

Regulatory Impact Statement

Improving the management of infectious diseases in the community: Proposed Health (Health Protection) Amendment Bill 2013

Agency Disclosure Statement

This Regulatory Impact Statement (RIS) has been prepared by the Ministry of Health. The Statement provides an analysis of options to address concerns around the surveillance and management of infectious diseases, and consequent risk to public health and safety. These concerns have arisen because the current legislative framework does not, in some situations, fully support effective front line public health practice. Specifically:

- reliable and useful information for surveillance of the rates and prevalence of some significant sexually transmissible infections (STIs) is not available due to lack of requirements for notification of these diseases
- legal provisions are inadequate for case management of a small number of individuals with infectious diseases whose behaviour may pose a significant risk to other people
- there is no clear legal basis for tracing people who may be sources of infection, or at risk of infection.

Concerns that the current legislation does not fully support public health practice have been articulated by staff in health agencies over a sustained period of time. Confirmation that the issues remain valid comes from 2013 information from the Public Health Clinical Network and advice from the New Zealand AIDS Foundation.

The preferred option to address these concerns would require amendments to current law. The proposed amendments would improve the notification framework for infectious diseases; make some sexually transmissible infections (STIs) notifiable (that is, HIV, gonorrhoea, and syphilis); introduce a graduated series of provisions to manage infected individuals whose behaviour is a risk to others; and provide a clear legal basis for the practice and scope of contact tracing. These measures are designed to increase the safety of the public, protecting them from the risk of infection from a number of serious diseases.

Other than the general public, the main stakeholders include medical practitioners, laboratories and district health boards. Costs of implementation will be relatively minor for these stakeholders. For example, the additional options for managing infected individuals whose behaviour is likely to harm other people and contact tracing are consistent with work that public health units already perform, so costs will be absorbed within existing baseline funding.

The public health management of infectious diseases has implications for privacy principles, wider human rights, and associated common law principles. These implications are addressed in the proposals. Concerns around privacy, in relation to notification of some STIs, are met by 'anonymising' or 'coding' of case data in routine cases. The proposals for case management will be more consistent than the status quo with the rights and freedoms set out in the New Zealand Bill of Rights Act and common law principles (such as those relevant to the dignity and liberty of the individual, and access to the courts). This greater consistency is achieved by proposing time-limitations, rights of appeal, and Court oversight. The proposals to allow for contact tracing will provide for

confidentiality to be maintained as far as possible. The proposals have been discussed with the Human Rights Commission, the Office of the Privacy Commissioner and the Ministry of Justice and appear justifiable under the New Zealand Bill of Rights Act 1990.

The proposals would have little to no impact on costs to business, and will not impair private property rights, market competition or incentives for business to innovate or invest.

Fran McGrath, Acting Director of Public Health, October 2013

Regulatory impact analysis

Status quo and problem definition

The Health Act 1956, the Tuberculosis Act 1948, and their associated regulations, provide the framework for law on infectious diseases in New Zealand.

Feedback from the health sector indicates that legal authority to take front line public health measures to manage infectious diseases is inadequate.

The Ministry also considers there is a small group of infectious diseases (HIV, gonorrhoea and syphilis) that have serious implications and therefore should be better provided for within the legislative framework to increase public safety.

Most importantly:

- reliable and useful information on the rates and prevalence of some significantly concerning sexually transmissible infections (STIs) is not available because these diseases are not legally able to be notified to health agencies (surveillance)
- notification of STIs can raise privacy concerns given perceptions of stigma around these diseases (notification)
- legal provisions for the management of a small number of individuals with infectious diseases whose behaviour puts other people at risk are inadequate (case management)
- legal authority for tracing people who are possible sources of infection, or at risk of infection, is very limited (contact tracing).

The problems with the status quo are that:

- there is risk that members of the public are infected with serious infectious diseases and the spread of these diseases remains unknown and is not able to be managed
- comprehensive and timely information on rates and trends of STIs is lacking, which hampers appropriate policy development for reducing and managing these STIs
- the lack of intermediate options for effective case management (that is, either voluntary compliance or detention) means that in practice usually only limited action is able to be taken to manage and assist people whose behaviour puts other people at risk
- tracing and contacting people who may be sources of infection (and require treatment) is not undertaken in many situations, with the result that the source of infection cannot be identified (and treated). In addition, others at risk may have

no means of knowing they are at risk and hence do not take steps to prevent such risks.

Surveillance and notification

An important basis of public health surveillance is the 'notification' system, set out in both the Health and Tuberculosis Acts. Notification requires medical practitioners and laboratories to provide information to Medical Officers of Health at public health units about disease 'cases' when they are identified. Notification allows Medical Officers of Health to investigate sources of disease and determine what measures are needed to help prevent further transmission of disease. The data also enables reliable information to be collated on the rates and prevalence of disease.

