: from evidence to policy. *Med J Aust.* 2008;188(8 Suppl):S53-S56.
15. Harris M. Challenges in diabetes management. *Aust Fam Physician.* 2008;37(9):716-20.
16. Australian Government Department of Health and Ageing. MBS Online Medicare Benefits Schedule [Internet]. Commonwealth of Australia. Available from: <http://www9.health.gov.au/mbs/search.cfm>.
17. Inala Chronic Disease Management Service: a new model of care for the management of diabetes [Internet]. 2009. [Cited 2011 Nov]. Available from: http://www.health.qld.gov.au/qhafe/docs/020_icdms.pdf.
18. Baker IDI Heart & Diabetes Institute. Diabetes services [Internet]. Baker IDI Heart & Diabetes Institute; [Cited 2011 Nov]; Available from: http://www.bakeridi.edu.au/diabetes_services/.
19. Australian Government Department of Health and Ageing. Media Release. Australia's First Public Nurse-Led Walk-In Centre Launched in Canberra [Internet]. Commonwealth of Australia; 2010 May 12 [Cited 2011 Nov]. Available from: [http://www.health.gov.au/internet/ministers/publishing.nsf/Content/1FD15EB85F2CEF33CA257721000A919D/\\$File/nr087.pdf](http://www.health.gov.au/internet/ministers/publishing.nsf/Content/1FD15EB85F2CEF33CA257721000A919D/$File/nr087.pdf).
20. Antonanzas F, Juarez-Castello C, Rodriguez-Ibeas R. Should health authorities offer risk-sharing contracts to pharmaceutical firms? A theoretical approach. *Health Economics, Policy and Law*, 2011;6(3):391-403.
21. Australian Government Department of Health and Ageing. GP Super Clinics. South Australia 2007-08 [Internet]. Commonwealth of Australia; [Cited 2011 Nov]. Available from: <http://www.health.gov.au/internet/main/publishing.nsf/Content/pacd-gpsuperclinics-sa>.
22. Schattner P, Saunders M, Stanger L, Speak M, Russo K. Data extraction and feedback - does this lead to change in patient care? *Aust Fam Physician.* 2011;40(8):623-8.
23. Dunstan D, Zimmet P, Welborn T, Sicree R, Armstrong T, Atkins R, et al. Diabetesity & Associated Disorders in Australia - 2000. The Accelerating Epidemic. The Australian Diabetes, Obesity and Lifestyle Study (AusDiab). Melbourne: International Diabetes Institute; 2001.
24. Australian Government Department of Health and Ageing. Defuse the diabetes time bomb! [Internet]. Commonwealth of Australia; 1999 [Cited 2011 Nov]. Available from: <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-mediarel-yr1999-mw-mw99108.htm>.
25. Diabetes Australia. Diabetes in Australia [Internet]. Diabetes Australia; 2010 [Cited 2011 Nov]. Available from: <http://www.diabetesaustralia.com.au/en/Understanding-Diabetes/Diabetes-in-Australia/>.

Appendix 1 Changes to research questions

ORIGINAL RESEARCH QUESTIONS

The two **original** objectives of this research were directly related to these potential risks resulting from patient heterogeneity in service needs:

1. to identify which patients groups would be advantaged and which patient groups would be disadvantaged by the proposed diabetes coordinated care program; and
2. to identify and model some options to augment the existing policy to improve the benefits and reduce the risks within the proposed budget.

Given the changing policy environment and the absence of any public domain documentation about the proposed pilot, the objectives were revised to apply more generally to programs that replace elements of the universal access scheme of the MBS and have voluntary enrolment by patients and voluntary participation by GPs.

Hence, the key policy issue was generalised from the specific policy initiative to: How should the needs of a specific group of patients be addressed within a universal health care scheme such as the MBS?

The term “Tailored Health Care” (THC) is used to describe any initiative that is an alternative to expansion of MBS items as a strategy for addressing the needs of patients whose care needs are not necessarily met optimally within mainstream primary care. (This issue is discussed in more detail in the following section: Policy narrative and policy initiatives.)

The **original** research questions were directly concerned with the proposed diabetes coordinated care program and the original objectives:

1. Which patient groups will GPs have an incentive to enrol in the proposed program and for which groups of patients will there be no incentive to enrol in the program?
2. Which patient groups will do better under the proposed capitation policy, and which patient groups will be at risk, including both enrolled and unenrolled patients?
3. What are the broader system effects of such a policy, in particular the effect of increased demand for access to limited AHSs?
4. How can the proposed policy be augmented to maximise the benefits to patients with complex needs while remaining within the proposed budget?

All of these questions are based on policy simulation models that combine existing evidence, focus group finding and patient-provider scenarios with a range of simulation models to both raise and explore questions that would not necessarily be raised by pure empirical research. The same methods were employed for the revised research questions:

1. How can a policy simulation be used to inform any THC style initiative, prospectively?
2. What are the critical elements of an overarching policy framework for THC initiatives for Chronic Disease Management (CDM)?

RESULTS

- 1. Which patient groups will GPs have an incentive to enrol in the proposed program and for which groups of patients will there be no incentive to enrol in the program?**

Without information on the exact specification of the DCC pilot and intervention, the exact characteristics of patients for whom there is no incentive for a GP to enrol cannot be identified. This research identified that capacity for a patient to benefit is not a factor that enters the current policy narrative and hence there is no indication that GP incentive to enrol is related to the patient’s CtB from enrolment.

- 2. Which patient groups will do better under the proposed capitation policy, and which patient groups will be at risk, including both enrolled and unenrolled patients?**

Without the specifics of the DCC pilot or DCC initiative, the exact characteristics of patients in these two groups cannot be identified. However, this research did identify that patients whose GPs do respond to the changes such as decision support software will have a CtB. Patients at risk are those who would be better off if they accessed an option outside current care or DCC and unenrolled patients who have less access to AHS as a consequence of increased access by enrolled patients.

3. What are the broader system effects of such a policy, in particular the effect of increased demand for access to limited AHSs?

The policy narrative recognises that AHSs are currently not always accessed by patients. While the policy narrative does recognise the need for improved referral systems and communication across providers, it does not recognise the need for improved organisation and financing of AHS service providers. For example, if DCC provides GPs with an incentive to refer more appropriately (and frequently) then there will be an increased demand for AHSs. However, unless AHSs can work within service models that can accommodate this increased demand, changes in incentives for GPs to refer will not result in changes for patient access.

4. How can the proposed policy be augmented to maximise the benefits to patients with complex needs while remaining within the proposed budget?

By focusing on enrolling patients for whom there is a CtB from changed care, and providing the infrastructure required to support MDTs as well as general practice, there could be an improvement in the overall cost effectiveness of the scheme compared to a scheme that does not focus on patient CtB. This approach is similar to the idea of targeting new medicines and drugs that have additional cost to patients with the greatest CtB.

How can a simulation that is built entirely on “known unknowns” be validated? There are at least three ways that the validity of this approach can be tested, and these are detailed in Appendix 12 “Validation of the policy simulation”. In summary, this policy simulation is valid because it identified: i) “known unknowns” and implicit assumptions; ii) plausible alternatives and the associated risks; and iii) testable predictions such as that the over optimistic policy narrative will lead to the DCC pilot being underpowered to detect any hard clinical endpoints. (See Appendix 6 “Effect of optimal diabetes therapy on clinical end points”.)

Appendix 2 MBS Diabetes initiatives, 2002

The following editorial from 2002 was written by one of the authors of the report in conjunction with a GP and epidemiologist, Dr. Ben Ewald. It is included because it is a reminder that “some things never change”. This scheme was eventually replaced with a chronic disease management scheme with special MBS items for Diabetes Management and care planning. And these items were expected to be replaced by the Diabetes Coordinated Care Initiative.

Australian Prescriber Editorial 2002

Can we afford intensive management of diabetes?

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Key words: drug utilisation, general practice.

(AustPrescr 2002;25:102-3)

The Commonwealth budget for 2001-02 included financial incentives for general practitioners to provide systematic care to their patients with diabetes. This initiative is likely to increase the number of consultations with general practitioners, specialists and AHS professionals, and the number of drugs used and tests ordered. The annual cost to the Pharmaceutical Benefits Scheme (PBS) and the Medicare Benefits Scheme of treating patients with diabetes will increase. This expenditure will be in addition to the funds allocated through the budget initiative. Furthermore, the number of patients being treated will continue to increase as the prevalence rises and we become better at detecting previously unrecognised cases. In Australia, in 2000, 770 000 people had diabetes. The direct annual health care costs of diabetes in 1995 were \$1.4 billion¹ (approximately \$1800 per patient).

With both the number of cases and the costs of care increasing, there will be increased pressure in the health system and on individual general practitioners to provide more intensive care to more diabetic patients. What is not clear is how this change in competing priorities for limited resources will unfold. For example, will there be more patients on waiting lists for specialists and AHSs, will other patients be displaced, or will more funds be put into these areas?

Some idea of the costs of treating a patient with diabetes can be gleaned from the Australian Co-ordinated Care Trials (1997-2000). These trials included a total of 1654 patients with diabetes recorded as the primary diagnosis. Although these patients represented 15% of the intervention group there was no analysis of the effect of co-ordinated care on their health. Using the data from 10 of these trials, the annual costs per patient for Medicare and PBS services varied across trials from \$1900 to \$3200.² These costs are indicative of those associated with best practice care for older patients with diabetes. More intensive monitoring has significant cost implications, as it will often lead to more intensive treatment of blood glucose, lipids and blood pressure.

The National Diabetes Strategy states that the UK Prospective Diabetes Study (UKPDS) provides evidence that intensive treatment significantly improves clinical outcomes and reduces diabetes-related complications. However, UKPDS showed that the benefits of intensive treatment of blood pressure are at least as great as the benefits of intensive treatment of blood glucose. Approximately six patients need to be treated intensively for blood pressure over 10 years to prevent one patient developing any complication, and 15 need treatment to prevent one diabetes-related death.³ In contrast, only one case of microvascular disease (mostly retinopathy) was prevented for every 196 patients treated

with intensive glucose control for 10 years. Reductions in macrovascular complications or death did not reach statistical significance.⁴

Increased intensive management of diabetes will increase the workload of general practice in differing ways across the country. In a region where there is a high ratio of general practitioners to patients, the additional work may be easily absorbed. However, in an area where there is a low ratio of general practitioners to patients, the increased demands will only be accommodated by displacement of other care provided by the general practitioner, or diversion of this workload to other staff. If a general practitioner sees fewer patients with coughs and colds, this may in fact be a desirable outcome, however if it is at the expense of other important services then any health gain in diabetes may be offset by losses in other areas.

There are opportunities to reduce both the impact on the general practitioner's workload and the costs to the practice of providing systematic care. These include using diabetes educators and practice nurses, and better information management and decision support software. The budget initiative has the potential to improve the flexibility of funding, allowing practices greater scope in deciding how diabetes care is provided.

The additional costs of more intensive monitoring may be justified by future savings from a reduced need for hospitalisations to treat the complications of diabetes. The UKPDS included cost-effectiveness analyses for intensive blood glucose and blood pressure management. In both cases, more intensive management was found to be cost saving in the trial setting. It was expected to have additional costs, but still to be cost-effective in a community setting.^{5,6} Whether the additional costs of more intensive management for a number of conditions would be considered to be cost-effective is unclear. The pharmaceutical and diagnostic test costs of each condition managed intensively are clearly additive, but the health benefits may not be. Furthermore, the UK results may not be generalisable to Australia.

The Australian example most frequently cited in the co-ordinated care trials was the patient who could not access cheap podiatry services, but then required an expensive hospital admission for the treatment of 'diabetic foot'.² The fund-holding model in the trials was intended to provide funding for the additional podiatry services which would be offset by the savings from reduced hospitalisation for complications. The evidence of either reduced hospital admissions or the subsequent savings was not apparent from the trials, partly because of their short duration and partly because improved care was more expensive. Despite up to 60% of all patients in some trials having diabetes, any impact on their health within the two-year period was not sufficient to generate the intended savings.

