Policy allowing patenting of human DNA

Determinant	Impacts of DNA patenting policy on determinant
Expression of cultural values and practices	Enforcement of patent can result in loss/challenge/undermining of cultural values
(Note: it was felt this	Commercial pressures restrict the idea of "normal" and widen the concept of "disease"
determinant was especially significant).	Challenging values around health knowledge as public good (commercialisation/loss of individual access, control)
	Commodification of the human body (loss of control over personal/whānau genetic material)
	Loss of intellectual property rights/kaitiakitanga of hapū/ whānau genetic knowledge.
Access to, and quality of, health care	Patenting will limit access to health care by increasing its costs (both testing and treatment)
	Potential for diverting funding into expensive (advertised) genetic-based health care away from other health services
	Could direct research and development effort into issues/ problems affecting large numbers and wealthier populations
	The policy may stimulate the development of genetic tests (and increase availability), but this is contestable as patenting could restrict development of tests if it blocks access to further research work on a gene
	Increased demand (cost to society) of secondary health services – but on the other hand, testing can eliminate the need for further surveillance, leading to a saving in health care costs. Overall more likely to be increased demand and costs.
Creation and distribution of wealth/	Could stimulate research leading to economic growth (or inhibit – depending on behaviour of patent-holders)
skills development opportunities/ availability and quality	Patenting requires research 'secrecy' reducing collaboration and skills development
of research	Opportunity costs in health and other sectors.
Individual factors (personal choices based on knowledge about genetics)	 Potential increase in unnecessary concern 'Societal' pressure interacting with/affecting personal choices.



GUIDANCE

At the conclusion of the Health Lens exercise, information or uncertainty about some issues may lead to a decision to re-scope the project, re-examine particular health determinants and/ or collect more information on a particular issue. Completing the impact assessment matrix subsequently may also lead to further work.

Health impact assessment is an interactive and learning process that may be repeated at different levels of detail to "tease out" issues of importance.

NEXT STEP

Following completion of the Health Lens:

Undertake the 'impact assessment phase'. It is the second part of the appraisal stage and is found at the end of the appraisal section (on page 54).



The Health Appraisal Tool 22

Introduction

The Health Appraisal Tool comprises three components with which to examine the proposed policy. **All** are to be used. They are:

- A) Impacts of the policy proposal on determinants of health
- B) Appraisal for partnership, participation and protection
- C) Inequalities appraisal.

GUIDANCE

General guidance to help with Health Appraisal Tool

- Agree on assumptions and anticipated policy outcomes prior to completing the table

 remind each other of these.
- Refer back to the policy's objectives:
 - what are the objectives of the policy proposal?
 - what is the presently proposed means of achieving the objectives?
- Focus on the 'big' impacts and prioritise impacts after each component of the tool.

 After the three components of the Health Appraisal Tool have been completed, an overall prioritisation is done. This is the impact assessment phase, which is covered at the end of the appraisal stage. The prioritisation for each component can be compared with each other, and compared with the final one generated in the impact assessment stage.
- Repeat the exercise with alternative policy options or outcome scenarios. To be useful, an HIA must compare at least two options. It is often in making comparisons that the important factors emerge.
- Try not to agonise too much over the detail it is important to be rigorous but it is also important not to get 'stuck'. Use common sense and pragmatism.
- It is acceptable to return to important impacts and consider them more fully or seek more information. Use question marks as responses if not sure.
- It is important to consider potential determinants, outcomes or areas of inequality that are **not** listed in the set of examples provided here. Consciously try to think 'outside the square' and consider other areas.
- It will take quite a while do not rush it.



A) Impacts on determinants of health

The initial work on identification of determinants of health completed in the scoping stage is repeated more rigorously here using a matrix. Table 4 on the following page provides the format for consideration of a range of potential determinants of health that could be affected by public policy. Table 4a is the same format but completed as an example.

Enter into Table 4 the relevant determinants of health that relate to the particular policy being assessed (identified earlier in this section). Add others that may be particular to the policy being assessed. Then sort and group them, and complete the matrix (Table 4). Questions to help complete Table 4 on the next page are provided after the table.

