Regulatory Impact Statement

Quality Improvement Agency

Agency Disclosure Statement

This Regulatory Impact Statement has been prepared by the Ministry of Health. It provides analysis of alternative options for strengthening quality and safety support functions.

Two alternative options are assessed:

1. a Crown Entity (Crown agent)
2. a new branded business unit within the Ministry of Health.

No direct compliance obligations will arise for health care providers from either option as its role is to promote the voluntary uptake of quality improvement activities. Over time, such activities may be added to contractual or accountability requirements.

After consideration of both options the Ministry of Health is of the view that a stand alone agency operating as a Crown Agent is the preferred option. This option has the two key advantages of establishing a separate expert governance board crucial for buy in from the sector and cementing clinical leadership in this important area, whilst still being required to give effect to Government policy.

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Status quo and problem definition

Status Quo

A commitment to improving quality and safety is integral to ensuring that New Zealand's health and disability system is effective and efficient and delivers the best possible health outcomes. The question to which this paper is responding is which institutional form would most effectively implement that commitment.

The New Zealand Public Health and Disability Act 2000 (NZPHD Act) requires the Minister of Health determine a strategy for the development and use of:

- nationally consistent standards and quality assurance programmes for health services and consumer safety; and
- nationally consistent performance monitoring of health services and consumer safety against those standards and programmes.[1]

Although the NZPHD Act recognises the importance of quality and safety, the mechanisms through which quality and safety improvement has been pursued have been unable to implement a cycle of continuous quality and safety improvement.

Quality and safety improvement activities occur at all levels of the health and disability sector. Responsibility for quality improvement at a national level currently sits with both the Ministry of Health and the Quality Improvement Committee (QIC).

Problem definition

The Clinical Reference Group considers that a 1-2 percent reduction in the rate of adverse events is achievable with good quality improvement techniques and training suggesting possible savings in the region of $8-20m per annum. It is important to note that these savings may not be realised as 'bankable' savings, given high overheads and incentive issues. Effective quality and safety activities will, however, improve value for money, enable increased service volumes and free resources to provide additional services (if not dollar savings).

The MRG identified the following problems:

- there is a lack of national coordination in undertaking some quality activity, such as data collection;
- there is a narrow focus on hospital care, rather than a whole of system view;
- the short-term financial incentives on DHBs lead them to under invest in safety and quality; and
- there is a perceived lack of independence from the regulatory, funding and performance functions of the Ministry of Health, leading to a lack of confidence and ownership by health professionals in supporting quality and safety improvement.

While existing arrangements have achieved modest quality and safety improvements at a national level, achieving continuous improvement has been difficult. Quality experts argue that a strong focus/mandate to drive quality-related actions, greater coordination of appropriate quality interventions at a national level and strong clinical engagement are pivotal to achieving sustained quality gains and underpin the proposals contained in this assessment.

[1] New Zealand Public Health and Disability Act 2000, s9(1)(a) and (b)

Objectives

The objective of the structural change signalled in this assessment is to overcome the identified barriers to quality improvement by establishing an entity that will have strong sector support and a clearly defined mandate to drive sustained quality improvement, including a decrease in adverse events across the wider health system (including primary care and the private sector). The goal of the new entity will be to improve quality and safety across the health system through reducing unwarranted variation, increasing adherence to evidence-based practice and reducing the incidence of adverse events. Effective change will be measured by a decrease in adverse events and increased patient satisfaction. It will also result in greater health sector productivity and efficiency.

Regulatory impact analysis

After considering the recommendations of the MRG, Cabinet directed the Ministry of Health, in consultation with Treasury and the State Services Commission, to report back to Cabinet on the MRG's proposals [CAB Min (09) 37/13-15 refers]. Responding to this, two options have been identified and are discussed in further detail below:

Option 1 - a Crown agent

Option 2 – a branded business unit inside the Ministry of Health.

The status quo is not considered to be a viable option a view supported by the Clinical Reference Group.

Whichever option is chosen, the Ministry of Health would continue to retain responsibility for quality and safety regulation and performance monitoring functions. The Ministry would also retain a policy function to enable us to advise the Minister and, in the case of the Crown entity option being chosen, would be responsible for monitoring the performance of the entity as is the case for all health sector Crown entities.