The Health Act lists 'notifiable infectious diseases' in its schedules. Some current examples of notifiable infectious diseases are AIDS, rheumatic fever, measles, mumps, cholera, and non-seasonal influenza. The Health Act provisions for notifiable infectious diseases apply only to the specified diseases. Figure 1 illustrates the current legal categories for diseases under the Health Act.

Fig. 1: The current legal categories for diseases under the Health Act



Notification has two purposes. Firstly, it ensures that information on all cases of notifiable infectious diseases is able to be reviewed both locally and nationally to detect outbreaks/clusters of disease and analyse patterns and trends. Secondly, notification enables the relevant Medical Officer of Health to take action to protect

public health if this is deemed appropriate. For example, notification of a case of typhoid would enable the Medical Officer of Health to investigate the source of infection and ensure that the person does not work at a school while infectious.

While AIDS is listed as a notifiable infectious disease, HIV is not. AIDS is the late stage of disease caused by HIV infection and both conditions are infectious. Current diagnosis and early treatment capabilities mean that fewer cases of HIV now progress to AIDS. This means that the proportion of HIV cases compared to AIDS cases has grown to the point that HIV has largely supplanted the risk posed by AIDS. To illustrate this point, in 2012 there were 15 people newly diagnosed with AIDS, while 124 people were newly diagnosed with HIV. Specification of HIV infection as a notifiable infectious disease, in addition to AIDS, would enable more accurate and timely information about this serious and life-long condition.

The sexually transmitted infections of gonorrhoea and syphilis are also omitted from the Health Act schedules of infectious notifiable diseases despite having potentially serious effects for those infected. Medical practitioners/ laboratories are not required or authorised (unless criteria in the *Health Information Privacy Code* are met) to notify cases of these diseases to the relevant Medical Officer of Health. This means that existing surveillance data on these diseases, from sexual health clinics, family planning clinics, and laboratories, is likely to be under counting cases.

The existing data suggests that the number of syphilis cases is relatively low. However, there is an increasing trend of co-infection with AIDS. The biology of syphilis (lesions) and the behaviour of a small group of co-infected individuals create a very high-risk of infection for which the contact tracing and case management provisions discussed in this paper will be useful.

Existing data indicates that the case-load of gonorrhoea is significant and increasing. Of equal concern is a growing global threat of multidrug-resistant gonorrhoea which could lead to gonorrhoea becoming untreatable. According to information on case numbers from such facilities as sexual health clinics, there were 3317 new cases of gonorrhoea diagnosed in 2012 (improved diagnosis may have contributed to some of this increase). Gonorrhoea is associated with the risk of mother to child transmission (two cases of gonorrhoea were diagnosed in children aged under 1 year in 2012). All of the provisions discussed in this paper would assist public health officers respond to reduce the gonorrhoea infection rate.

HIV, gonorrhoea, and syphilis are all infectious with serious personal health consequences for infected people. Where these infections are detected in a timely manner and treated appropriately, outcomes are good - provided compliance with treatment is adequate. However, the implications of untreated infection, both for the infected person and the people they may infect, are causing significant concern among those working in the health sector. The public health risks associated with these diseases are easily comparable with existing notifiable infectious diseases.

Case management

Where a person with an infectious disease does not voluntarily modify their risk of infecting other people, the Health Act and the Tuberculosis Act both provide for

detention of that person. Hence in practice there are only two choices currently available for managing cases of infectious individuals: supporting a person to voluntarily modify behaviour, or detention.

Detention must be authorised by a Medical Officer of Health (for diseases to which the Health Act applies), and by a court order (under the Tuberculosis Act). Detention is a very significant use of state power. Detention is also expensive, difficult to manage effectively, and because of this, is rarely used. Detention under the Health Act is potentially for an unlimited period of time (infections such as HIV never become non-infectious and currently persist until death), and it is not subject to review by the Courts.

Currently, there is no legal duty to comply with treatment for most infectious diseases, although under the Health Act a person with a venereal disease must 'submit to treatment' ('venereal diseases' is defined quite narrowly with four diseases listed in addition to gonorrhoea and syphilis, but not including either HIV or AIDS).

Contact tracing

Contact tracing is an internationally recognised public health strategy to reduce the spread of infectious disease in the community. A person with an infectious disease has been infected by someone and may often unknowingly infect others. Contact tracing is the identification of and communication with persons who may have been in contact with the infected person. Contact tracing allows contacts to become aware of their infection risk, seek testing and diagnosis, and take steps to prevent further transmission. This also helps public health practitioners identify the source of the infection. Contact tracing is done on a confidential basis wherever possible, without disclosure of the identity of the original case.