The only certain and immediate consequence of more intensive management of diabetes is increased pressure on the resources of both general practitioners and the broader health care system. Any health benefits for patients may not be for some years. General practitioners may be consistently referring patients to podiatrists, diabetes educators and ophthalmologists, but are these services available in all regions to low income patients? Will preventive advice on lifestyle changes be provided to patients at risk? Will other patients with other needs find themselves less able to access care? If there are insufficient resources to provide intensive management to all patients with diabetes, there will be some patients who will miss out on some or all aspects of this care. It may be that these are the very patients who would benefit most from improved management, better access to AHSs and preventive advice.

References

1. National Diabetes Strategy 2000-2004. Canberra: Commonwealth Department of Health and Aged Care; 1999.
<http://www.health.gov.au/pq/diabetes/pubs/nds0004.htm>
2. The Australian Coordinated Care Trials: Final technical national evaluation report on the first round of trials. Canberra: Department of Health and Aged Care; 2001.
<http://www.health.gov.au/hsdd/primcare/acoorcar/pubs/acct/contents.htm>

3. Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38. UK Prospective Diabetes Study Group [erratum appears in Br Med J 1999;318:29]. Br Med J 1998;317:703-13.
4. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study Group. Lancet 1998;352:837-53.
5. Gray A, Raikou M, McGuire A, Fenn P, Stevens R, Cull C, et al. Cost effectiveness of an intensive blood glucose control policy in patients with type 2 diabetes: economic analysis alongside randomised controlled trial (UKPDS 41). United Kingdom Prospective Diabetes Study Group. Br Med J 2000;320:1373-8.
6. Cost effectiveness analysis of improved blood pressure control in hypertensive patients with type 2 diabetes: UKPDS 40. UK Prospective Diabetes Study Group. Br Med J 1998;317:720-6.

Appendix 3 Using the HTA model as a starting point to identify the “known unknowns”

An HTA model emphasises the significance of heterogeneity in patient response to, or CtB from, a given technology or therapy. Also, patients for whom there is no benefit of the proposed intervention are identified. An HTA model identifies that there is no value to providing patients for whom there is no CtB from the intervention, even if there is a CtB for the owner of that technology (increased revenue). This principle, exploring patient heterogeneity in response to a given intervention, is central to HTA and is also relevant to a policy simulation such as DCC.

One limitation of HTA models is that they are decision theoretic and therefore do not include strategic interactions between providers and patients. There is a possibility that a GP could choose to enrol a patient in a THC because there is a financial benefit, without considering whether the patient has a CtB. There is also a possibility that a GP could choose to not enrol a patient with a CtB because there is a financial disincentive. For examples of applied economic models that involved multiple interactions that could be strategic, we used examples of applied game theory models. One example is that used to explain risk sharing contracts between health insurers and firms.²⁰ The key issue is the identification of “players”, “types” of players and strategic interactions between these types of players.

A second limitation is that HTA models tend to assume homogeneity of the actual intervention, that is, the intervention will be provided in the same way to all patients. However, heterogeneity in the provision of DCC is an inevitable consequence of variability in the access to services and also variability in the capacity of GPs to respond to an intervention by improving the care they provide to a given patient.

Appendix 4 Scenarios to avoid (Detailed)

The more detailed version of the scenarios to avoid suggest some of the risks from policy omissions and possible risk management strategies.

1. **Patients whose current outcomes are good and have no CtB from enrolling into an alternative scheme.**

In this situation, clear, unbiased and accurate advice as to whether the patient has a CtB from a THC pilot will improve the patient's consent decision. Consider the situation where such a patient has a preference for staying within mainstream MBS rather than enrolling in a THC model. In this case, information about CtB could be critical to the patient's enrolment decision. If the prevailing policy narrative (and possibly a standard informed consent process) suggests that all patients have a CtB, then the patient's decision could be based on an inaccurate perception of the benefits of enrolment.

2. **Patients whose current outcomes are poor and for whom improved outcomes are likely to be conditional on the GP changing clinical practice.**

If some GPs are practicing in ways that time-limit their consultations, then an intervention that improves the opportunity to delegate appropriately to a practice nurse could improve a patient's care and outcomes. However, if improved care is more clinically complex than existing care, then such delegation is likely to be ineffective and will instead require the GP to change practice by providing longer consultations. In this case for some GPs the success of an intervention is dependent upon these GPs' capacity to change practice.

3. **Patients whose current outcomes are poor and who are likely to benefit from options other than either current care or THC, for example a multidisciplinary team at a Tertiary Diabetes Centre (TDC), a nurse led clinic, an IHS or a migrant health centre.**

For some patients, the best way to improve their care and outcomes is through a multidisciplinary team. A referral network is not necessarily a multidisciplinary team (MDT). The providers might not come together at any stage to discuss patients whose care they share. Some large primary care clinics have either government subsidies or the economies of scale to support a MDT. (For example, GP Super Clinics (public) and Camp Hill Medical Clinic (private)).^{d,21} Some MDTs service specific populations, for example, those located in IHSs have a focus on providing care for Indigenous Australians. It is possible that a THC such as the Diabetes Pilot provides an incentive to choose between either continuing as usual (current care) or enrolling (a THC). There may be no reference to a third option outside the GP's standard referral network. In this case, an informed consent process that explicates all options available to a patient will improve both the patient's and the GPs' consent process.

^d <http://www.camphillmedical.com.au/home> (Accessed November 2011)

Appendix 3 Brief Profile of 18 participants in Diabetes Research Focus Groups

DH

DH is a white male in his early 50's. He was diagnosed with diabetes approx. 10 years ago after urinating constantly at night and resultant blood tests confirmed a diagnosis of diabetes.

WR

WR is an Aboriginal man in his early 50's. He was diagnosed 20 years ago and found out he had diabetes after drinking a lot of sugary drinks and woke up one morning and couldn't see.

RD

RD is a white male in his mid 60's. He had blood tests prior to a hip replacement 10 years ago and was diagnosed with diabetes. He was not surprised due to family history and was also suffering from exhaustion at the time.

RA

RA is a white male in his early 60's. He had problems with vision and resultant tests showed he had diabetes.

DM

DM is an Aboriginal male in his mid 50's. He is obese. He had high blood pressure and constant headaches and resultant blood tests showed diabetes.

GW

GW is an Aboriginal male in his late 60's. He was diagnosed 30 years ago following regular blood tests.

JW

JW is an Aboriginal male in his early 50's. 10 years ago he had blood tests because of family incidence and results showed he had diabetes.

CG

CG is an Aboriginal male in his late 40's. He presented with heart issues 10 years ago and at the same time was diagnosed with diabetes.

LB

LB is a white female in her late 20's. She was diagnosed with type 1 diabetes, 3 years after a series of health issues.

KC

KC is a white female in her early 30's. She was diagnosed at 10 years of age; she was on holiday and was drinking excessively – went to toilet constantly during night and wet bed and was constantly exhausted. On 1 day she drank 2 litres of coke; Mother alarmed and admitted to hospital where she was diagnosed with type 1 diabetes. She has had medical procedures which are not elaborated on as they are likely to identify her.

EB

EB is a white female in her early 30's. She was diagnosed with type 1 diabetes 10 years ago after presenting with symptoms of lethargy, sleeping a lot and drinking lots of fluids.

MC

MC is a white female in her early 30's. She was diagnosed with type 1 diabetes 20 years ago. MC had a virus which developed into measles and then pneumonia; she lost a lot of weight and diagnosis was confirmed.

AD

AD is an Aboriginal female in her late 60's. She was diagnosed with type 1 diabetes after suffering depression and ongoing sleep apnoea.

SB

SB is an Aboriginal female in her late 50's. She was diagnosed with type 1 diabetes 5 years ago following regular blood tests.

BD

BD is an Aboriginal female in her late 60's. She was diagnosed with type 1 diabetes 30 years ago after suffering from lethargy and excessive urination.

RS

RS is an Aboriginal female in her late 20's. She was diagnosed with type 2 diabetes in 2011 after suffering from blurry eyesight and numbness in feet; blood tests at an Aboriginal Health Clinic confirmed diagnosis.

CB

CB is an Aboriginal female in her late 50's. She was diagnosed with type 1 diabetes in 2011 following regular blood tests at an Aboriginal Health Clinic.

NC

NC is an Aboriginal female in her early 50's. She was diagnosed with type 1 diabetes in 2011 following regular blood tests at the Aboriginal Health Clinic.

Appendix 4 Summary of focus groups

Diabetes Policy Research Project - Summary of Focus Groups

The following provides a brief summary overview of the key issues arising from the focus groups. Special emphasis is placed on the issue of informed consent given the Diabetes Coordinated Care Program will be recruiting people to participate in the pilot program.

Summary	Policy Simulation Typology
<p>A series of Focus Groups involving 18 participants were held with the aim of drawing out participants experiences with diabetes - their “patient journey”. A number of key questions were posed including the following;</p> <ul style="list-style-type: none"> • the range of health providers consulted to assist in management of their diabetes, • whether they were aware of health professionals consulting each other to monitor, plan and/or improve their health care, • types of support received from GP’s, • their opinions on whether GPs need more assistance to provide the best quality of care to people with diabetes, • financial costs of care, • whether they felt they could make an informed decision to join a pilot program on diabetes treatment based on the knowledge of the quality of care they were currently receiving, and • the information they would need to assist them in making a decision to join a pilot program (informed consent). 	<p><i>Service Delivery models</i> <i>Service Delivery Models</i></p> <p><i>GP Type</i> <i>Service Delivery Models</i> <i>GP Type Informed Consent</i></p>
<p>Health providers</p> <p>In addition to their GP the range of health and allied health professionals consulted at some time by some of the people included;</p> <ul style="list-style-type: none"> • dietitians, • ophthalmologists, • endocrinologists, • podiatrists, • cardiologists, and, • dermatologists. <p>Only a small number reported they consulted with a Diabetes Educator and while a number saw a dietitian there was some concern expressed over their helpfulness in managing their diabetes. Only one participant reported that they saw a Practice Nurse in a GP practice, whereas in the Aboriginal Clinic everyone sees the Practice Nurse as they conduct blood tests, check weight and after the consultation with the GP they attend the chemist with a list of prescriptions and drop them off to peoples’ homes.</p>	<p><i>Service Delivery Models</i></p> <p><i>Referral Networks</i></p> <p><i>Allied Health Professionals</i></p> <p><i>Indigenous Health Service</i></p> <p><i>Service Delivery Models</i></p>
<p>Health professionals consulting each other</p> <p>The majority of participants reported that their GP is their care planner and other professionals formally report to them but from their experiences many doubted that there is much interaction between other professionals on care plans. One participant suggested that as there is competition between the professionals this does not assist communication and that there is a hierarchy with the endocrinologist sitting at the top. Another participant noted that their</p>	<p><i>Allied Health Professionals (Quality and Quantity)</i></p>

<p>endocrinologist writes letters copying to all health professionals but does not include allied health professionals.</p> <p>It was also suggested that there is a disconnect between the public and private health system with long waiting times to see an endocrinologist in the public system; noting that they appear to be under huge pressure and do not have time to consult with other health professionals.</p> <p>The majority of participants suggested that there needs to be significant improvement in communication between all professionals they have a relationship with. It was also commented that there has to be a move away from labelling people as “diabetics” and the need to refer to people with diabetes to reflect they are more than their disease.</p> <p>The Aboriginal Health Worker from the Aboriginal Health Service on hearing responses from their community indicated that a role for the Aboriginal Health Service should be to provide more connections between patients and their professionals.</p> <p>One group agreed that the critical elements in providing care for people with diabetes were what they termed the 3 C’s –</p> <ul style="list-style-type: none"> • Competence • Caring • Communication. 	<p><i>Service Delivery Models</i></p> <p><i>Service Delivery Models</i></p> <p><i>Service Delivery Models</i></p> <p><i>Service Delivery Models</i></p> <p><i>Service Delivery Models</i></p> <p><i>GP Type</i></p>
<p>Types of support received from GP’s and provision of more assistance</p> <p>The responses to these questions were varied. A majority indicated that the GP focussed on the issue at hand and may not be aware of the larger picture in relation to lifestyle issues because of lack of time or capacity. It was suggested that while some focussed on “wellness” issues others resorted to use of fear such as not mixing alcohol with particular drugs and diet control etc. A number of Aboriginal participants commented that they sometimes felt fearful and afraid irrespective of the messages being provided and that they sometimes suffered information overload. A number indicated how difficult it is to make changes to diet and lifestyle.</p> <p>A few participants commented that there was no excuse for a GP not having competence in the area while others said that they personally had more awareness of their condition because they had been living with it for a long time and a few indicated that there was a need for assistance to GP’s through referrals to other professionals.</p> <p>A number of participants suggested that to have diabetes can be a lonely and isolating experience and that even families do not understand the issues. It was stated that to have diabetes is a 24/7 issue.</p> <p>There was a general thrust that the whole notion of investing in GP’s is fraught. It was generally noted that GP practices do not pay enough attention to diabetes and the service is somewhat limited. It was suggested most GP practices are referral agencies and with greater access to information on the internet GP’s roles may not be as influential. It was suggested that an alternative approach would be to establish diabetes centres of excellence and even have a home service run through local government.</p>	<p><i>GP Type</i></p> <p><i>GP Type Patient Type</i></p> <p><i>Patient Type Referral Networks</i></p> <p><i>GP Type Referral Networks</i></p>
<p>Financial costs of care</p> <p>The majority of participants reported that the financial costs are significant. All</p>	<p><i>Service</i></p>