GUIDANCE

Ensuring focus

It is recommended that only the most obvious or important specific determinants are noted initially and the matrix is completed using these. Grouping of the determinants is also suggested. A partially completed matrix is shown on Table 4a, page 49.

Remember that the exercise is to identify the effects of the policy on determinants of health, not the other way round (potential effects of determinants on the policy).

Look out for, and identify, specific determinants that have a regional character (ie, determinants that relate to particular geographic regions).



Table 4: Matrix for determinants of health

Summary of impact on determinants of health (2 nd column)* ⁵				-	
Differential impacts on particular that may interact groups with with the policy being respect to each determinant					
Differential impacts on particular groups with respect to each determinant					
How measurable is the impact?*3					
Identify any measurable indicators*! or qualitative impacts*2					
Description of impact on each determinant of health					
Health determinants specific to policy (identified earlier in this section)					

*1 eg, unemployment rates, changes in income levels

*4 other influences that could affect the health impacts of the policy eg, if benefit cuts were being introduced along with market rents (the policy being assessed) there would be a cumulative impact



^{*2} eg, interviews with key informants, qualitative survey, anecdotal information

^{*3} classify as qualitative, estimable or measurable (quantitative)

^{*5} positive, neutral or negative

GUIDANCE

Questions to help fill out Table 4:

- In the first column, list the specific determinants of health relevant to the policy proposal that were identified from Table 3.
- Describe the impact of the policy on each of these determinants of health. Remember that you are considering impacts on **determinants** only (not health outcomes).
- What measurable indicators are available to substantiate the choice of each impact?
- To what extent can each impact be measured? (classify as either qualitative, estimable or measurable).¹³
- Will the policy proposal exacerbate or reduce health inequalities for any groups, with respect to each determinant? If so, in what way? Consider Māori, low socioeconomic groups and people with disabilities in particular.
- What other influences are there on the determinant of health? Are there other policies, legislation or interventions that may interact with the policy being assessed?
- In summary, is each impact positive, neutral or negative?



Table 4a: Matrix for determinants of health (example: impacts of improved passenger transport)

Health determinants specific to policy (identified from table 3)	Description of impact on each determinant of health	Identify any measurable indicators" or qualitative impacts?	How measurable is the impact?	Differential impacts on particular groups with respect to each determinant	External influences that may interact with the policy being assessed	Summary of impact on each determinant of health (2nd column)**
Social support and social cohesion	Improved availability of bus services enables people to be mobile and maintain social support networks	Qualitative information could be sought through surveys or interviews	Qualitative	Particular impact on people without car access, those on low incomes, older people, unemployed	Availability of alternative public transport More affordable cars	Positive
Air quality	Potential for improvements in air quality through reduced use of cars	Local air quality monitoring	Measurable	Particular impact on people with respiratory conditions, older people, children	Regional and national Air Quality Standards Vehicle emission standards	Potential positive impact over the medium to long term
Access to: - employment and education opportunities - health care, disability services, social services - facilities for people with disabilities	Timetable and routes affect access to public services	Qualitative information through surveys	Qualitative	Access to services, employment etc. for families/people without cars and people with disabilities	Availability of alternative public transport and of walking and cycling tracks	Positive
Physical activity	a) Increased physical activity through walking to bus stops/train b) Decreased physical activity if availability of new bus routes within a central city area means that people choose to take the bus instead of walking	Qualitative information through surveys	Qualitative	Not applicable	Walking and cycling policies of local authority	a) Positive b) Negative

*1 eg, unemployment rates, changes in income levels

*2 eg, impacts identified from interviews with key informants, surveys or anecdotal information

*3 classify as qualitative, estimable or measurable

*4 positive, neutral or negative

*5 these are grouped determinants, in this case arising from public transport



Description of impact

Aside from detailing potential impacts, there are two other options for recording responses in the Table 4 'description of impact' column:

- · insufficient information available to make a decision or call
- unlikely to be significant impact.