There is little in the Health Act or the Tuberculosis Act which provides authority for public health practitioners to conduct contact tracing. There is no obligation on the part of the infected individual to provide information on the possible sources of their infection or the people they may have subsequently infected. Therefore, contact tracing is conducted only when information is volunteered by the infected person. Current legislation does not provide authority for public health practitioners to obtain information that is not volunteered.

Tuberculosis Act

For historical reasons, New Zealand has a stand-alone Tuberculosis Act, and therefore, we have two statutes for infectious disease, both with slightly different provisions for detention of infected people. In clinical and public health practice, it is appropriate to manage tuberculosis in the same way as for other serious infectious diseases.

Objectives

The objective of the policy proposals outlined in this paper is to provide for more effective management of significantly concerning infectious diseases that pose risks to the public.

Specific policy objectives are to provide:

- comprehensive and timely surveillance information on infectious diseases, including certain serious STIs
- a more effective range of case management options for infected people whose behaviour puts other people at risk
- comprehensive, appropriate and accurate tracing of people who are sources of infection or have been exposed to the risk of infection, so that timely testing and treatment can be undertaken and people at risk of exposure have information to help ensure they can take steps to avoid risk of infection
- an appropriate balance between the interests of public health and human rights.

There is no legislative, budget, or time-specified requirement to review the legislation discussed in this paper.

Regulatory Impact Analysis: Options

Two options have been considered for this analysis:

Option 1: Status quo

No legislative change for notification, case management, or contact tracing.

Surveillance

The present list of notifiable infectious diseases is not comprehensive and does not include some significant sexually transmissible infections: HIV, gonorrhoea, and syphilis. There is little doubt that these STIs present a risk that is equivalent to other listed notifiable infectious diseases.

The benefits of notification need to be balanced against the privacy concerns of individuals with an STI who may fear disclosure of their personal identifying details and therefore not come forward for testing. This concern is particularly acute for HIV, as considerable stigma was associated with HIV/AIDs when these diseases first emerged in the 1980s.

Under the status quo option, this current gap in surveillance information would remain. Health agencies will continue to find it difficult to determine the steps required to reduce the rates and prevalence of these diseases. This means that the current rates and prevalence of these diseases are likely to continue and the cost of treating these diseases will remain unaffected. In the case of gonorrhoea (high and increasing case-loads and multidrug-resistant varieties), there is the possibility that treatment costs could increase.

Case management

Where individuals with an infectious disease do not voluntarily modify their behaviour to reduce the risk of infecting other people, detention is currently the only option available to safeguard the public. Detention is seen as disproportionate in most cases, difficult to justify, and as a result, orders for detention are rarely made. There have been only two known cases involving detention under the Health Act since the 1950s. Detention under the Tuberculosis Act is invoked more frequently (about one order every two years).

A further gap in the present management framework is that for most diseases an infected person has no duty to accept treatment. Therefore, in almost all situations, medical practitioners must rely solely on their clinical influence to gain voluntary compliance in the small group of individuals who, for a range of reasons, do not want to accept treatment.

Under the status quo option, the provisions for detention are likely to remain rarely used. Medical practitioners would continue to rely almost solely on their clinical influence to gain voluntary compliance. It is reasonable to expect that under the status quo the infection rates in this high-risk group will remain unchanged and the cost of treating these diseases will be unaffected.

Contact tracing

The lack of legal support for contact tracing would remain. A person with a significant infectious disease would have no obligation to provide relevant information to health agencies about sources of exposure or people who may have subsequently been exposed. This means that contact tracing can only occur where individuals voluntarily comply with information requests. Where contact information is not voluntarily provided, contacts would remain unaware of their potential infection and treatment options. Contacts will also, potentially, continue to unknowingly infect other people. Under the status quo option, it is reasonable to expect infection rates to continue the current trends and the cost of treating these diseases to be unaffected.

Option 2: Amendments to current legislative frameworks

Health (Health Protection) Amendment Bill

Option 2 proposes to introduce a Health (Health Protection) Amendment Bill (Amendment Bill), which would amend the current Health Act 1956 to:

- allow a subset of notifiable infectious diseases to be notified on an ‘anonymised’ or coded basis
- make HIV, gonorrhoea and syphilis notifiable on an ‘anonymised’ basis, with provision to de-code where necessary
- make additional case management options available to deal with infected people whose behaviour is likely to harm other people
- place reasonable duties on infected individuals to provide health agencies with timely information to allow contact tracing
- list tuberculosis as a notifiable infectious disease in the Health Act (and its relevant regulations) and repeal the Tuberculosis Act and its regulations
- make other minor technical amendments to ensure that relevant Health Act regulations are also captured in the definition of infectious diseases and update out-of-date references in the Health Act.