<p>expressed the view that if people did not have sufficient financial resources they would be less likely to be able to achieve effective treatment.</p> <p>Participants referred to costs relating to purchase of medication, test kits, insulin pumps, the “gap” between specialists fees and health cover, loss of time and wages, special food (which is much more expensive than normal food lines) and alternative measures for treatment and management of diabetes.</p> <p>It was noted that people with a health care card receive reimbursement for their diabetes treatment and that given the significant costs associated with diabetes assistance should be broadened. It was also noted that once people turn 18 assistance cuts out as though people no longer require treatment beyond 18. It was also noted that people may pay more for diabetes related medication than other medications that are on the PBS list.</p> <p>With respect to the Aboriginal community people are able to be registered with the Aboriginal Family Clinic (Aboriginal Health Service). This means that people are entitled to a full health assessment, followed by development of a care plan and eligibility for the “Closing the Gap” card which ensures they receive free treatment and do not incur costs for medication. However it was noted that neither ophthalmology costs nor dental care are covered.</p>	<p><i>Delivery Models</i></p> <p><i>Service Delivery Models</i></p> <p><i>Service Delivery Models</i></p> <p><i>Indigenous Health Service</i></p>
<p>Informed Consent</p> <p>A majority of participants felt they could make an informed decision to join a pilot program based on the knowledge of the quality of care they were currently receiving. One participant considered that informed consent would not be as critical for diabetes as compared with some other diseases. However, common sense dictated that if you are ever going to join a pilot you would receive a complete and thorough examination to assess your fitness to join.</p> <p>With respect to being asked to join a pilot program on diabetes treatment and the information they would want to assist them in making a decision to join the responses were quite comprehensive. It was noted that a person newly diagnosed with diabetes would most probably have different perspectives to people who have had diabetes for a number of years.</p> <p>A majority of participants readily identified the following issues as being the relatively straightforward issues requiring responses before joining, eg;</p> <ul style="list-style-type: none"> • How will I benefit from the pilot? • Will my diabetes condition improve if I join? • Will my treatment improve if I join? • How will it affect me financially? Will I be better or worse off? • What if I join and part way through I decide to not continue with the pilot – what will happen? Will I be able to return to my previous arrangements without any difficulty/repercussions? • What if my condition deteriorates – what remedies will be available to me? <p>Other more significant issues requiring attention included the following;</p> <ul style="list-style-type: none"> • Overall Management <ul style="list-style-type: none"> • Clear objectives of the pilot. • Clear understanding of the funding and auspicing of the pilot. • The level of expertise of people running pilot. • Availability of expert advice. • Time required. • Would need to ensure that participants rights are preserved. 	<p><i>The letters in parentheses relate to the 21 elements of TP-QIC (see Appendix ?; adapted from Cohn et al, 2011)</i></p> <p><i>Clinical Audit (H)</i></p> <p><i>Clinical Audit (H)</i></p> <p><i>(M)</i> <i>(M)</i> <i>(M, R)</i> <i>(U)</i> <i>(T)</i></p> <p><i>(P)</i></p> <p><i>(J)</i> <i>(O, U, W)</i> <i>(K, M)</i> <i>(K, M)</i></p>

<ul style="list-style-type: none"> • All participants expenses to be covered. • There would be a need for good communication and information provision. • There would need to be good management of participants' conditions and be able to have access to specialists as required. 	<p>(K, N) (V)^e (O, U, W) (A-F and G-W)</p>
<ul style="list-style-type: none"> • Control Group <ul style="list-style-type: none"> • Would have concern about the control group and would need to know about the non-control group and their experiences. • Considered it to be problematic in achieving improvement through one group of people who are the control group. • If people were on multiple medications there would need to be a very large cohort to disentangle all the medications being used to assess the effectiveness of the pilot. 	<p>(M)</p> <p><i>Clinical Audit</i> (H)</p>
<ul style="list-style-type: none"> • Ethics and Methodology <ul style="list-style-type: none"> • Need to know the ethical basis of the pilot and the research design and methodology. • Needs to be clear advice on how the information collected is used. • Identify whether other trials are occurring and the results. • Clear information on data storage and use. • Information on the drugs involved and what side effects are known. 	<p>(J, V)</p> <p>(J, V) (J+)^f (V) (L)</p>
<ul style="list-style-type: none"> • Pilot Outcomes <ul style="list-style-type: none"> • Advice on long term outcomes and how these are to be measured. • If pilot does not work clear understanding of the implications. • If there are any complications from pilot how these will be managed. 	<p>(J+) (N, P) (P, T)</p>
<p>In addition to the above the other concerns for Aboriginal people were;</p> <ul style="list-style-type: none"> • Privacy issues • Access to interpreters if required • Access to transport • The need for other Aboriginal people to be involved in the pilot • Being involved in research and not getting reimbursed • Being afraid of the unknown • Being able to sign a form with all the relevant information set out in it. 	<p>(V) (^g) (U) (H) (U) (K, L, M) (G)</p>

^e‘V’ relates to confidentiality of data during pilot but might also include detail of post-pilot use in, for example, reports, journal publications

^f ‘J – Provides information about the reasoning behind/rationale of the new system’, but might also include evidence from other trials.

^g**TP-QIC should reflect cultural variation either through modified form or translators/interpreters**

Appendix 5 Informed consent in a strategic contest

Strategic/non-strategic actions in obtaining informed consent in four health care contexts were reviewed. What can we learn from this review for patient enrolment in 'Tailored Health Care'?^h

Ideally, informed consent results from the participant and/or patient deciding that there is a 'CtB' from an intervention, based on information that is offered by a health care provider. Such interactions are central to the process of obtaining consent and subsequent enrolment, as seen in the policy simulation. For example:

- How do patients respond to GP information on their CtB in terms of enrolling or not
- How does a GP respond to information about their own standard of care as revealed by the clinical audit implicit in the informed consent process
- Would they respond differently to an explicit clinical audit of their care
- How does GP optimism overestimate patients' CtB
- How do providers operate, 'non-strategically' and 'strategically', in the range of choice sets, which they provide to the participants and patients.

The decision by the patient to provide '**Informed consent**' (IC) is a function of their understanding of their '**Capacity to Benefit**' (CtB); the patient's expectation of the most positive health outcome as a consequence of being presented with and receiving the best available clinical option. Capacity to benefit is considered here as a function of:

- The **Quality** (Q) of the intervention
- The 'completeness' of the **Information** (I) provided by the clinician/system
- The current **Health Status** (HS) of the person being asked for consent

Examples from four other health care contexts were used to illuminate: what constitutes quality of intervention; what are the dimensions of completeness of information from the point of view of both clinicians and patients; how does a patient's current perspective on their state of health influence their own evaluation of the CtB from an interventional change; and how can patients relate these parameters to their current treatment. What counts as quality, what should they know and what expectations can they have of both feeling and getting better? (The other contexts are discussed fully elsewhere.)

^h'**Tailored health care scheme**' is proposed as a term to describe any initiative in the Australian Primary Health System that is an alternative to expansion of MBS items as a strategy for addressing the needs of patients whose care needs are not necessarily optimally met within mainstream primary care.

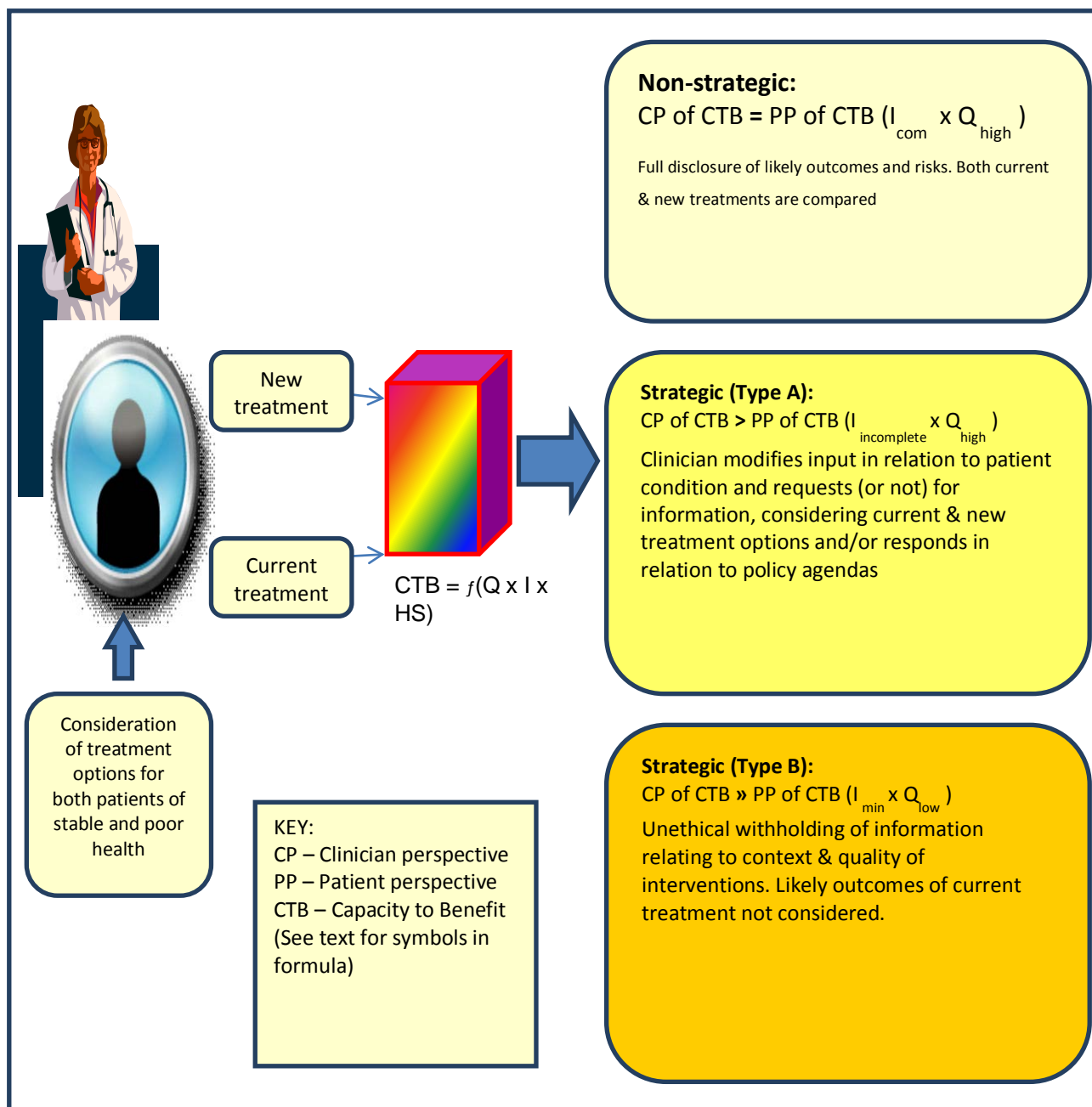


Figure 1 *Non-strategic* and *strategic* actions for the consideration of current and new treatments in relation to CTB

As is noted above, inherent in the complexity of these interactions is the notion of clinician *strategy*. **Figure 1**, above, outlines both *non-strategic* and *strategic* actions for the consideration of current and new treatments, and for providing patients with the opportunity to select the best available option – the CtB.