The non-financial costs and benefits of the options are summarised in Table 1.

Crown agent

Three types of Crown Entity were considered:

- Crown agent
- Autonomous Crown Entity
- Independent Crown Entity.

Of these options, we consider a Crown agent strikes the appropriate balance between the need for the organisation to be perceived as independent (in order to generate engagement and support from the health sector), while also ensuring its activity is coordinated with Government policy and with existing quality and safety regulatory functions.

If this is Government's preferred option, a Crown agent would be established under the Crown Entities Act 2004. A Crown entity creates an arms length relationship with Government giving the entity a degree of autonomy to set its own priorities. This type of entity would be governed by a board which is both appointed by, and accountable to, the Minister of Health.

As a Crown agent, the agency would be required to "give effect to Government policy", whilst still having a significant degree of operational independence. The process of agreeing accountability arrangements with the Government would assist in ensuring that Government was able to influence the high-level direction of the organisation's work programme, and

ensure that its work contributes to, and aligns with, the regulatory and monitoring functions carried out by the Ministry of Health.

A Crown entity established specifically to undertake quality improvement activities will provide a sustained focus on health sector quality and have a clear Government mandate for action, set out in their Statement of Intent and other accountability documents. It would require additional resources to meet the administrative and accountability requirements of any Crown entity, including developing an annual Statement of Intent and Annual Report, and servicing its requirements under the Official Information Act.

Officials expect the Crown Entity to have operating costs 55 to 65 percent higher than option two, with an initial operating budget of $2 - $2.5 million per year.[2] This does not include transition costs or the funding used for external contracts. Some of this cost might be able to be offset by enabling the agency to charge users for purchasing quality programmes. (More detailed costing information is attached as Appendix 1).

Because of its perceived independence, this organisational form is strongly favoured by many members of the Clinical Reference Group.

New branded business unit within the Ministry of Health

A new branded business unit (BBU) could be established within the Ministry of Health. The BBU would carry out the support and information functions of a quality and safety improvement system, along with a new expert advisory board to provide oversight for the BBU's activity. This arrangement would be similar to that of Medsafe and could have its own ring-fenced funding and be physically located outside of the main Ministry offices to enhance the perception of separation from regulatory and monitoring functions.

This option gives Government the most direct levers into quality and safety improvement activity although as discussed below, the most direct levers may not be the most effective. As a unit inside the Ministry, though separate from the regulatory and monitoring functions, it is most likely to ensure coordination of the various functions of a quality and safety improvement system.

As this entity would be part of the Ministry of Health, this option may not have the independence expected of it. More specifically, regardless of the managerial and accountability arrangements put in place for its operation, a dedicated business unit may be seen as being constrained in its ability to set its own agenda and advocate for a sustained focus and greater investment in quality and safety improvement.

This option would be fairly simple to implement, requiring no legislative change. A BBU inside the Ministry would be able to build on existing infrastructure, limiting some of the costs that would need to be met by an external entity

The Clinical Reference Group considers a lack of perceived independence means that this option is less preferable than an independent organisation. They argue that health professionals may have a perception of 'capture' by the Ministry, with a subsequent risk the organisation will fail from the outset due to a lack of buy-in from quality and safety experts and health professionals generally.

Table 1: Costs and Benefits of Options for a Quality Improvement Agency

[2] This is comparable to CHFA, which has an operating budget of $2.7 million.