Notification

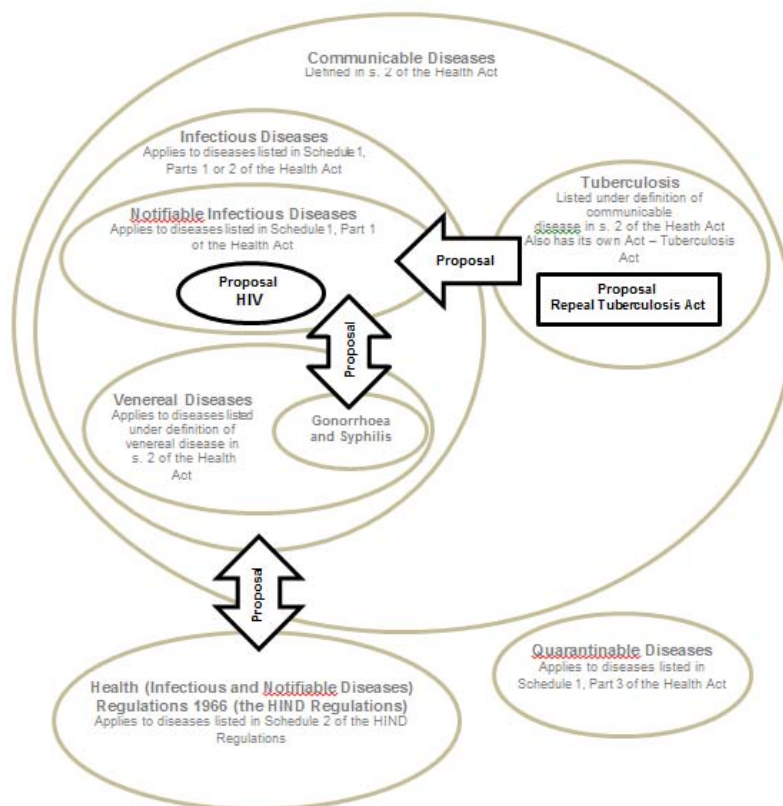
The proposed Amendment Bill would provide explicit authority for certain infectious diseases to be ‘notifiable’ on an anonymised/coded basis. This would apply to a small subset of diseases, with most diseases being notified on a named basis as at present. Provision of case details, without personal details, would be sufficient for most purposes to allow collection of information for disease prevalence and trend analysis. Anonymised notification is viewed as appropriate in circumstances where

there are perceptions of stigma. Anonymising information may help to reduce the risk that individuals may be apprehensive about coming forward for testing.

For very few cases where the behaviour of an individual presents a significant risk of harm to others, the Amendment Bill would allow for anonymised information to be 'de-coded'. De-coding notified information would be achieved by allowing the Medical Officer of Health, in specified situations, to require the notifying health practitioner to provide identifying details such as name, address and national health index number of the infected person. This would allow the individual concerned to be traced, contacted and managed as appropriate.

The proposed Amendment Bill would specify HIV, gonorrhoea and syphilis as notifiable infectious diseases, and would provide for them to be notified on an anonymised basis. This means that the medical practitioner or laboratory would not provide the name or any personal identifying information about the infected individual on notification. AIDS is already listed as an anonymised notifiable infectious disease (while the Health Act does not explicitly allow this, neither does it prohibit it), but most other notifiable conditions require personal identifying information as part of the notification. Figure 2 (next page) illustrates how these diseases would be included in the legal categories for diseases in the proposed Amendment Bill.

Fig. 2: Illustration of the proposed amendments to make HIV, gonorrhoea, syphilis and tuberculosis notifiable infectious diseases (and repeal the Tuberculosis Act)



These changes would provide improved information on sources of infection in the community while protecting individual privacy where appropriate. Consequently, the

steps required to reduce infection rates could be better targeted. Combined with the use of other proposals discussed in this paper, it is reasonable to expect that these measures would have a downward influence on infection rates and, as a result, costs of treatment.

Case management of infected individuals

The proposed Amendment Bill would introduce additional community case management provisions so that a range of options is available to deal with infected individuals whose behaviour puts other people at risk of infection. The range of options would allow for step-by-step case management that could be applied as appropriate to the circumstances. Having a range of options available would allow the least restrictive, but still effective, intervention to be applied. The additional case management options being proposed are:

- community management directions for:
 - supervision
 - counselling
 - testing
 - travel restrictions
 - school closure
 - residence restrictions;

- court orders:
 - to require compliance with treatment
 - for isolation/detention.

The proposed Amendment Bill would enable Medical Officers of Health to give community management directions if the officer believes, on reasonable grounds and where specified criteria are met, that an infected individual poses a risk of infecting other people with a listed notifiable infectious disease. The Amendment Bill would specify that community management directions be time-limited for up to six months (but be able to be renewed) and be subject to appeal.