Before attempting to make an overall assessment, it is important to acknowledge that there is likely to be some degree of uncertainty about the policy's potential impact on determinants. You may need to go away and collect more information using policy or HIA specialists or knowledgeable people in the subject area. The table is designed to help you identify what is not known.

GUIDANCE

The next step is to complete Table 4 for several different policy options and compare the results. If policy alternatives are not being considered at the stage the HIA is done, the table could be filled out for the status quo and the proposed policy, with the status quo being used as the basis for comparison.

After completing the table, prioritise the most significant impacts by highlighting them. The main purpose of Table 4 is to identify the more strongly positive or strongly negative impacts and key issues or concerns, in order to help generate recommendations that can address these issues. The eventual goal of HIA is to make an overall assessment based on the table's information in terms of whether the policy proposal is generally positive or negative. Table 6 in the impact assessment section is supplied to help with this.

At this stage, it is appropriate to start to form a view on which impacts are the most significant, but avoid drawing a firm conclusion prematurely. It will also be important at this stage to highlight any areas of particular concern and major effects regarding Māori health and health inequalities.

B) Appraisal for partnership, participation and protection

In order to recognise and respect the principles of the Treaty of Waitangi, and with a view to improving health outcomes for Māori, the NZ Public Health and Disability Act 2000 (Part 3) provides mechanisms to enable Māori to contribute to decision-making on, and to participate in the delivery of, health and disability services. Fundamental to the principles of the Treaty is the notion of partnership. This principle should be reflected throughout the HIA process.

Health impact assessment helps to ensure that proposed policies consider the expectations of the Act, including the principles of partnership, participation and protection, by applying the following questions. Refer to the "What else do you need to know?" section for definitions.



Questions:

	of partnership)
	How does the policy proposal provide for opportunities for Māori to contribute to the poliprocess? (the principle of participation)
	How does the policy proposal contribute to improved health outcomes for Māori? (the principle of protection). Please explain where it does or does not.
	Considering the determinants of health in the previous section, what is the potential effect of the policy proposal on Māori health? impact on the mental and physical health and wellbeing of Māori whānau/families/ communities
-	impact on the spiritual and cultural values of Māori whānau/families/communities
_	impact on Māori with disabilities and their whānau/families.

NEXT STEP

The next step is to make an assessment of whether the principles have been taken into account adequately and take the assessment through to the impact assessment stage of the appraisal (Table 6).



C) Inequalities appraisal

This section of the tool considers specifically the potential for the policy to have impacts on health inequalities. Inequalities in health occur across a range of areas, including socioeconomic status, age, gender, ethnicity, disability and geographic location. Note that one measure of socioeconomic status is the New Zealand Deprivation Index (NZDep), which takes the following variables into account:

- · access to a telephone
- · income including whether on a benefit or having an income below an income threshold
- employment status
- access to a car
- · living in a single parent family
- · educational qualifications
- · home ownership
- · living space.

These are all variables that have relevance when conducting a health impact assessment.

Complete Table 5 (on the following page) for each policy option and note impacts. Some impacts may be new, others will endorse previously noted items. In this case there may be reason to vary 'answers' to the analysis framework that the matrix provides.

It is acknowledged that there may be some crossover in responses to the different parts of this appraisal tool. The intention is to repeat aspects from different 'angles' in order to ensure that every potential impact and effect on health inequalities is covered.

After using this tool you should have identified the major contributors to health (or ill-health) of the specified policy, and the main potential impacts on health inequalities. Consider how the planning of this policy could incorporate steps to reduce any potentially negative impacts on health inequalities.

For example, a policy to reduce vehicle emissions may impact more heavily on people on low incomes. A step to mitigate this effect would be to subsidise the cost of tuning vehicles or upgrading fuel quality.

GUIDANCE

After completing the table, prioritise the most significant impacts by highlighting them. If several components of the tool highlight particular impacts, these may be especially important.