Proposal	Benefits/opportunities	Costs/risks
Option 1: A Crown agent	Provides statutory authority for explicit quality improvement functions and gives the agency authority to act in pursuit of those - ensuring a clear and sustained focus on quality improvement. The board is directly accountable for their performance to the Minister of Health. Accountability mechanisms such as the SOI and an agreed work plan can provide a platform for cohesive quality activity across the health sector. Minister able to assure the appointment of appropriate quality and safety expertise to the entity's board. The separation from the regulatory and monitoring functions of the Ministry of Health means this agency may be more trusted and supported by health professionals. Crown Entity structure amenable to the MRG recommendation to become part or fully self-funding, potentially offsetting the cost to Government. This option is supported by the Clinical Reference Group and the Ministry of Health.	Adds an additional agency to the health system Potential that the arms-length arrangements could lead to non-alignment with regulatory and monitoring functions. The establishment of a Crown Entity creates an organisational boundary and hence transaction costs between the entity and the Ministry of Health, including the need to establish a monitoring function for the new agency within the Ministry of Health. There will be some duplication. This option requires legislative change and as such is more complex to implement. Establishment and ongoing running costs are higher under this option (see Appendix 1)
Option 2: A branded Business unit inside the Ministry of Health	Avoids adding system complexity as it does not require the creation of a new external entity. High level of alignment with policy direction and responsiveness to the Minister of Health. Has administrative efficiencies and requires little transition funding. Cheaper than the Crown Entity option Can be set up to pursue clearly identified policy objectives/functions and be ring fenced from other activities within the Ministry, including having a separate Vote and Minister. Does not require legislative change and is the easiest and most rapid option to implement. Supports coordination with the Ministry's regulatory and monitoring functions. Supports continuity of existing quality work inside the Ministry of Health.	Risk that funding for this work could be reallocated across the Ministry of Health to areas of greater need. Business Unit may be seen as constrained in its ability to set its own agenda and advocate for a focus on quality. Not perceived by the sector to be independent and therefore less likely to have the same degree of sector buy-in (especially with regard to reporting of adverse or 'near miss' events). Closeness to Ministry regulatory and monitoring activity.

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The functions of the proposed quality and safety agency will focus on information gathering, some public reporting (including of serious and sentinel events) and disseminating information and resources to support the implementation of evidence-based quality and safety improvement programmes in frontline services. The activities of the agency will therefore be integral to supporting the Minister to satisfy statutory obligations under the NZPHD Act.

Establishing the agency as a Crown agent functionally independent of the Ministry of Health has the advantage of being able to speak with an independent voice whilst still required to have regard for government policy and being accountable to the Minister, through the formal governance and accountability regime of the Crown Entities Act 2004.

While the functions of the new agency should determine its form, we note ex State Services Commissioner Don Hunn's comments that:

Machinery of government changes do not tend to happen merely because of the existence of an abstract set of design criteria. Context is crucial. They tend to occur in response to perceived problems or inadequacies. Criteria may have a significant effect on the ultimate design, but other considerations will also be relevant such as political judgements about the suitability of different organisation forms, or practical considerations about the relative ease with which changes can be made.

The SSC's guidance on organisational design includes a constitutional convention dimension. One of the considerations within the constitutional convention dimension is the need for independence. The SSC apply the following test: "if an activity must be, and must be seen to be, undertaken free of political interference, and there are no compelling reasons for close Ministerial oversight, the non-departmental form may be preferred."

Arguably, this is one of the pivotal questions guiding decisions about the appropriate entity form for the proposed quality agency. The goal of the new entity will be to improve quality and safety across the health system through reducing unwarranted variation, increasing adherence to evidence-based practice and reducing the incidence of adverse events. Achieving a culture of quality improvement is based on trust. The entity structure which best achieves patient and clinical engagement, and hence clinical leadership, will be the most effective in delivering desired quality improvement outcomes.

The appearance of independence is strongest with a Crown entity.

Conclusions and recommendations

After consideration of both options the Ministry of Health is of the view that a stand alone agency operating as a Crown Agent is the preferred option. This option has the two key advantages of providing independence – crucial for buy in from the sector – whilst still being required to give effect to Government policy.

Consultation

Extensive feedback was received by the Minister on the MRG report. Analysis of the options has been informed by that feedback.

The options considered here have also been informed by a Clinical Reference Group, established for this project, of senior doctors, nurses, allied health professionals and health managers with expertise in quality and safety improvement, and an officials group comprising the Treasury, State Services Commission and Department of Prime Minister and Cabinet. The Crown entity option is favoured by many members of the Clinical Reference Group because of its perceived independence from the Ministry.