The Medical Officer of Health would not be able to make directions for detention or to require compliance with treatment. The Bill would allow the Courts to make orders for treatment, isolation and detention. Orders for isolation/detention would differ from the Health Act status quo in several respects, while not being too dissimilar from provisions in the Tuberculosis Act. Firstly, the detention powers would be exercised by a Court, rather than by a Medical Officer of Health (as is the case now under the Health Act). Court orders would be time-limited and subject to review. The Courts would also be able to make orders for treatment in appropriate cases, with stringent criteria set out in the amended Act. Criteria could refer to non-compliance with community management directions or other advice aimed at reducing the risk of infecting other people, or where non-compliance increases the risk of anti-microbial resistance. Orders to require treatment would not involve compulsory enforcement and would specifically exclude the use of physical force. In effect, this would be very similar to the current legal duty to accept treatment for the present list of venereal diseases. The Amendment Bill would specify that court orders be time-limited for up to six months (but be eligible for renewal) and be subject to appeal.

The Amendment Bill would impose a duty on the person concerned to comply with directions and court orders. A new offence is proposed for intentional non-compliance with directions/court orders. An individual would be liable, on summary conviction, to a fine not exceeding \$2,000. (This is comparable to the fines under the Tuberculosis Act for not complying with isolation orders.)

Amendments to the Health (Infectious and Notifiable Diseases) Regulations 1966 (the HIND) would define the processes for both directions and court orders. Regulations would include procedures for the form and scope of directions and court orders, with processes for reviews and appeals, including documentation and reporting requirements, and specific requirements for educational institutions.¹

These proposals would provide health practitioners and Medical Officers of Health with a range of options to manage people with infectious disease and assist people who pose significant risk of harm to others. Health practitioners and Medical Officers of Health would have the ability to apply the least restrictive option in a fit-for-purpose way. If these additional options proved effective for some individuals, the risk of disease transmission via this high-risk group may be reduced. If infection rates were reduced, it would be reasonable to expect a reduction in the cost of treating these diseases. It is reasonable to assume that increased costs associated managing community directions would be off-set by a reduced number of infected individuals in the community.

Contact tracing

The proposed Amendment Bill would place a duty on people with relevant notifiable infectious diseases to provide, as far as is practicable, information relevant to the circumstances and source of their condition. Information would include names, identifying details, and addresses of other people that may have been the source of infection or who may have subsequently become infected.

The proposed Amendment Bill would also specify that failure of infected individuals to provide specified information, or co-operate with contact tracing procedures, would constitute an offence and the individual may be liable to a fine not exceeding \$2,000.

Contact tracing would also require amendments to Health Act regulations to define the practice and scope of 'contact tracing'. This would define the information to be collected, obligations to the person providing the information, procedures for contacting other affected people, safeguards for information filing and retrieval, and related reporting requirements.

If contact tracing can be more effective, infection rates may be reduced which would reduce the costs of treating these diseases.

¹ The Health Act's Regulations already allow Medical Officers of Health to 'exclude' students and teachers from schools in defined circumstances. The proposed Amendment Bill would add the ability to close a facility for a specified period of time. Care will be taken in adding HIV to these Regulations, to prevent inappropriate exclusion of HIV-positive children from preschools and schools.

Tuberculosis Act

The proposed Amendment Bill would include tuberculosis as a notifiable infectious disease under the Health Act. All provisions relating to notifiable infectious diseases would then also apply to tuberculosis. The inclusion of community management directions and court orders in the amended Health Act means that the provisions of Health Act and the Tuberculosis Act would be aligned. A duplicate statute dealing with tuberculosis would no longer be required and the Tuberculosis Act and its regulations could be repealed. This option, combined with the other measures discussed in this paper, would improve the management options for cases of tuberculosis. This option would improve efficiency in frontline public health practice by bringing all infectious disease management under a single set of provisions.

Preferred Option: Legislative amendment

Legislative amendment is preferred because the status quo does not provide an effective range of options for the management of infectious diseases, and certain serious STIs are not covered under the Act. This poses a risk to the health and safety of members of the public, through risk of passing on infection and not receiving timely treatment.

Option 1 results in incomplete information being provided about infectious conditions to understand their source and spread. It only provides a narrow range of options for the management of infectious diseases.

Incomplete information has two main risks. Firstly, there is an inadequate basis to develop a population level strategy. Secondly, individuals who require follow-up to reduce the risk of harm to others cannot be identified. Where voluntary compliance is not gained, the current case management options are 'detention or nothing'. Detention is rarely deemed appropriate (used) and therefore, the remaining option is 'nothing'. There is always likely to be a small number of individuals for whom clinical support will not be enough to ensure appropriate voluntary behaviour modification. Therefore, legislative change is the only option for managing the risks to other people's health associated with this group, and Option 2 is the preferred approach.