The relation of CTB and informed consent for clinical trials, for anaesthesia, for private health insurance, and for screening was used to construct a model for the fifth area of IC: THC for the management of diabetes in general practice.

The health care contexts

Clinical trials

The treatment arm of a *clinical trial* is usually very specific in terms of the intervention(s). Earlier phases of the research evaluate possible side effects and information on trial procedures determine the duration of the study. Informed consent is given on the basis of information of a specific intervention with time-limited involvement. Eligible participants are usually chosen on the basis of a pre-existing condition, with such participants being given the choice of randomisation to two or more treatment options, arms of the study. The CtB in absolute terms is not known even though benefits of participation will be advanced.

Anesthesia

Informed consent for anaesthesia is preceded on the decision to elect for surgery, the 'treatment' is specified, and the duration is limited. Whilst there are risks and side effects to anaesthesia, the short-term CtB is immediate; the long-term benefit is more likely to be related to the success of the surgery, which will vary in duration. Those eligible for the surgical procedure have previously made their choice from among treatment options based on a pre-existing condition; such options will likely to have evidence-based benefits.

Informed financial consent

Informed financial consent is made following a commitment to a policy schedule, where the individual may not present with a pre-existing condition. Individuals making changes to new health funds or policies, with a pre-existing condition will have conditional clauses imposed, but decisions to commit are based on the individual's estimate of the future CtB and are made at a point in time. Eligibility is defined by age, medical history, lifestyle decisions and genetic risk factors, among others; duration of receiving benefits is unpredictable.

Screening

Screening is a pre-intervention; participation potentially involves making follow-up decisions in relation to diagnostic tests. The decision to continue or to stop the screening process can, in theory, be made at any point in time. In practice though, it appears difficult to refuse additional diagnostic tests (Ransohoff, McNaughton Collins & Fowler, 2002). Therefore, the first decision whether or not to undergo screening is critical. This creates a decision-gap between the screening and the potential diagnosis, and intervention: what counts as the intervention; what evidence informs the pre-intervention decision; how specific is the intervention; can the duration be defined; who is eligible?

In the summary of the four contexts above, the focus is on defining parameters, which characterise the uncertainty inherent in complex decisions. As each case is considered in order, the specificity of the intervention 'decreases' or becomes obfuscated by the uncertainty surrounding the expected outcome. As a contrast, the duration of knowing the dénouement of the CtB increases, with eligibility called into question and dependent on the success of the surgery, unpredicted health events and positive test results. Furthermore, such complexity is dependent on the evidence base of the intervention, the health status of the patient and the information that is 'strategically' (non-strategic and strategic) included in any pre-intervention participant-clinician communication.

Implicit in such participant-clinician communication is the notion of trust. Based on the expectations of people, as a starting point with unfamiliar practitioners, both health care, as an institution, and clinicians, as professionals, command, in the main, an *institutional* trust. For single-episode encounters, such expectation may be enough, where specific outcomes are required. Repeated interactions with the same clinicians allow the development of more *secure* expectations on the basis of past history and anticipation of future interactions (Tarrant, Dixon-Woods, Colman & Stokes, 2010). Whether such trust is a 'double-edged

sword' in complex patient decision-making is unclear. Does secure trust build a reliance on, say, doctors' advocacy for screening or for new management programs?

An examination of the informed consent process may provide answers to the relationship between autonomy of the patient and the responsibility of the professional to see such autonomy as a factor in the reciprocal interactions underpinning secure trust. Furthermore, in a multi-professional program of associated treatments does such thing as 'Team Trust' play a role in patients' clarity of their current care and suggested alternatives?

Based on the above four contexts, the added complexity of informed consent in a multi-professional program of associated treatmentsⁱ, where the intervention is a government-funded change in the management processes of such available treatments, is explored.

The management of diabetes as Tailored-health-care (THC)

For a proposed change in the multi-professional management of diabetes, most patients have a diagnosed pre-existing condition, which is being treated, although newly diagnosed patients may be added to the program. Here, the informed consent relates to enrolment of patients into the new organisational structures of the proposed program – the 'new tailored health care'. Here, the expected outcomes, among others, would be:

- Earlier initiation of insulin for type 2 diabetes
- Increased co-ordination of care by:
 - Greater access to members of multi-professional team
 - Improved data collection and sharing of electronic records.

The tool, *Process and Quality of Informed Consent (P-QIC)*, was developed by Cohn, Jia, Smith, Erwin & Larson (2011) for use with clinical trials. They found that P-QIC was useful in both identifying strengths and weaknesses in the consent process and helping investigators develop and improve consent interventions.

Table 1, below, identifies the 20 items of P-QIC. The authors in listing the 20 items in two categories 'Essential element of communication' and 'Essential element of information' do not order the items in degrees of 'essentialness'; the current authors have posited such ranking in **Table 1**, below. P-QIC provides a non-strategic inventory of actions. Utilising the complete range of essential elements, both basic (minimum) and complete, in the informed consent process equates to non-strategic enrolment. Omission of basic essential elements would be unethical.

ⁱ Associated treatments: Components of the type 2 diabetes guidelines include – primary prevention; case detection and diagnosis; patient education; blood glucose control; diagnosis, prevention, and management of chronic kidney disease; management of diabetic retinopathy; blood pressure and control; lipid control; and prevention and detection of macrovascular disease. *National Evidence-Based Guideline on Prevention, Identification and Management of Foot Complications in Diabetes* (Part of the Guidelines on Management of Type 2 Diabetes) 2011. Melbourne Australia

P-QIC Items (with original P-QIC Order Number, Cohn et al, 2011)	Basic (minimum)	Complete
Essential elements of communication		
Greets and shows interest in the participant as a person (1)		✓
Uses language that is easy to understand; avoids medical jargon (2)		✓
Stops and answers questions during the interaction; provides specific and complete answers to questions or concerns (17)		✓
Checks for participant understanding of information (eg, asks participants to explain the study in their own words) (18)		✓
Assures that the participant reads or is read aloud the consent form before signing (19)	✓	
Offers the participant the opportunity to accept, decline, or take more time to decide about enrolment in the study (20)	✓	
Essential elements of information		
Provides information regarding why the participant was selected for the study (3)	✓	
Provides information about the scientific purpose of the study (4)	✓	
Provides step-by-step information about the study procedures (5)	✓	
Provides information about the risks, discomforts, and side effects that may occur as part of the study (6)		✓
Provides information about the benefits of participation (7)	✓	
Specifies the duration of study participation (8)	✓	
Discusses how research-related costs will be covered (9)		✓
Explains alternatives to participation in the study (10)		✓
Discusses the difference between the research study and standard treatment (11)		✓
Makes clear that participation is voluntary and avoids coercive pressure (12)	✓	
Provides information about how to terminate participation (13)		✓
Provides information about remuneration for participation (14)		✓
Describes how confidentiality of the data will be maintained or protected (15)	✓	
Provides institutional review board and investigator contact information (16)		✓

Table 1: Essential elements of P-QIC adapted from Cohn et al, 2011

Ideally, to recruit patients to the new program of THC, a complete informed consent process would be adopted. To guide such a process, **Table 1**, (Essential elements of P-QIC, adapted from Cohn et al, 2011) has been 'translated' to reflect its possible use in the implementation of THC rather than a clinical trial, see **Table 2** - '*Translated*' essential elements of P-QIC (TP-QIC).

TP-QIC: '<i>Translated</i>' P-QIC Items for informed consent in general practice	Basic (minimum)	Complete
['New System' means here the reformulated management system of the treatment of diabetes in general practice. Changes (translations) are shown in bold italics with original		

	P-QIC Order Number, Cohn et al, 2011]		
	Essential elements of communication		
A	Greets and shows interest in the patient as a person (1)		✓
B	Uses language that is easy to understand; avoids medical jargon (2)		✓
C	Stops and answers questions during the interaction; provides specific and complete answers to questions or concerns (17)		✓
D	Checks for patient understanding of information (eg, asks patients to explain the new system in their own words) (18)		✓
E	Assures that the patient reads or is read aloud the written consent form before signing. Any verbal consent is confirmed in writing (19)	✓	
F	Offers the patient the opportunity to accept, decline, or take more time to decide about enrolment in the new system (20)	✓	
	Essential elements of information		
G	Provides the patient with a written consent form (<u>new item</u> ; see 19, above)	✓	
H	Provides information regarding why the patient was selected for the new system (3)	✓	
J*	Provides information about the reasoning behind/rationale of the new system (4)	✓	
K	Provides step-by-step information about how the new system will proceed with all members of the diabetes team (5)	✓	
L	Reconfirms information about the risks, discomforts, and side effects that may occur as a result of current treatment and with all clinical treatments in the new system (6)		✓
M	Provides information about the benefits of participation in the new system, including the number of clinicians in the team, the monitoring and control of diabetes, assessments for complications (7)	✓	
N	Specifies the duration of participation in the new system, including what happens when Government funding ends (8)	✓	
O	Discusses how new system -related costs will be covered by Government funding (9)		✓
P	Explains alternatives to participation in the new scheme, reviews how current treatment will be affected/stay the same (10)		✓
R*	Discusses the difference between treatments in the new system and current and/or standard^j treatment (11)		✓
S	Makes clear that participation is voluntary and avoids coercive pressure (12)	✓	
T	Provides information about how to terminate participation in the new system, ie, revert^k to current/standard treatment (13)		✓
U	Provides information about remuneration for participation of patients in the new system for patients, GPs and other members of the clinical team (14)		✓
V	Describes how confidentiality of the data will be maintained or protected between members of the clinical team using new IT systems (15)	✓	
W	Provides contact information of the funding body and principal investigator of the evaluation team (16)		✓

^jStandard treatment may relate to what is currently practiced in the surgery and/or standard as defined by clinical guidelines (see footnote No. 2, p13)

^kPractice needs to consider what will be standard for patients exiting from new system; will practice maintain two systems? What osmosis will occur between new system and current/standard treatment?

Table 2: ‘Translated’ essential elements of P-QIC (see **Table 1** for comparison) for informed consent in relation to the management of diabetes in general practice (adapted from Cohn et al, 2011) [* ‘I’ and ‘Q’ are omitted from labels as both letters are used as abbreviations earlier in the text]

Figure 2, below, uses the items from TP-QIC (**Table 2**), above, to generate three informed consent forms:

- **Informed Consent Form A**, where enrolment is based on the GP’s classification of eligibility, might use E, F, G, H, J, K, M, N, S & V.
- **Informed Consent Form B**, where enrolment is based on eligibility and bespoke diagnosis, might use E, F, G, H, J, K, M, N, S & V **PLUS** A, B, C, D, L, P, R & T.
- **Informed Consent Form C**, where enrolment is based on eligibility, bespoke diagnosis, the patient’s evaluation of both their own and the GP’s positive/negative, and consideration of non-participation, might use all 21 items of TP-QIC.

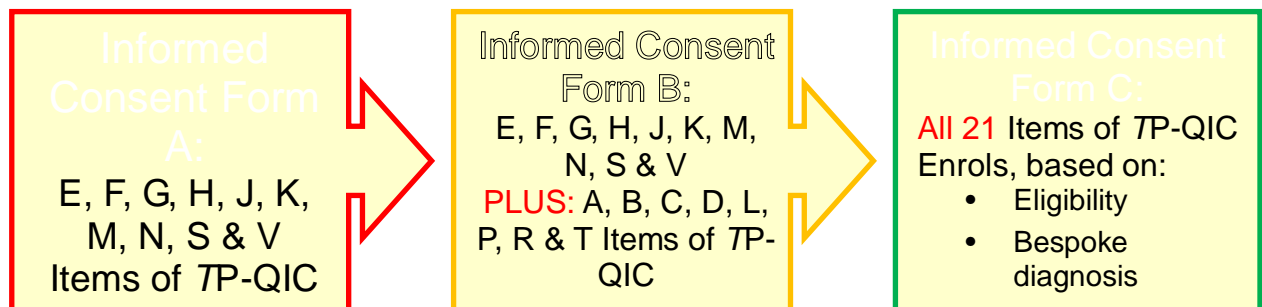


Figure 2: Relation of TP-QIC to Informed Consent Forms

These posited informed consent forms with greater or lesser ‘essentials of communication and information’ are a few among many templates in the complexity of clinician-patient dialogues surrounding CtB. Importantly, the 21 ‘essentials’ map closely on to the issues of consent raised in the focus groups. Thus, in the evaluation of the new system in relation to enrolment, the role of the informed consent process in the provision of optimal care should be monitored, but, more importantly, with those patients whose care is, currently, suboptimal.