The Treasury and State Services Commission do not consider that an adequate case for a separate quality focused Crown entity has been made. They consider that there is significant scope within current arrangements for improving the effectiveness of the quality and safety programme and functions. Treasury and SSC recommend strengthening the role of the current QIC and giving the committee greater oversight and influence over the Ministry's quality and safety programme.

Implementation

It is proposed that whatever Government's preferred option, an interim board (utilising section 17 of the NZPHD Act and refreshing the existing QIC membership) be created to direct establishment of the new entity and to appoint an interim head.

The Ministry of Health will form an establishment unit to support the interim board and undertake the preparatory work required for establishing the new quality entity. The interim board and establishment unit will be responsible for transitioning the existing quality improvement work programme, of both QIC and the Ministry, to the interim entity. Depending on the timeframes for establishing the final quality agency, the interim board could also develop a draft work plan.

At the point of transition to the new entity, the Minister will need to finalise decisions on board membership. This will involve either revising the membership or transitioning the existing 'board' to either the:

- board of the Crown entity (and therefore with decision-making authority); or
- the advisory 'board' (s11 committee) advising the Minister on the work of the BBU.

The establishment unit would be dissolved once the new entity was in place.

Monitoring, evaluation and review

Whichever option is preferred by Government, the Minister of Health and the Ministry of Health will have a role in monitoring, evaluating and reviewing the effectiveness of the entity responsible for driving the improvement of quality and safety across the health and disability sector.

Beyond the standard monitoring processes, Cabinet has also agreed to a further review of the DHB model within the three next years. This review will assess whether more

fundamental reform will be needed to create strong enough incentives for efficiency, and to enable the sector to lift its performance within a more sustainable growth track [CAB Min (09) 37/13-15 refers]. This will include an assessment of the extent to which Cabinet's preferred option for a quality agency has been effective in improving the quality and safety performance across the health sector.

Appendix 1

Costings for Quality Agency Options

From a preliminary assessment of the resource implications of the changes, officials have concluded that the proposed changes can be carried out by reprioritisation within existing output classes and appropriations.

To support recent Cabinet decisions, the Director General of Health will be undertaking a review of the Ministry of Health. This review will also better position the Ministry to deliver the Government's priorities and improve sector performance within the tighter fiscal environment. The costs of implementing the review, along with any other cost pressures will, as noted in a recent Cabinet paper, "require efficiencies to be identified and/or reprioritised from lower priority spending and outputs". [SOC (09) 102 para 48 refers.]

Resourcing for the changes discussed in this paper will be considered alongside this review. The costs estimated here are only indicative, and will be subject to the same scrutiny as other areas of Ministry activity during the organisational review, and in the future.

Estimated costs of the options

A new Crown Entity (Option 1), can be achieved as follows:

Overall, based on experience with similar entities, officials expect the Crown Entity to have operating costs 55 – 65 percent higher than the within the Ministry option, with an initial operating budget of $2 - $2.5 million per year. [This is comparable to CHFA, which has an operating budget of $2.7 million.] This does not include transition costs or the funding used for external contracts.

- Some of the resources currently appropriated as Department Expenses (DE) for the Quality and Improvement Team (approximately two FTEs) will need to be reprioritised to provide liaison, and to monitor the new Crown Entity;
- It is assumed that the Crown Entity will require about 30 percent additional core funding over and above that provided to the existing quality team in the Ministry, to accommodate the additional overhead. This assumes some sharing of corporate functions with the Ministry. This will be funded by reprioritising a proportion of the current DE for the Quality and Improvement Team and a contribution from DHBs, where some of the proposed functions for the new QIA are currently undertaken. (As discussed in the Cabinet paper, if DHBs are to have a sense of ownership – and hold the agency to account – direct funding is important.)
- Resources currently used to support the Quality Improvement Committee (NDE) are assumed to transfer to the new Crown entity for governance expenses;
- Part of the resources currently appropriated as NDE for relevant quality improvement and innovations contracts will be able to be transferred to the new agency. The range of funding that may be available from these contracts is $4-12 million per year. This will be determined in consultation with the Minister during the implementation phase.
- Implementing the reconfiguration, including supporting the Minister, policy analysis, and Departmental Expenses associated with project management support (requiring

approximately 1.5 – 2.0 FTEs), can be resourced from existing Vote Health Departmental Baselines.