The proposals in Option 2 create additional powers for contact tracing and community management. If an individual with an infectious disease creates health risks for others and specified criteria are met, court orders to provide for a legal duty to accept treatment and detention can be made. The proposed changes clarify or extend some legislative provisions and provide for a series of steps which can be escalated according to the level of risk. The additional powers are consistent with the current work of public health units and costs will be absorbed within baselines.

The proposals recognise the importance of balancing the interests of public health with the rights of individuals. The proposed Amendment Bill would introduce a range of powers to be exercised, as appropriate, in relation to particular individuals with significant infectious diseases. Powers at the lesser end of the range (such as requiring a person to attend a particular health care programme or refrain from certain activities) would be able to be exercised by a Medical Officer of Health in the community. The more restrictive powers (such as isolation/detention) would only be

exercised following a court order. All restrictive powers would become time-limited and subject to appeal.

The relevant provisions in the proposed Amendment Bill would provide a range of options, particularly less restrictive ones, to manage infected individuals and to achieve a better outcome for the public.

Tuberculosis Act

The Tuberculosis Act 1948 and regulations provide for a management regime that is separate from the generic infectious disease provisions in the Health Act. The reasons for this are largely historical. The separation is no longer relevant or helpful. Option 2 proposes to include tuberculosis in the Health Act as amended and revoke the Tuberculosis Act and the Tuberculosis Regulations.

Other minor technical amendments

Other minor technical changes are proposed. These include:

- Amending the definition of 'infectious disease' in the principal Act so that it is clear the definition includes diseases listed in the Health (Infectious and Notifiable Diseases) Regulations 1966 as well as the diseases listed in the Schedules to the Health Act.
- Updating the definition of 'child care centre'. The current definition of child care centre in section 125(1) of the Health Act is the meaning given in section 105(3) of the Children and Young Persons Act 1974. This Act has been repealed, and this term is not used in any other legislation. The current equivalent is now 'early childhood education and care centres' found in section 310 of the Education Act 1989.

Net benefit of proposal

A regulatory impact assessment, including quantification of financial implications, was undertaken for the Public Health Bill as approved by Cabinet in 2001. The overall assessment of costs and benefits as indicated in the RIS and cost benefit analysis carried out at that time remains current. However, the proposals for this Amendment Bill would be significantly more limited. Therefore, both the costs and benefits of the proposed Amendment Bill are narrower than previously expected. Costs and benefits identified below provide further clarification.

Government

The legislative framework would be simplified by including tuberculosis in the Health Act and repealing the Tuberculosis Act and its regulations. This would improve efficiency in frontline public health practice.

Public health practice would be more effective due to better infection source tracing and reliable surveillance information through notification of HIV, syphilis and gonorrhoea. It is reasonable to expect that these measures will have a downward influence on rates of infection, and therefore costs of treatment, over time.

Public health practice would be more transparent due to the use of courts for authorisation of restrictive public health powers, while providing a range of less intrusive options for Medical Officers of Health to use in the community.

Changes to the provisions for use of restrictive powers would have neutral cost implications. Although the Amendment Bill proposes a somewhat greater use of courts as decision-makers, the number of cases per year has been forecast to be fewer than five people (based on evidence of the very limited number of detentions over the last ten years). Detention is itself a relatively expensive option, and the increase in 'intermediate' Medical Officer of Health administered community management options proposed (i.e. community supervision) may result in reduced overall costs in managing people with infectious conditions.

In 2001, the estimated cost to the Ministry for developing the Public Health Bill and planning for its enactment was between \$100,000 and \$250,000 for the years 2002/03 to 2004/05 (personnel and operating costs). The total cost of the first year post enactment of the proposed Amendment Bill is expected to be significantly less than \$250,000. This calculation takes into account the implications of the more narrowly focused proposals outlined in this paper and the accompanying Cabinet paper, as well as the fact that in general, the policy development for the proposed Amendment Bill has already been undertaken during development of the Public Health Bill. This cost would be met within baselines.

Implementation costs would consist of information for the health sector, the general public, and particular stakeholders such as the NZ AIDS Foundation. Costs for the Ministry of Health would be for some additional training and the development of guidelines and manuals. Some additional court officer training may also be required. All costs would be met within baselines.

A change which can be more clearly quantified relates to application of the *Eligibility Direction 2011* to HIV as an infectious disease. The *Eligibility Direction* defines which individuals are entitled to receive publicly funded health and disability services. These people, generally speaking, are New Zealanders. Hence a person who is not a New Zealander, and who does not fit any of the other *Eligibility Direction* criteria (such as coming from a country with whom New Zealand has reciprocal arrangements) must pay for diagnostic or treatment services in New Zealand. However, exceptions are made in the *Eligibility Direction* to this general principle on public health grounds. Given public health risk to others, otherwise ineligible persons with an infectious disease are eligible to receive publicly funded health services.