References:

1. Cohn EG, Jia H, Smith WC, Erwin K & Larson EL (2011) Measuring the process and quality of informed consent for clinical research: development and testing. *Oncology Nursing Forum*, **38**, 4, 417-422.

2. *National Evidence-Based Guideline on Prevention, Identification and Management of Foot Complications in Diabetes* (Part of the Guidelines on Management of Type 2 Diabetes) 2011. Melbourne Australia
3. Ransohoff DF, McNaughton Collins M, Fowler FJ (2002) Why is prostate cancer screening so common when the evidence is so uncertain? A system without negative feedback. *American Journal of Medicine*, **113**, 663-7.
4. Tarrant C, Dixon-Woods M, Colman AM & Stokes T (2010) Continuity and trust in primary care: a qualitative study informed by game theory. *Annals of Family Medicine*, **8**, (5), 440-446.

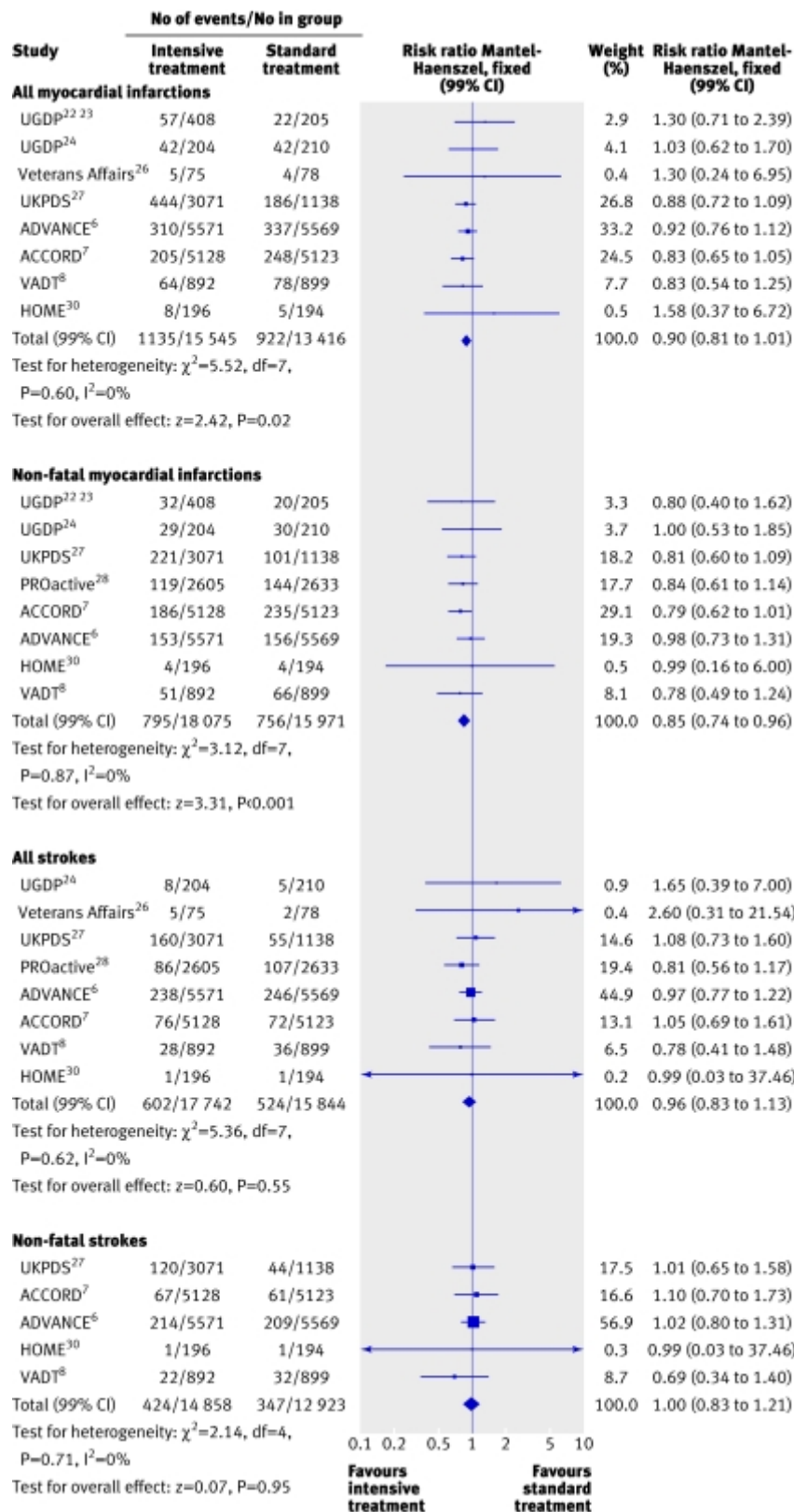
Appendix 6 Effect of optimal diabetes therapy on clinical end points.

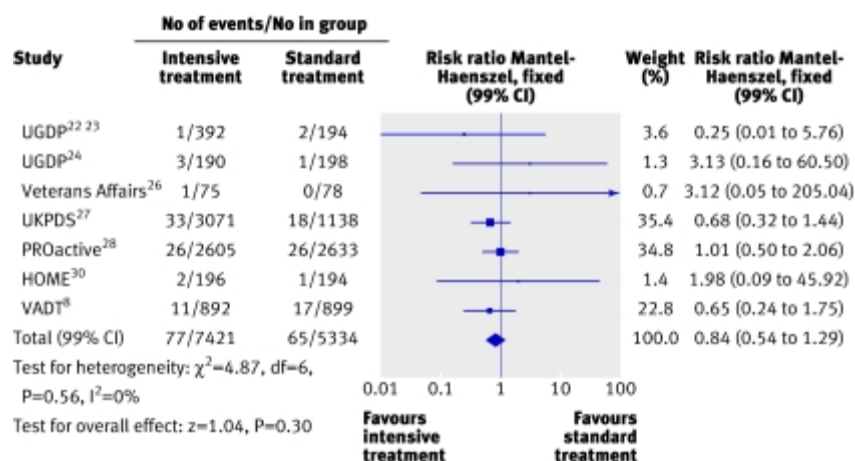
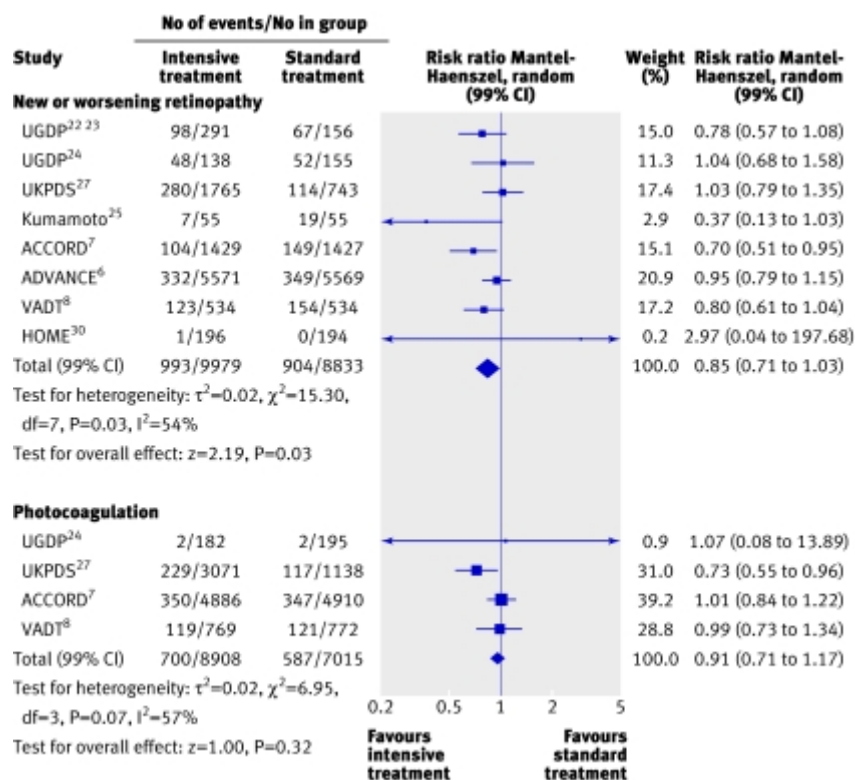
A meta analysis of intensive glucose lowering showed a 15% reduction in the risk of non fatal myocardial infarction (overall rate 4.6%) with no change in total mortality. Over a treatment period of five years, 117 to 150 patients would need to be treated to avoid one myocardial infarction. One severe episode of hypoglycaemia would occur for every 15 to 52 patients. New or worsening retinopathy would be reduced by 15% (overall rate about 10%) while amputations were not reduced significantly (about 1% overall). Thus for a typical large practice with 100 patients with type 2 diabetes the best treatment of glucose seen within a trial would have a maximum effect of preventing retinopathy in 1 patient so it is likely within general practice no measurable effect would be seen over 5 years.

If statin treatment was increased from 50% of patients to 100% of patients in this practice and events decreased by 42 per 1000 people allocated to statin treatment over 5 years then 2 events would be prevented in this practice (Kearney 2008).

If blood pressure control were intensified, then the risk of stroke would be reduced by 31% or 13% per 5 mm Hg change in systolic BP and 12% per 2.5 mm Hg reduction in diastolic BP (Reboldi 2011). With a stroke rate of 3.4% over 5 years then one stroke might be avoided in the GP population with intensive BP therapy over 5 years. Another study (and Cochrane meta analysis) has shown that tight control (<130 mm Hg vs 130-140 mm Hg systolic BP) in patients with diabetes and CVD produced no reduction in events compared with usual control (Cooper –deHoff 2010, Arguedas 2009).

Thus in a general practice of 100 patients best practice intensive treatment might reduce events in 1-3 people over 5 years. Thus about 1500 intervention practices and 1500 control practices would be required to see a significant difference in events. Thus the only risk markers that can be assessed without the small sample effect dominating the result are: BP, HbA1c and lipids.





1. Boussageon R, Bejan-Angoulvant T, Saadatian-Elahi M, Lafont S, Bergeonneau C, Kassai B, Erpeldinger S, Wright JM, Gueyffier F, Cornu C. Effect of intensive glucose lowering treatment on all cause mortality, cardiovascular death, and microvascular events in type 2 diabetes: meta-analysis of randomised controlled trials. *BMJ*. 2011 Jul 26;343:d4169. doi: 10.1136/bmj.d4169.
2. Ray KK, Seshasai SR, Wijesuriya S, Sivakumaran R, Nethercott S, Preiss D, Erqou S, Sattar N. Effect of intensive control of glucose on cardiovascular outcomes and death in patients with diabetes mellitus: a meta-analysis of randomised controlled trials. *Lancet*. 2009 May 23;373(9677):1765-72
3. Cholesterol Treatment Trialists' (CTT) Collaborators, Kearney PM, Blackwell L, Collins R, Keech A, Simes J, Peto R, Armitage J, Baigent C. Efficacy of cholesterol-lowering therapy in 18,686 people with diabetes in 14 randomised trials of statins: a meta-analysis. *Lancet*. 2008 Jan 12;371(9607):117-25.