Table 5: Health inequalities matrix ##

Does the policy proposal have Describe the effects on a potential effect on health inequalities in respect of:	Describe the effects on health inequalities	Identify any quantitative measure/s	How measurable is the impact – qualitative, estimable or calculable?	Summarise the impact on health inequalities – positive, neutral or negative
Deprivation and income groups §§				
Age				
Gender				
Disability				
Ethnicity				
Regions or local areas				
Rural areas				
Other				

"This table is adapted from the UK Dept of Transport, Local Govt and the Regions Integrated Policy Appraisal tool (see bibliography for full reference) "Income groups may be identified by socioeconomic measures such as the NZDep index (a 10-point index of deprivation derived from Census data)



Impact assessment

This is the second phase of the appraisal stage. You have identified potential impacts on determinants of health, on Māori, and on inequalities using one of the two appraisal tools. The next task is to identify the extent, nature, measurability and risk of those potential impacts.

You are now asked to prioritise the identified impacts. It is advised that you select the most significant impacts and keep the list of impacts as small as possible. This makes the exercise more manageable.

GUIDANCE

For each anticipated effect on particular health determinants (both direct or indirect health impacts) or health inequalities consider the:

- likelihood of the impact occurring
- severity of impact and numbers of people affected
- likely timescale of achieving the predicted impact
- strength and type of evidence
- distribution of the impact across the population, considering in particular, the impact on Māori
- practical ways to improve positive impacts and minimise negative impacts, both within the proposal and external to the proposal.

Remember that positive as well as negative effects on health and wellbeing are being considered.

The resources and methods used for this work will include those that have already helped to identify the potential impacts. Nevertheless, additional information may be needed, and in a comprehensive assessment a literature review or other specific research may need to be undertaken or commissioned.

The following table, Table 6, may be used to plot the impacts and record the information about these predicted health impacts. It can be used to further analyse information gained from using either the Health Lens or the Health Appraisal Tool. Particularly in the latter case, the successive stages of appraisal may add shape and emphasis to impacts already identified. In some cases opposing positive or negative impacts may come to light arising from the same source.

The table begins by allowing a listing of all of the potential impacts that have been identified up to this point:

- Determinants of health that are affected, including direct impacts (such as noise and certain pollutants) and indirect impacts (such as social cohesion and income) from Table 4.
- Impact on Māori health from page 51.
- Health inequalities from Table 5.



Table 6 presents a simple grading system for the working group to rate its considered assessment. This work is, to an extent, a subjective process, as it aims to correlate diverse information and that is why it is important to make it a group exercise. As much evidence on the associated health effects as possible needs to be referenced, although it is acknowledged that assessment of measurability and risk of impact may be based on subjective perceptions.

In determining the extent and nature of the impacts, it may also be useful to assess the significance or severity of the impact and identify whether it is a precursor for other impacts. That is, will it result in or contribute to further positive or negative impacts?

As is the case for the appraisal tools, work on the Table 6 matrix may identify uncertainties or knowledge gaps that require further investigation.

When prioritising impacts, you need to question whether the issues that have been identified are those that are the most 'known' or discussed. It may be tempting to focus on impacts that are well known or on the public or government agenda, rather than more significant impacts in lesser-known areas. You may need to reflect on this and take steps to move outside your 'comfort zone'. Inevitably, it is much easier to focus on direct effects. It is harder to address indirect effects and changes over time that result from interactions between components.

The issue of change that occurs over time and space is a challenging issue for those involved in impact assessment. For example, methods used may overlook additive, synergistic, or neutralising effects. In other words, some thought needs to be given to longer term change which might occur, given the adoption of particular policies.



Table 6: Impact assessment matrix

	List of identified potential impacts (both direct and indirect) of proposed policy on health determinants, Māori health and health inequalities (identified in Table 4 and 5)		Likelihood of impact occurring (low, medium, high)	Severity or significance of potential impact (small/low, medium, high)*	Scope of potential impact (affects small or large number of people)*	Expected time to take effect (short term, medium term, long term)	Measurability of potential impact (qualitative,	Possible actions to enhance positive or diminish negative impacts
	Positive	Negative					calculable)	
Impact on Determinants (From Table 4)								
Impact on Māori (From page 51)								
Impact on Inequalities (From Table 5)								

*These two aspects are very important when seeking management or mitigation responses. For example, the common cold may have a mild effect across large sections of the population, whereas SARS will have a very severe effect across a smaller group. This distinction will have implications for the policy response.