People with gonorrhoea or syphilis are already covered by the *Eligibility Direction* because, though presently not 'notifiable' conditions, these two diseases are listed in the Health Act as 'infectious diseases' (see Figure 1). HIV is not listed as either notifiable or infectious.

Most people with HIV receive publicly funded health care because they are New Zealanders or are otherwise covered by the *Eligibility Direction*. Listing HIV as a notifiable infectious disease (as proposed) would mean that a relatively small proportion of people with HIV who are not at present eligible for publicly funded care (for instance because of their immigration status) would become eligible. The cost of antiretroviral treatment for HIV is around \$11,000 per person per year (2012 figures). Numbers of new HIV cases per year are still relatively low, with 124 cases of HIV newly diagnosed in 2012. It is expected that no more than 5 – 10% of those cases would involve people otherwise ineligible for publicly funded services.

Therefore, the maximum increase in costs of diagnosis and treatment of HIV, as a result of implementing the proposal to list HIV as an infectious notifiable disease, is expected to be in the order of \$140,000 - \$150,000 per year in total, based on diagnoses in 2012. This cost would be absorbed within baselines and would be offset by the savings and benefits of improved treatment. Improved treatment can reasonably be expected to reduce community transmission and reduce the potential for anti-microbial resistance associated with sub-optimal treatment. Public health unit and medical practitioner personnel and resources are already deployed to implement a wide range of Health Act responsibilities. The overall policy package is expected to be fiscally neutral, with one-off implementation costs being absorbed within baselines.

Providers of health and disability services

For DHBs, the proposed changes would clarify or extend some legislative provisions and provide for a series of community management options proportionate to the level of risk. The additional powers are consistent with the current work of public health units and costs would be absorbed within baselines.

For medical practitioners and laboratories, the proposal for notification of HIV, gonorrhoea and syphilis is not expected to result in significant additional costs because:

- it is a relatively simple step for laboratories to update their reporting procedures to ensure they report the additional conditions
- laboratories and medical practitioners already have processes in place to share such health information.

Society

Wider society would benefit from a transparent balancing of the public's expectations to be protected from avoidable infectious diseases, and individual rights to freedom and privacy, including:

- the extent to which actions of high-risk people with infectious diseases may be restricted when voluntary measures have not proved effective
- review and appeal safeguards on public health directions and orders
- a transparent and reasonable application of powers to restrict infected individuals' freedoms through clear criteria and principles, with community interventions that are commensurate with the risk to the public health, and the use of court orders.

The public would also benefit from more proactive management of infectious disease through reduced likelihood of transmission of disease, timely identification of the source of disease.

It may be argued that the proposed introduction of more stringent expectations and procedures for the case management of infected individuals will increase compliance costs. However, the proposed new procedures reflect current good clinical practice and are supported by the health sector.

The balance of the benefits for people, and society as a whole, of improved protection from infection and improved surveillance information would be balanced against the confidentiality and privacy issues that arise from these provisions. This

balance would be reflected in the draft legislation and subsequent draft regulations that Cabinet will consider.

Consultation

Stakeholder consultation

In September 2013, departmental consultation on the proposals discussed in this paper confirmed that the corresponding departmental submissions presented on the equivalent earlier proposals remain relevant.

Also in 2013, the Public Health Clinical Network advised the Associate Minister of Health of the need to update the legislation for infectious diseases and the New Zealand AIDS Foundation has also commented on the need to improve the management of HIV.

The proposals to update legislation for infectious diseases are not new. From 2001 to 2008 the proposals received both public consultation and Parliamentary consideration.

Case management

In 2007, public consultation identified that provisions for managing serious infectious diseases should carry a greater range of procedural safeguards than currently exist under the Health Act. At that time, it was considered that powers of detention should no longer be able to be exercised by a statutory officer but instead, only by the Courts. Also, other safeguards such as time-limits and appeal mechanisms were considered to allay concerns about the appropriate use of restrictive powers.

Provisions relating to detention and court orders are significant powers, and although defensible on public health grounds, they may still attract legitimate public and media interest. The provisions proposed were subject to a thorough Bill of Rights vetting in 2007 by the Ministry of Justice in the context of the proposed Public Health Bill and were accepted as justifiable limitations, as provided for in the New Zealand Bill of Rights Act 1990.

Contact tracing

In 2007, public consultation identified that contact tracing should only apply where voluntary communication was not proving effective or when the public risk was significant.

Tuberculosis Act

The policy intention of the last 15 years has been to replace the Tuberculosis Act with a single, consolidated statutory framework for the management of infectious diseases. Between 2001 and 2007, this policy was consulted on and supported.