4. Reboldi G, Gentile G, Angeli F, Ambrosio G, Mancia G, Verdecchia P. Effects of intensive blood pressure reduction on myocardial infarction and stroke in diabetes: a meta-analysis in 73,913 patients. *J Hypertens*. 2011 Jul;29(7):1253-69.
5. Cooper-DeHoff RM, Gong Y, Handberg EM, Bavry AA, Denardo SJ, Bakris GL, Pepine CJ. Tight blood pressure control and cardiovascular outcomes among hypertensive patients with diabetes and coronary artery disease. *JAMA*. 2010 Jul 7;304(1):61-8.
6. Arguedas JA, Perez MI, Wright JM. Treatment blood pressure targets for hypertension. *Cochrane Database Syst Rev*. 2009 Jul 8;(3):CD004349

Appendix 7 Model input tables

GPs work in a range of ways. In a previous section in this report a typology of Dr. Comprehensive and Dr. Six Minute was identified. This typology allows a link between GP practice style and heterogeneity to be specified for both response to the intervention and in patient outcomes pre and post intervention.

The quality of care provided by GPs can be assumed to be either constant across GPs or variable. Alternatively, the “gap between actual and optimal care” identified in the Primary Health care reform reports could be driven by: variability across patients for a given GP; by variability across GPs for a given type of patient; or a combination of both.

How should this input table be completed?

- > If you believe that all GPs are of the same “type” then put 100% in either Dr. Comprehensive types or Dr. Six Minute Types.
- > If you believe that GP heterogeneity will not impact on current patient outcomes then select the same % in the two cells for the last column. Otherwise, use different values.
- > If you believe that all GPs always provide optimal care, then input 100% in each of the cells in the last column.
- > If you believe that comprehensive GPs are more likely to provide best practice care to patients with complex chronic disease, then select a higher proportion in the top right cell than the lower right cell.

Table 2 Input table 1: GP types

GP types		
	% of GPs in type	% of CD patients who have optimal care
Dr. Comprehensive	50%	80%
Dr. Six Minute	50%	50%

GP response to information on own practice

As part of the trial eligibility process, GPs will have an opportunity to reflect upon the quality of the clinical care they currently provide to a given patient. For some patients, improved quality of care could simply involve more delegation to PNs and referral to allied health providers. Both GPs could accommodate this.

However, what if the increased use of longer consultations is critical to improved care and GPs are paid more for these longer consultations that would otherwise be the case to provide an incentive to increase their use. There could be a financial gain to Dr. Comprehensive but a financial loss to Dr. Six Minute, relative to usual practice. (See Section on Typologies) Will Dr. Six Minute only improve care for some, but not all patients if he or she works within the 6 minute constraint.

The standard consent and trial eligibility process is assumed to require only that the patient has a diagnosis of diabetes and does not meet the exclusion criteria, for example, does not have a co-morbidity of dementia. The process of establishing patient classification, which requires assessment of the patient’s service needs, is assumed to occur after consent in the proposed models. In enhanced consent, a clinical audit that assess GP quality of care it is assumed to occur during the consent process.

How will a GP respond to information about their current quality of care? Will they improve care for all patients? Or will they work within the constraints of the financial opportunity cost of six minute medicine?

- > If you believe that the capacity to respond to information about opportunities to improve clinical care is equivalent across GP types, then select the same % in first and last row for each column
- > If you believe that a standard informed consent process will provide the same opportunity to improve quality of care as an enhanced consent, then enter same % in each column for a given row.
- > If you believe that a particular type of GP will always respond perfectly to information about own quality of care (improve it to best quality for all patients) then enter 100%.

Is the implicit assumption 100% for each cell?

Table 3 Input table 2: GP response to information about own optimality

GP response to information about own optimality		
% who respond	With standard consent	With enhanced consent
Dr. Comprehensive	50%	70%
Dr. Six Minute	30%	50%

GP optimism is a term used to describe whether a GP will tell a patient with no CtB from THC, or CtB more from other care models, that they have a CtB. It is referred to as optimism but it could also be a strategic choice by a GP to enrol patients for whom there is a financial benefit for the GP but not benefit to the patient.

As part of the informed-consent/trial-eligibility process, GPs will have an opportunity to review the patient’s characteristics and current outcomes. The GPs will also be able to consider the feasibility of making the changes in practice that they would need to make for their more complex patients, should that GP’s care be currently suboptimal. The informed consent process will provide varying degrees of information about the patient’s current outcomes, current care, and If a GP has a CtB financially from enrolment of a given patient, will they be more likely to suggest that patient has a CtB, even if this is unlikely? Is the GP’s optimism about CtB strategic or simple optimism?

Table 4 Input table 4: Pre intervention distribution of access to AHSs

	Pre intervention				GPs work within different GP-centric models of care. GPs in large clinics could have access to MDTs, whereas GPs in smaller clinics might only have access to networks of providers.
	GP only	GP plus PN	GP plus Network	GP in a MDT	
Proportion of GPs in each model	20%	35%	25%	20%	Different models of GP-centric care have varying degrees of adequacy of access to allied health.
Adequacy of AH in a given model					
Quantity and quality	10%	20%	35%	60%	
Quantity only	50%	50%	50%	35%	
Limited	40%	30%	15%	5%	

Table 5 Input Table 5: Post intervention distribution of access to allied health

Pre intervention	Post Intervention				How does GP access to different models of care change as a consequence of the intervention? The resultant changes in quality of service are derived by combining this table with the previous table inputs.
	GP only	GP plus PN	GP plus Network	GP in a MDT	
GP only	20%	20%	40%	20%	
GP plus PN		25%	65%	10%	
GP plus Network			50%	50%	
GP in a MDT				100%	

Table 6 Input table 6: Distribution of patient characteristics

Type	Complex	Sensitivity to quality			What is the distribution of characteristics across patients? Service use might vary considerably within these classifications. These classifications define capacity to benefit from a given model rather than The version we constructed assumes that all patients who are less complex are not sensitive to the quality of their care, which is assumed to meet some minimum because of their attendance at a GP clinic.
		GP quality (as % of complex)	AH quantity (as % of complex)	AH q and q (as % sensitive to quantity)	
Complex	25%	75%	75%	25%	
less complex	75%	0	0	0%	

Table 7 Input Table 7: Patients decision to enrol

Patient's perception of CTB	If no CtB	CtB	
Complex	90%	100%	<p>Patient's decision to enrol is a function of their perception of their own CtB and their current health status.</p> <p>Is a patient who is involved in a standard consent process more or less likely to have an accurate perception of their CtB and the reasons why their current outcomes are as they are, compared to an enhanced consent?</p> <p>If a GP only enrolls patients for whom there is a potential CtB, is it more likely that they will be able to accommodate this smaller number of patients within their current practice constraints?</p>
less complex	80%	100%	

Table 8 Input table 8: distribution of HbA1c by broad outcome type

	Probability of control	Probability of 7%< HbA1c >= 9%	Probability of HbA1c > 9%	
Good	95%	5%	0%	<p>If a patient has good outcomes generally, the key indicator of control could still be above 7%. But have good control of other indicators, e.g. blood pressure and weight. The worse their outcomes the lower the probability of controlled HbA1c.</p>
Moderate	75%	15%	10%	
Poor	20%	40%	40%	<p>Within each of these intervals we used actual distributions from two data sources. The simulation selects randomly from the relevant distribution.</p>

Table 9 Input table 9: Insufficient information available on diabetes patient records

Probability of insufficient information on patient		
Optimal care	5%	<p>If there is insufficient information available on a patient at the time of assessing enrolment, then this makes it more difficult to assess their CtB from changed care.</p> <p>According to a study on whether data extraction improves patient records and clinical outcomes, around 45% of patients with a diagnosis of diabetes had no record of HbA1c in that field in their records.</p> <p>Do all patients diagnosed with diabetes have records available that allows CtB to be assessed pre enrolment?</p> <p>If a given patient has optimal care are they more or less likely to have complete patient records?</p>

Table 10 Input table 10: max increase and decrease in HbA1c over year and max HbA1c

Maximum increase	Maximum decrease	Maximum HbA1c
2	2	12

Appendix 8: GP heterogeneity: an example

The possibility that GPs are heterogeneous in the context of diabetes care can be illustrated with reference to the results from a study on an intervention designed to provide feedback to GPs using clinical audit and data extraction tools.²³ The study included 15 practices and 69 GPs. The authors suggested that this study showed that it was possible for the intervention to have a modest improvement in recording of clinical data for patients but not to result in clinically meaningful changes in clinical outcomes.

At baseline, of the 3879 patients with a diagnosis of diabetes who had attended a participating practice in the previous 30 months: 34% had an HbA1c recorded in the previous 12 months and it was of $\leq 7\%$; and 44.5% had not had an HbA1c recorded in the previous 12 months. In the 12 months after the clinical audit these proportions changed to 34.9% and 41.4% respectively. These results suggest a small reduction from 61% to 60% in the proportion of all diabetes patients who had an HbA1c recorded and whose HbA1c was $\leq 7\%$. It also suggests that while the average clinic had 269 diabetes patients, only 142 had an HbA1c result recorded in the correct field in the previous 12 months.

There are many factors that could lead to such a small effect of the intervention (improvement in records and quality of clinical outcomes) and such low current recording rates. One factor is that 40% of patients with a diagnosis of diabetes could have attended the clinics within the last 30 but not the last 12 months. Factors identified by the authors include:

- > that test results needed to be entered in specific fields rather than in the free text fields;
- > GPs might not have been given adequate training and the intervention might not have been sufficiently intense; and
- > "self-selected practices might already have had above average levels of data recording, especially given that nine out of the 15 practices had participated in the APCC program, making further improvements more difficult."

Heterogeneity of GPs could be relevant to the interpretation of these results in the context of informing a Diabetes Pilot, for two reasons. First, the possibility that these clinics were above average in terms of data recording, suggests that there is variability across clinics in the community, despite similarity in MBS incentives and in access to GP desktop software. Second, the possibility the authors raise that the existing clinical and data recording results are difficult to improve upon would have different implication for policy, depending upon whether there was high vs. low homogeneity of these results across GPs. For example, the result of 45% patients with diabetes not having an HbA1c recorded is consistent with both of the following situations:

- > 50% of GPs did not have a record of HbA1c for 65% of patients and 50% did not have a record for 15%; and
- > All GPs had no HbA1c recorded for 45% of their patients.

The following scenarios are relevant to a policy simulation, if we assume that variability in GP characteristics contributes to variation in current patient outcomes. What if a patient and GP sit down to discuss enrolment in the Pilot and the GP observes that he or she has not recorded an HbA1c measure in the last year? Will there be an informed and transparent conversation about why a given patient's outcomes are currently poor? What if the factors that limit outcomes in current care are not addressed by the intervention? Is improved primary care with the same GP the best option to improve outcomes for all patients? What if that patient could have better care within the current system, but outside main stream general practice, for example in an Indigenous Health Service (IHS)?

Appendix 9 The ratio of diagnosed to undiagnosed cases of diabetes: a “known unknown”

A 1999 Australian study, AusDiab, found that for every person with diabetes there was another who was not diagnosed.²³ In 1999 and up to the early 2000s, the imperative to detect undiagnosed cases of type 2 diabetes was a dominant thread in the policy narrative. Incentives were introduced to improve the rate at which patients who were at risk of type 2 diabetes were detected.²⁴ Some groups, such as Diabetes Australia suggest that this ratio of one diagnosed for every undiagnosed person with diabetes still applies in 2011.²⁵

Whether or not the estimates of high levels of undiagnosed type 2 diabetes from the late 1990's still stand is relevant to diabetes care policies. In 2011 there are estimated to be 850,000 people diagnosed with type 2 diabetes in Australia, assuming 85% of all diabetes is type 2. This estimate is an 81% increase from 469,350 in 1999.¹ If the one to one ratio of diagnosed to undiagnosed still applied in 2011, then the following results would also apply:

- > there are around 850,000 cases of type 2 diabetes which, when detected, would double the number of patients who need to be accommodated within primary care.

Without additional primary data of the type of the original and subsequent AusDiab study, hard empirical evidence as to whether this ratio has changed in the previous 6 years is not available. But does that mean that the original ratio should be continued to inform policy on primary care of diabetes; should we be planning for an additional 850,000 patients with newly diagnosed diabetes?