REPORTING

Formal reporting is an important component of health impact assessment but it does not necessarily need to be exhaustive. A report is an important record of both the process and the outcome to feed back to participants, or contributors to the process, and to help those receiving recommendations to understand the context in which they arose. The report should be appropriate to its purpose. Good communication between the decision-makers and the assessors will ensure that an appropriately detailed report is produced.

The reporting stage focuses on identifying the practical changes that could be made to a proposal to minimise the harmful effects and maximise the beneficial effects on health. These can be presented by way of recommendations to the agency or management group introducing/ developing the policy. Recommendations for stakeholder agencies can also be made.

This stage will be contingent on the internal reporting procedures of the organisation. It is important to note that reporting will need to be done in different ways depending on which level of appraisal is done. In general, more detailed appraisal will require more detailed reporting.

As a minimum the report would include:

- · reporting on the HIA process and the people, organisations and resources that were involved
- · reporting on the methods used in the HIA
- · reporting on the partnership, protection and participation appraisal
- · reporting on the impacts
- making recommendations to maximise positive impacts and minimise negative impacts.

Often an HIA of a particular policy will identify opportunities or issues with related policies, including those managed by other agencies. Reports need to be sufficiently targeted for these other agencies to understand and respect the process and try to adopt the recommendations.

The report should be given to all participants, stakeholders and those who were consulted.

There should be a peer review process undertaken to ensure the report is robust and accurate.

It is advisable to set up a peer review group to review the report before it is finalised.

Making recommendations

The final part of appraisal is to draw conclusions and make recommendations for adjusting the policy proposal or policy alternatives. It may help to group the impacts in order of significance (ie, how important or severe) and scope (ie, how widespread) and comment on the expected time to take effect. This also helps to identify issues that affect a smaller or more vulnerable part of the community. Select other types of grouping if you wish.



There are four tiers of response:

- 1) **There is not enough information** need to seek further information, continue the appraisal and re-do the table.
- Modify policy proposal to enhance positive impacts opportunities to provide or extend health benefits are not fully realised.
- 3) **Modify policy proposal to address negative impacts** for instance, if an identifiable group within a population is negatively affected.
- 4) **No action required** because there is no feasible way of enhancing potential positive impacts on health (or avoiding negative impacts).

Use judgment to identify the most significant impacts and issues, and translate these into recommendations to the decision-making body (and to other stakeholder agencies if appropriate).

The ultimate result is an agreed set of recommendations for modifying the policy proposal/s so as to maximise health benefits or minimise adverse effects on health. The recommendations must be made within the context of complex social, political or material constraints. They will be influenced by the current context for proposal implementation and the constraints operating locally, such as the resources available and the relative priority given to health and health gain. There are likely to be regional factors to be taken into consideration. Negotiation among the decision-makers may be necessary if their views differ about the appropriate actions to take.

It is important to note the recommendations from an HIA will form just part of a bigger picture involving recommendations from other perspectives (for instance, economic analysis, consideration of impacts on gender or disability). The purpose of HIA is to predict the health consequences of each policy alternative so that the policy-makers can make the best trade-offs between health, wellbeing and other policy goals.

Occasionally it may be possible to define a single solution to achieve optimum health and wellbeing benefits of the proposed policy. However, in most cases a series of options will need to be formulated and presented. Formal option appraisal may need to be undertaken. Alternatively a less formal approach may be sufficient.

It is critical to formulate recommendations that will have both the most impact on the policy and the most chance of being implemented. This process is iterative so you may not achieve it all in one step. You may need to refer back to contributors to get agreement once the evidence is factored in.

It is important to bear in mind the 'baseline situation', for example, the consequences of a change in alcohol law would be different for a heavy drinking community, compared with a light drinking community.