General comments

The proposals outlined in this paper revisit a number of proposals consulted on between 2001 and 2007. In 2008, the measures were also consulted on extensively during the Select Committee consideration of the Public Health Bill. The views of those previously consulted indicate that the measures proposed for the Amendment Bill would solve the immediate problems still faced in managing certain infectious diseases. There was support for addressing gaps in legislation which create risks to

people's health, especially with respect to HIV. With respect to notification, contact tracing, and the extent to which the legislation should include 'last resort' powers (such as detention) to assist in managing serious infectious diseases, the proposals in this paper present a reasonable package, not inconsistent with legislation in other countries and supportive of good public health practice.

Therefore, the proposals on detention and court orders reported back by the Select Committee in 2008 are recommended again for inclusion in this Amendment Bill.

Following advice from the Public Health Clinical Network in 2013, officials believe that the measures proposed for the Amendment Bill would address immediate problems faced by the sector in managing certain infectious diseases. Because of the history of previous consultation and consideration, further stakeholder consultation is not regarded as necessary.

It is possible that some stakeholders may criticise the proposals on the basis that they are duplicative of provisions already contained in the Public Health Bill, and that that Bill has already progressed through the first stages of the Parliamentary process. However, action to improve the legislative framework for infectious diseases stands on its own merits, irrespective of the legislative vehicle.

Government departments and agencies consultation

The following departments were consulted on this paper: Customs, Internal Affairs, Education, Justice, Business Innovation & Employment, Primary Industries, Social Development, State Services, The Treasury, Women's Affairs, Police, Te Puni Kokiri, Human Rights Commission and the Privacy Commissioner. The Department of the Prime Minister and Cabinet and Parliamentary Counsel Office were informed of the proposals.

Issues requiring ongoing discussion, for example, the Bill of Rights and privacy issues, will be further discussed with the Ministry of Justice.

Conclusions and Recommendations

These proposals are based on four specific policy objectives to provide:

- comprehensive and timely surveillance information on infectious diseases, including STIs
- additional case management options relevant to infected people whose behaviour puts other people at risk
- comprehensive, appropriate and accurate tracing of people who are sources of infection or have been exposed to the risk of infection, so that timely testing and treatment can be undertaken and people at risk of exposure have information to help ensure they can take steps to avoid risk of infection
- an appropriate balance between the interests of public health and human rights.

Legislative changes are required to improve the management of infectious diseases.

The costs of the preferred option are neutral and will deliver the highest level of net benefit.

Therefore, Option 2, regulatory change by way of a Health (Health Protection) Amendment Bill, is recommended to achieve the required policy objectives.

Option 2 would introduce a Health (Health Protection) Amendment Bill (Amendment Bill), which would amend the current Health Act 1956 to:

- allow a subset of notifiable infectious diseases to be notified on an 'anonymised' or coded basis
- make HIV, gonorrhoea and syphilis notifiable on an 'anonymised' basis, with provision to de-code where necessary
- make additional case management options available to deal with infected people whose behaviour is likely to harm other people
- place duties on infected individuals to provide health agencies with accurate, comprehensive, and timely information to allow contact tracing
- list tuberculosis as a notifiable infectious disease in the Health Act (and its relevant regulations) and repeal the Tuberculosis Act and its regulations.
- make other minor technical amendments to ensure that relevant Health Act regulations are also captured in the definition of infectious diseases and update out-of-date references in the Health Act.

Implementation

The Ministry of Health is responsible for publicising and implementing the proposed changes.

Front line implementation would be through the ongoing work of public health units. Public health units may incur increased costs because of their obligations relating to contact tracing, obtaining/executing court orders, arranging community case management and dealing with requests for reviews and appeals. However, the increase in the range of case management options proposed (including community supervision and home detention) may result in fewer infected individuals in the community and therefore, a reduced overall cost in managing people with infectious diseases. The net cost is estimated to be neutral.

The proposals provide for the notification of HIV, gonorrhoea and syphilis. They also create a legal basis for notification of infectious diseases without including personal identifying information in specified situations, as well as establishing powers for contact tracing, community case management and court orders in specified situations. The proposed changes would clarify or extend some legislative provisions and provide for a range of case management options for infected people which can be escalated according to risk.

Medical practitioners and laboratories that are already required to notify all notifiable cases would have to add three more diseases. There are practically no costs involved.

Any risk that people may be reluctant to come forward for testing for HIV would be mitigated by providing anonymised notification that does not include personal identifying information. This measure has safeguards that allow for personal information to be sought in cases where the behaviour of people with infectious conditions puts other people at risk.

Timing for implementation, including when provisions in the new Act come into force, would take account of the need for information, training and notification changes.

Monitoring, evaluation and review

The Ministry of Health would be responsible for evaluation of the proposed changes. The Ministry would continue to evaluate feedback from public health units, including formal reporting, as well as medical practitioner/laboratories notifications of notifiable infectious diseases as is current practice. The Ministry will also evaluate information it receives from key organisations such as the Public Health Clinical Network and the New Zealand AIDS Foundation.