An alternative to additional primary data is service use data. Some support for the view that the strategy to improve detection of cases of diabetes could be claimed to have been successful comes from MBS test data. Figure 1 shows the per 100,000 capita test for the MBS item for monitoring ongoing diabetes compared to that for diagnosis of diabetes. It shows that since 1995, this ratio has halved and the dramatic growth in the number of tests for monitoring diabetes reached a plateau in 2005. While the tests for diabetes diagnosis have increased on a per capita basis, it is possible that the cases of monitored diabetes appear to have steadied. This data suggests that the ratio of diagnosed to undiagnosed diabetes could be much higher than one to one. However, it is also possible that changes in testing practices explain this change over time, and that there is no change in the ratio of diagnosed to undiagnosed.

In conclusion additional primary data from a well designed study will provide a more accurate estimate of this ratio than MBS service data. However, if the objective is to inform primary care planning policy, then the MBS service data could be more useful than an accurate but older estimate, particularly when policy influenced by this estimate could have changed the underlying structural parameters.^m

¹AusDiab 2000 report estimated that there were 938,700 people over 25 with diabetes, either known or unknown. The study also estimated that half of these patients did not know that they had diabetes. This study did not use the type 1, type 2 classification, but given that at least some of these patients would have had type 1, this figure of 469,350 is an over-estimate and hence the growth would be underestimated by the figure of 81%.

^mEconomists refer to this as the “Lucas critique”; the limitations of using historical data to make predictions about policy, when that policy changes the underlying variables. While Lucas referred to the role of rational expectations, his result is generalisable. A neat summary of his Nobel prize winning critique is available on http://www.nobelprize.org/nobel_prizes/economics/laureates/1995/press.html

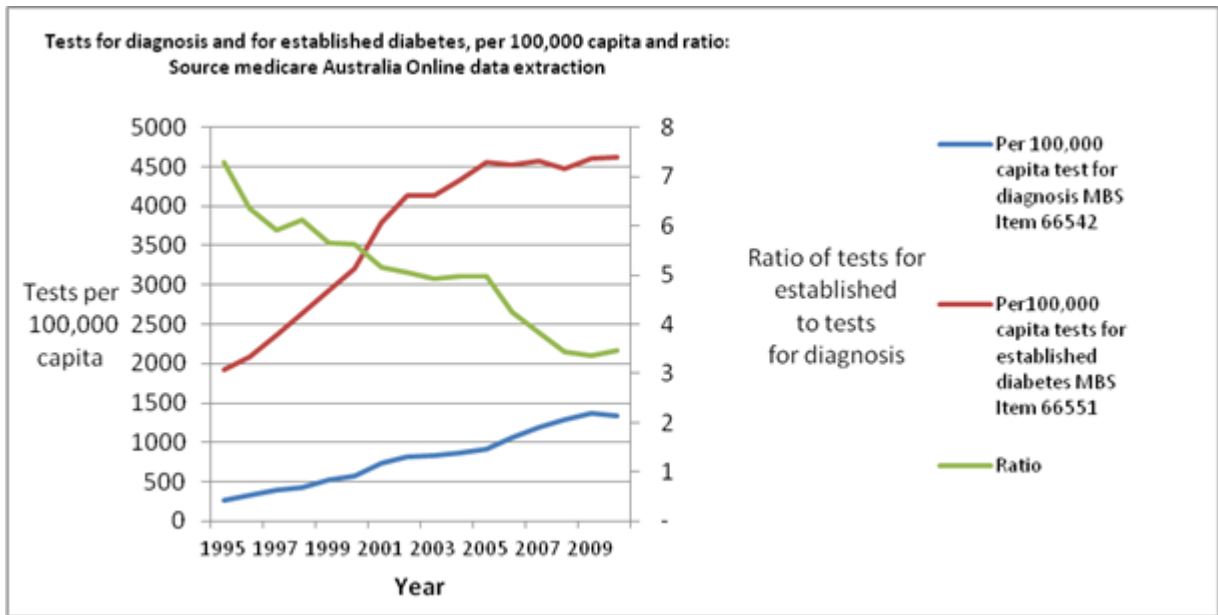


Figure 2 Tests for diagnosis and for established diabetes, per 100,000 capita and ratio

Appendix 10 Policy simulation in primary care – some issues for modellers

One of the two objectives of this research project was to develop a formal method of policy simulation for health system policy. The five parts to this process are outlined below. In the case of this particular policy problem, there was no data available about the specifics of the proposed policy or pilot. The focus then was on understanding the implications of the known unknowns.

The process is iterative: the simulation process identified new issues and wider consultation and further discussions within the team improved the characterisations used to structure the model.

Part 1 involves characterizing patients, providers, service delivery models and the intervention. The specific steps are:

- > Characterise the policy narrative – what is included, what is omitted. This step involves research on the policy history and, most significantly, the discussion in the public domain.
- > Identify and characterise the players (patients, providers) and settings (service delivery models) that constitute diabetes care within the primary care setting. This step involves extensive consultation and builds on researchers' understanding and experience of the health care system.
- > Identify and characterise the intervention. Given the absence of public domain documentation of the intervention for the existing pilot, we used the general policy discussion to identify this.

Part 2 involves identifying scenarios (interactions between players, settings and interventions) and the likely health outcomes for patients. The scenarios that should be discouraged and those that should be encouraged are identified.

Part 3 involves identifying strategies that could minimise the risks of scenarios that have poor patient outcomes compared to alternatives, and also how to elicit informed patient preferences for care in situations where patient health outcomes are unlikely to be impacted by the intervention.

Part 4 is the construction of a mathematical simulation (computer model). To simplify the analysis, we assumed that: i) GPs would only approach patients to ask for consent to enrol if there was no financial disincentive to that GP; and ii) that there was no systematic bias in the payment system against certain types of patients, for example, complex patients. However, the possibility that two GPs would have differential incentives to enrol a given patient is modelled.

The steps in Part 4 are:

1. For each element (patients, providers, service models) and intervention, select two or three key characteristics that can be used to optimally specify and hence simulate both heterogeneity within each of these elements and heterogeneity of response to the intervention. These variations within each element are referred to types.
2. Specify the intervention in terms of how it either:
 - a. Changes the distribution across variations within one type (e.g. increase the proportion of service models that include additional allied health providers.)
 - b. Changes the way that a given variation of a type responds to a given context (e.g. change the proportion of care provided by a GP that is optimal quality.)

3. Specify a cohort of patients who are assigned characteristics and hence types (probabilistically). These proportions (e.g. % who are not complex, % who are sensitive to quality of allied health) can be changed by users of the tool.
4. Similarly, specify a cohort of GPs with characteristics.
5. Randomly assign GPs to patients. (More extensive models could assume different types of patients go to different types of GPs, for example, more complex patients tend to go to more comprehensive GPs).
6. Randomly assign GP/patient combinations to service models.
7. Specify health outcomes and allied health service use for patient/GP/service model outcomes. (Part of this analysis uses the distributions of HbA1c from true patient cohorts to assign an initial and changed HbA1c for each patient).
8. Use this model to simulate the following:
 - a. Partial and comprehensive reporting (report on all or just enrolled patients)
 - b. Risk management strategies around patient consent and workforce constraints.

The outcome of this process is a simulated “data set” of a cohort of 10,000 patients and 100 GPs whose care and outcomes are followed for a year. The probabilistic approach allows the effect of small sample size for each GP to be represented.

ENGAGING PRIMARY HEALTH CARE RESEARCHERS

Researchers from an EBM paradigm found policy simulation a difficult technique and tended, initially, to be very skeptical of its value. A typical response when a structural parameter was introduced to such a researcher is: “But there is no evidence of its value so how can we assume it has a value of x%?” A number of devices were developed during the research in order to address this issue. For example, the assumption made implicitly by the researcher was elicited, the plausibility that it could have a different value was established, and the significance and possibility of managing the risks associated with the uncertainty were demonstrated. A key distinction for EBM researchers was that between: i) assuming a parameter has a value of x%; and ii) using this value to test whether it matters if a parameter has a value apart from that assumed implicitly (typically 0% or 100%).

Specification of input tables

Input tables were specified in a way that successfully facilitated discussion about parameters for which there is no clear evidence of their value. In particular, complex or “difficult” unknown parameters were linked back to *Types* and then related back to their “structural roots”. For example, there is no good estimate of the variation across GPs in the quality of care that they provide to diabetes patients and how baseline quality of care would influence response to an intervention. From an economic perspective, this would be a useful estimate because it would allow the likely cost effectiveness of a policy to be estimated.

Two approaches were adopted. In the spreadsheet model the “user” was required to enter the proportion of GPs who provided suboptimal care. However, this approach did not sufficiently differentiate the possible values of this estimate. The alternative was to define a GP in terms of one of two possible ‘consultative’ responses to the prevailing MBS schedule: *Comprehensive* or *Six minute*. This approach allowed “users” to discuss: how these GPs might practice; the relation to the quality of care for patients with chronic disease; and how this would differentiate their response to aspects of an intervention. Hence the “structural roots” of the difficult parameter - the proportion of GPs who provide suboptimal care - were identified.

Assumptions of existing initiatives

Assumptions underlying existing initiatives were incorporated in the input tables. This illustrated to users, even though there might be an unwillingness to make explicit assumptions about a particular parameter, that there might be implicit assumptions about parameters underlying current policy initiatives. For example, does the prevailing policy agenda assume, implicitly, that all GPs have the same incentive to take up clinical decision support software for complex patients? Such an implicit assumption is inconsistent with the view that that Dr. Six Minute types would be less likely, compared to Dr Comprehensive types, to adopt such software because there is a financial disincentive to extend their consultation time. Even if users are not comfortable with making assumptions about the value of a given parameter, alternatives, which accord with their tacit knowledge of health care processes, may be preferable.

Scenarios: interactions between patients, GP type and setting of care

Scenarios were generated through focus groups and discussions within the research team. These scenarios captured sufficient heterogeneity, in the characteristics of GPs, patients and service delivery models, to allow risk management strategies to be identified, without specifying estimates of these relevant parameters. It was not necessary to have evidence of the proportion of patients who had no CtB in order for discussions relating to implications; it was sufficient to gain agreement that this proportion was greater than 0%.

Appendix 11 Do all Australian GPs do 14 minute medicine (on average)?

In Australia, there have been (informal) claims that some general practitioners (GPs) have an imperative to see patients within a 6 minute window. This rationale for this claim is usually that the financial incentives inherent in the Medicare item structure.(1) A GP can earn a higher hourly income with 8 short consultations in an hour compared to 4 longer consultations, where all these consultations are charged as Item 23s.

Short consultations have a role in efficient delivery of primary health care, however there is evidence that for some patients, longer consultation times tend to be associated with increased medical interventions, fewer prescriptions, greater patient enablement and heightened patient satisfaction. The end result is better patient outcomes, particularly for patients with chronic conditions .(2) Evidence also suggests that longer consultation times lead to less return visits and reduced doctor stress.(2)

Other evidence suggests that the mean consultation time for Australian GPs is around 14 minutes, which is well in excess of 6 minutes. Britt et al (3) reported a mean consultation time of 14.8 minutes with an associated range of 1 minute to 106 minutes. She also found a high level of variation in mean consultation length per GP (mean of means 14.8 minutes, range 3-39 minutes). (3)

Research suggests that level B consultation times are statistically significantly longer among female GPs (mean 13.7 minutes, 95% CI 13.3-14.0 minutes) than male GPs (12.7 minutes, 95% CI 12.5-12.9 minutes)(3). Such differences are partly attributable to the treatment of different medical conditions, as female GPs treat more psychosocial, endocrine and female-specific health complaints.(4)

More significantly, Britt et al found that there is variability in consultation time that can be attributed to the characteristics of GPs rather than the characteristics of the patient or the needs at a consultation. Longer consultation lengths have been shown to be associated with older age,(2, 5) holistic orientation,(2) FRACGP qualification,(5) graduating in Australia (5) and rural practice.(5) Characteristics such as these may be used to describe different types of GPs practicing in Australia.