- Other health Crown entities include:
  - The Mental Health Commission (annual budget about 1.7m, 10 FTEs)
  - CHFA (annual budget about 2.7m, 8 FTEs)
  - PHARMAC (annual operating budget about 13m, 35 FTEs)
  - ALAC (annual operating budget about 12.7m, 30 FTEs)

Reconfigured arrangements for quality improvement, within the Ministry of Health (Option 2), can be achieved as follows:

- Operating costs of $1.3 – 1.6 million in first year (including some implementation costs);
  - A proportion of the resources currently appropriated as Department Expenses (DE) for the Quality, Improvement and Innovation Team (approximately seven FTEs and associated operating costs) will be able to be used to fund the reconfigured Quality board;
  - Direct committee costs are assumed to be the same;
  - Implementing the reconfiguration, including supporting the Minister, policy analysis, and project management support (requiring perhaps 1.0 FTE for a year), can be resourced from existing Departmental Baselines.
- As above resources currently appropriated as NDE for relevant quality improvement and innovations contracts will be able to be used by the new board to commission work once the existing contracts are completed. (Between $4 and $12 million of NDE contracts)

Key assumptions are:

- As noted in a previous Cabinet paper [SOC (09) 102 para. 48 refers], the Ministry of Health is currently transitioning from 1475 FTEs (incl. vacancies) at 1 July 2009 to a planned 1390 FTEs by 1 July 2010. The changes outlined here take this into account.
- No redundancy costs have been included in these estimates.
- The introduction of a separate quality agency introduces the additional running costs associated with running a new entity. Against this, efficiencies may be found through greater agency focus and/or potential reprioritisation from lower priority outputs – this is unlikely to result in lower expenditure, but rather, if it occurs, in better value for money.
- The budget for the new arrangements may vary, and will be driven by the agreed work programme and subject to change to reflect Government priorities and organisational/operating expectations.

QUALITY	Current	Estimated steady state - Quality Crown entity	Estimated steady state - within MoH BBU
Committee costs	250,000		250,000
MoH support	1,000,000		1,000,000
External contracts	TBC	TBC	TBC
Governance costs		250,000	
New agency - staff and overheads		1,500,000	
MoH staff - monitoring and liason		240,000	
External contracts			
Total	1,250,000	1,990,000	1,250,000
Transition costs (conservative)		240,000	180,000

Resourcing for the changes discussed in this paper will be considered alongside a broader review. The costs estimated here are therefore only indicative, and will be subject to the same scrutiny as other areas of Ministry activity during the organisational review and in the future.

Appendix 2

Risks and Mitigations

The table below identifies the major high level risks associated with each proposal, together with actions to mitigate likely impacts:

Risk	Mitigation
Crown Entity	
The arms-length arrangements of the Crown entity could lead to non-alignment with regulatory and monitoring functions undertaken by the Ministry.	Manage alignment through the SOI development process. Though the SOI focuses on planning for three years, the SOI itself is produced annually, commented on by the Ministry and signed off by the Minister of Health. The output agreement, between the funder (the Ministry) and the quality agency, provides a further opportunity for oversight and to ensure alignment.
The potential for fragmentation due to the proliferation of health entities.	As for above.
Branded Business Unit	
Not seen as sufficiently independent by the sector and therefore unable to achieve the level of sector buy-in required to achieve quality improvement goals.	Government could choose to emphasise the discrete role and functions of the BBU through a range of actions including locating the unit away from the main Ministry offices, identifying a specific (Associate) Minister for quality improvements and/or establishing a discrete Vote allocation within the Vote, or a discrete Vote.
Funding for this work could be reallocated across the Ministry of Health to areas of greater need.	Can establish a separate allocation within the Vote or a discrete Vote.
Constrained in its ability to set its own agenda and advocate for a focus on quality.	Clearly identify policy objectives and functions – can be ring-fenced from other activities in the Ministry.