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Guidance in making recommendations

The following are some general questions that could be asked to help with making recommendations:

- Who are the likely 'winners' in the policy proposal, how many of them are there, and how will they be affected?
- Who are the likely 'losers', how many of them are there, how serious is the loss, and how could they be compensated?
- What steps could policy-makers take to reduce or mitigate any negative impacts on health and wellbeing and on health inequalities from the policy proposal?
- What are some ways in which current policy or practice could be changed to enhance the positive impacts or to reduce inequalities between population groups?



Stage Four: Evaluation

STAGE FOUR: EVALUATION

Evaluation must be factored into the health impact assessment process and should not be too complex or unwieldy. It needs to be included as an organisational task and costed/ planned during the scoping stage. Setting clear objectives for the HIA in the scoping stage becomes critical for evaluation, as the evaluation will also look at whether the objectives of the HIA were met. It is important to feed results back in to the policy-making process, and to share the evaluation with others to demonstrate whether, how and why HIA works. Evaluation could be done by either the 'in-house' policy team doing the HIA, or by an external evaluator or peer reviewer.

Both process evaluation and impact evaluation should be used to assess the HIA. Process evaluation aims to assess how the HIA was done and provide information that will be useful in future HIAs. In comparison, impact evaluation analyses the extent to which the recommendations made by the HIA were taken on board in the final policy decision-making.

Outcome evaluation, where the impacts predicted by the HIA are evaluated, is more difficult to do in practice. It is challenging to evaluate whether health impacts will eventuate, as there are complex, multi-causal pathways involved and long timeframes required to track health impacts over time. It is possible to evaluate whether predicted health impacts from the HIA were accurate, but as this is a difficult process, it should only be undertaken by skilled practitioners/evaluators with adequate resources.

Evaluation can provide a valuable insight into how:

- · the process of HIA can be improved through reflection
- · various proposals can be modified to achieve health gain
- the accuracy of predictions made during appraisal can be assessed
- resources were used money, staff and stakeholders involved.

In addition, evaluation:

- is the basis for feedback to stakeholders and the community
- generates commitment to HIA institutional and stakeholders
- develops evaluation skills that can be applied in other settings.

Current best practice for policy agencies involves clear monitoring to identify if the outcomes sought by the policy are being achieved. Such monitoring programmes can be designed to include an evaluation of the public health outcomes and the assumptions and predictions that were introduced into the health impact assessment. Some suggested evaluation questions are shown on the next page.



Some questions to record and evaluate the HIA

GUIDANCE

Questions about the process of the HIA^{23,24}

Now you have completed the HIA, you will need to document how you went about it and the methods used so that your organisation can learn from your experience for future HIAs. Include details on time, place, and resources used (financial, staff time, consultants, etc) and participants. Record also what the policy proposal sought to achieve, what geographical area it covered and what population groups were affected.

Then answer the following questions:

- What evidence was used in the HIA, and how was it used to inform development of recommendations? Was the evidence in the literature on the consequences of similar proposals properly searched?
- How were the issues identified during scoping addressed?
- How were the potential health impacts on vulnerable groups explored and assessed?
- How were the health impacts of alternative policy options explored?
- · Were efforts to mitigate any negative effects concentrated on the largest impacts?
- Were the approaches used to ensure transparency in the HIA decision-making process effective or are there other ways you would recommend?
- Given the resources used, (financial, staff time etc) what were the associated opportunity costs?
- How and when were the recommendations delivered to the relevant policy-makers?
- What did those involved in the HIA think about the process used and what changes would they make if they were to do it again?
- Were the aims and objectives of the HIA met?

Questions about the impact of the HIA

- How was the HIA used in the policy development and advice process?
- Was the policy proposal changed as a result of conducting the health impact assessment?If so, what changed?
- Were the recommendations of the HIA accepted and implemented by policy-makers?
 If so, how and when, and if not, why not?
- What unintended consequences resulted from the HIA, for example: working in partnership, cross-sectoral collaboration, raising the profile of health needs and putting health 'on the agenda'?