In the UK, Howie and Porter (6) defined three different types of GPs: slower GPs (median consultation times of 9 minutes or more), intermediate GPs (consultation times of median 7-8.99 minutes) and faster GPs (median consultation times of 6.99 minutes or less). Of the 85 GPs who participated in the study, 28% were described as faster, 47% as intermediate and 25% as slower. Consultation length distributions for the faster and slower GPs are shown in the Figure. These distributions highlight the heterogeneity in GP consultation lengths in the UK.

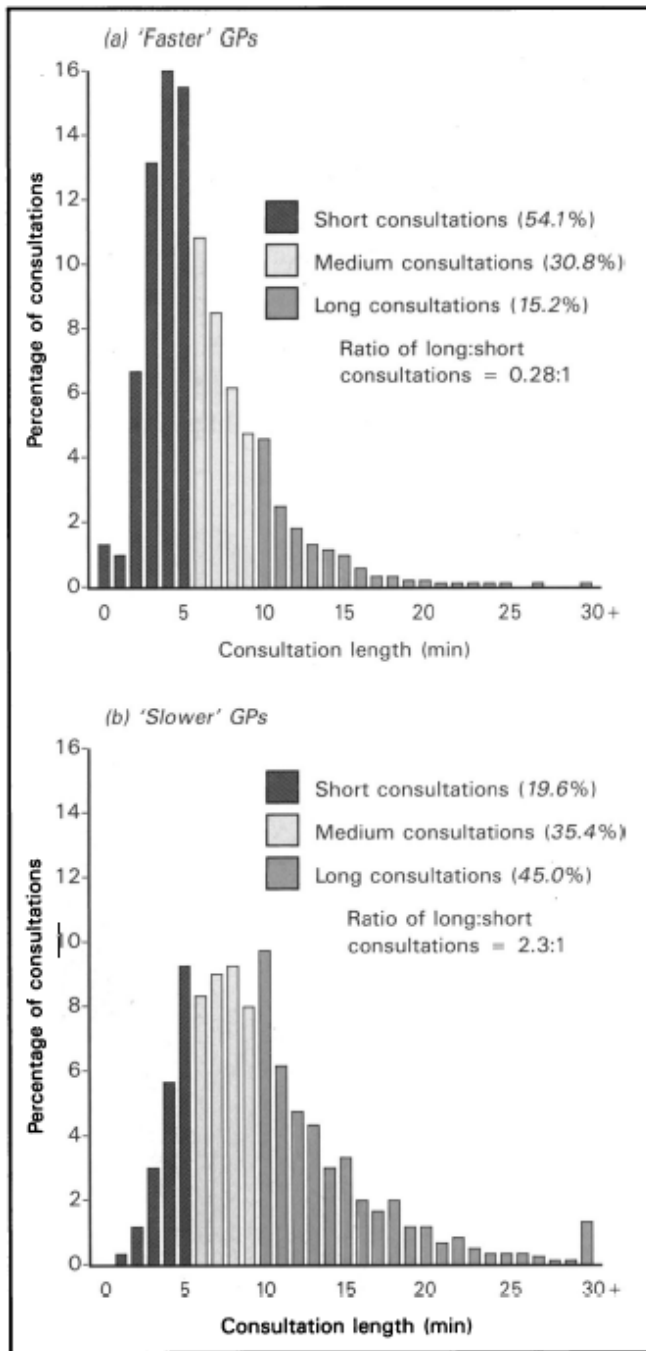


Figure 1: Distribution of consultation lengths for (a) faster GPs (n = 6858 consultations) and (b) slower GPs (n = 4460 consultations)(6)

The UK evidence provided further support to for defining different types of GPs within the Australian health care system. However, no equivalent study has been performed in Australia. But we can use data on GP service mix to support the plausibility that GPs vary in their mean consultation length. The Medicare Australia data was downloaded for seven different Divisions of GP and Australia. Figure 2 represents ratios of item 23 to 36 and item 23 to the group of items in A15 (care planning). It shows variability in this ratio across GPs, with Flinders, a rural SA division having the highest ratio of item 23 to either item. Variability across Divisions is caused by variability across GPs and hence it is plausible to assume that GPs can be represented as having a multi-modal distribution of mean consultation time.

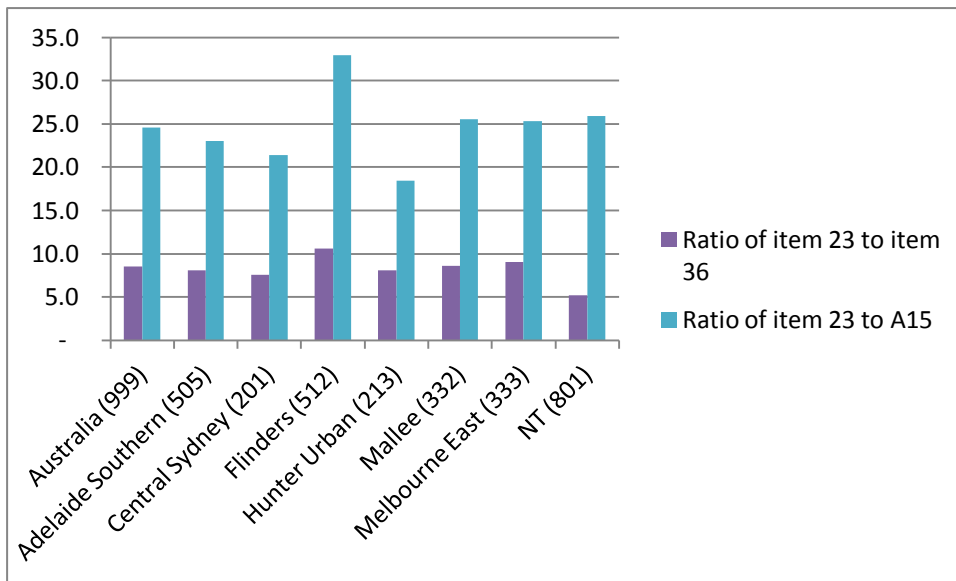


Figure 2: Ratio of item 23 to item 36 and item 23 to A15 (services) for 7 divisions of GP and Australia

Figure 3 represents item 23, item 36 and group of items A15 as a proportion of total services in each division. The variability across Divisions is illustrated.

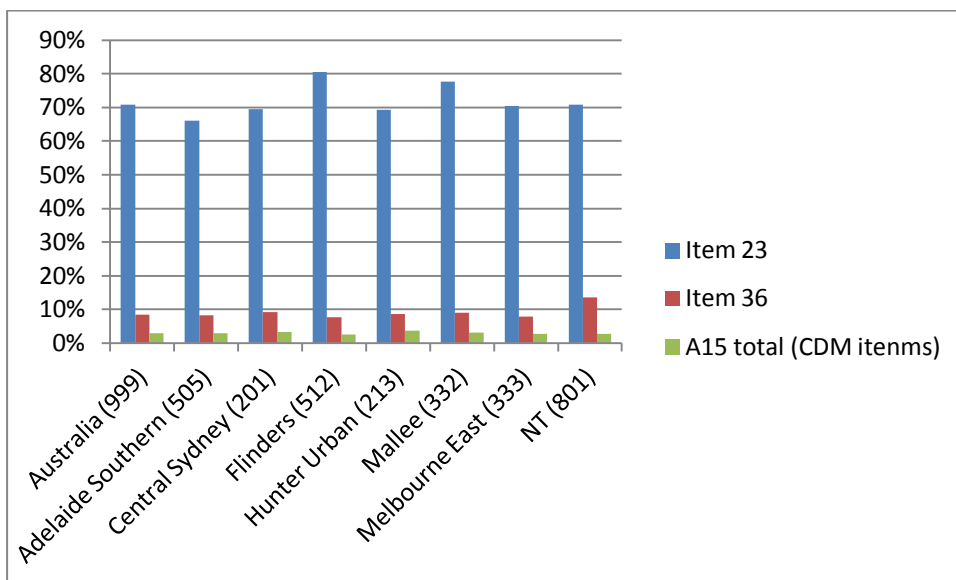


Figure 3: Proportion of total GP services that are item 23, item 36 or A15 (Care planning) for 7 divisions of GP and Australia

It is also worth noting that patient factors may impact upon GP consultation times. Patient factors associated with longer consultation times include older age, higher socioeconomic status, new to medical practice, more reasons for consultation, more health problems, social problems, psychological problems, female genital problems, chronic disease and receipt of clinical treatments. Conversely, patient factors associated with shorter consultation times include female gender and lack of a health concession card.(5) Patient factors such as these may also explain some of the observed variation in GP consultation times.

References

1. Cohen M, Kotsirilos V, Bajraszewski T, Hased C. Long consultations and quality of care: AIMA position statement. [online]
Available http://www.aima.net.au/docs/aima_position_statement_long_consultations-quality_of_care.pdf Accessed 18 January 2012
2. Sturmberg JP, Cilliers P. Time and the consultation – An argument for a ‘certain slowness’. *J Eval Clin Pract.* 2009; 15: 881-885
3. Britt H, Valenti L, Miller G. Time for care: Length of general practice consultations in Australia. *Aust Fam Physician.* 2002; 31(9): 876-880
4. Britt H, Bhasale A, Miles DA, Angelli M, Sayer GP, Angelis M. The sex of the general practitioner: A comparison of characteristics, patients, and medical conditions managed. *Medical Care.* 1996; 34(5): 403-415.
5. Britt H, Valenti L, Miller GC. Determinants of consultation length in Australian general practice. *MJA,* 2005; 183: 68-71
6. Howie JGR, Porter AMD. Long to short consultation ratio: A proxy measure of quality of care for general practice. *Br J Gen Pract.* 1991; 41: 48-54.

Appendix 12 Validation of the policy simulation

An empirical value of a parameter is not the objective of this research, hence it is not possible to assess the validity of the method by which a specific empirical evidence is achieved. For example, we do not know what proportion of GPs practice “short” rather than comprehensive consultations. Instead, the objective of the research is simply to identify that it is plausible that this variability exists and that it could be a factor that could influence patient CtB for enrolment. Furthermore, by definition, we cannot test whether all “unknown unknowns” have been identified. It is reasonable to argue that another group of researchers could have applied the same method and ended up with a different set of “known unknowns” and associated strategies. In this case, if the decision makers were willing to engage in the process of policy simulation, more specific gaps could have been identified. However, this is an argument for a wider application of this method, rather than of its limited validity.

But there are at least three tests of validity that can be applied.

THREE VALIDATION TESTS

The first test is simply that the process was able to identify “known unknowns” and also identify the implied value of these structural parameters, when an estimate was not available. For example, heterogeneity of GPs’ current practice and capacity to change practice was not part of the policy narrative, and was identified as a “known unknown”. The implied values of the parameters around the distribution of current GP practice were identified; homogeneity, all GPs have the same underlying distribution of long and short consultations and hence can be expected to respond uniformly to the initiative. And a plausible alternative assumption was identified; GPs could be characterized as those who practice predominately short rather than long consultations. And finally, the possibility that two patients with the same characteristics could have a different CtB from the initiative, depending upon the characteristics of their GP, was identified.

The second test is that the process was able to identify risks and associated risk management strategies. Policy simulation can identify that an alternative scenario regarding a known unknown is plausible, that is the probability is greater than 0%. What policy simulation cannot identify is the probability associated with a risk.

The third test of validation is predictions that can be made from the research. In this case, three predictions are made. The first is that the DCC pilot will involve a patient consent process that does not address patient’s CtB from changed practice, realistically. It will also not include a discussion or identification of issues concerning the requirement for GPs to change their practice and the issue of why a GP cannot change practice in the current system of care. The second is that given the level of optimism regarding patient CtB, the DCC Pilot will be under powered (in terms of duration and patient numbers) to detect any change in hard endpoints such as hospital admissions, strokes and MIs. The third is that the focus will be on identification of heterogeneity of the costs and service bundles across patients (classification for capitation) rather than heterogeneity of patient to benefit from the intervention and heterogeneity of GPs capacity to respond to the intervention.

In summary, validation of policy simulation is in its capacity to identify the gaps in the policy narrative and strategies to minimise the associated risks. It is not about generating empirical predictions about uptake or effect. Nor is it about finding the best estimate for a given parameter.