Brief report: Informed Consent for Multi Venue Problem Gambling Survey

The Question

The Ministry of Health has sought and received information from consumers' counsellors in the problem gambling treatment services ('treatment services') and other key stakeholders in order to evaluate and improve the delivery of this harm minimisation process.
There is a question whether written informed consent is required for the purposes of surveying key personnel in order to improve the deliverables of the current Multi-venue Exclusion Programme (MVE).

Anonymity and evaluation information

Clients engaging with services have their rights under the Privacy Act 1993 explained, and that anonymous information is required to be sent to the Ministry of Health and the Ministry is aware only of an allocated number with the personal information retained confidentially by the treatment service (see Intervention Service handbook). In the MVE evaluation, requests were therefore sent to the treatment services such that the counsellors would consider therapeutic issues around client participation, discuss the purpose of the evaluation information with the clients they considered to be appropriate to participate, providing the survey and assisting their client if necessary, in their response. Clients therefore had an expectation that anonymous information about treatment would be provided from time to time to the Ministry, and were provided with appropriate information, advice and assessment by their therapist in respect of participation in the evaluation.

Evaluation ethical requirements

Informed consent to research is a process rather than a single event, and may be verbal, written, or constructive. Where considerable risk of harm is involved, standards of full disclosure, comprehension, and voluntariness are required factors.[1] However, there is a range of research where risk may be low, and rather than apply the descriptor 'research' to all processes, it is arguable that especially where there is an evaluation of an existing model of health care, a common best practice approach, approval of an ethics committee for the process may not be required. If approval was required by an ethics committee to the survey, then a signed form of informed consent would usually be required.

NZ requirements

The requirements of NZ Health and Disability Ethics Committees are to

> 'provide protection for participants in research in the health and disability sector'[2]. It is 'primarily designed to: prevent studies that pose an unacceptable risk of harm to participants from going ahead (and) ensure that all participants in research are aware of what their participation will involve and have given informed consent'[3]

The Health & Disability Code (Right 7), speaks to 'services provided to a consumer', and where informed consent 'to a health care procedure' is required, it must be in writing if:

a) The consumer is to participate in any research; or
b) the procedure is experimental
c) the consumer will be under general anaesthetic; or
d) there is significant risk of adverse effects on the consumer

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[1] Foden & Beauchamp (1986)

[2] http://www.ethicscommittees.health.govt.nz/moh.nsf (Abacus underlining)

[3] Ibid

It is expected that in rolling out the survey, the person/organisation conducting the survey will ensure that any risk for participants is addressed. The information described above, is provided to inform whether ethics approval will be required and appears to refer to 'novel research', or a health 'procedure' where there is a considerable risk of harm to the consumer. However, it is in our view, inconclusive, in applying it to the proposed survey, which appears to be a review and evaluation of an existing health service, and therefore information has been reviewed from a range of relevant and compelling sources.

Published opinion

Evaluation of programmes provided in the health and disability sector or elsewhere is a common process and is in fact, best practice for the effective and efficient delivery of any such programmes. Journal publications note:

> 'Evaluation is important for determining the extent to which a policy has met or is meeting its objectives and that those intended to benefit have done so' and 'Methods of evaluation include both experimental and quasi-experimental, and indeed formative (process evaluation –i.e. how to improve services) and summative (outcome evaluation – i.e. whether the services achieve their goals) approaches'[4]

This is an important distinction to 'research' in that

> 'Put simply, a research proposal requires health service governance approval, *whereas service evaluation does not*.'[5]

Tertiary opinion

It is noted that the University College London in its UCL Research Ethics Committee advice states

> **'Service Evaluation** is undertaken to benefit those who use a particular service and is designed and conducted solely to define or judge current service. Your participants will normally be those who use the service or deliver it. It involves an intervention where there is no change to the standard service being delivered (e.g. no randomisation of service users into different groups). *This does not require ethical approval*'[6]

UK NHS requirements

The UK NHS National Research Ethics Service, looks to the intent of the project, and differentiates between research (where the primary aim is to derive generalisable new knowledge) and where the purpose is service evaluation or audit. It states that:

> 'Research is to find out what you should be doing; audit (and service evaluation) is to find out if you are doing planned activity and assess whether it is working. Some projects may have more than one intent, in which case a judgement will need to be made on the primary aim of the project'[7]

The NHS service further explains service evaluation, stating that service development and quality improvement may fall into this category, and that it

> 'usually involves analysis of existing data, but may include administration of interview or questionnaire', and there is 'no allocation of clients to the intervention: the health professional and patient have chosen intervention before service evaluation'[8]

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[4] Booth A (2009) Using evidence in practice. *Health Information and Libraries Journal*, 26: 255-258

[5] Ibid (Abacus italics)

[6] http://ethics.grad.ucl.ac.uk/exemptions.php

[7] NHS (2009) *Defining Research: NRES guidance to help you decide if your project requires review by a Research Ethics Committee.* London: National Research Ethics Service/National Patient Safety Agency.

[8] Ibid

The NHS service concludes that in these circumstances, the project does not require Research Ethics review. It further notes that there are several exemptions from the need to obtain ethics approval in health projects, including the aforementioned service evaluation, clinical audit, surveillance (to design strategies to manage outbreaks/educate the public around risk), and usual practice (in public health: help disease control).[9]

Conclusion

It is clear in our view, that the MVE project purpose and design has for its intent (or its primary aim) formative and summative evaluation of the MVE process, to identify what it achieves, address gaps, and to improve its effective delivery. The proposed survey will help facilitate this outcome.

For these reasons, Abacus firstly concludes that an ethics approval application is not required. If these more stringent requirements are not applicable, then it appears, for the reasons above, that alternatives to written consent are also appropriate.

In the process of working through the clients' therapists, these therapists are providing not only information, but safety processes. There is, as stated, a client expectation that the Ministry would receive information from time to time on therapeutic processes (Practitioner Handbook), and such an evaluation process would accord with best practice. It is therefore our opinion that, with the above-described safeguards in place, participation in the survey is evidence for constructive consent by the therapists' clients in the survey participation. We believe that the process also complies with the client safeguards required by the Health & Disabilities Act (the client code).

This survey informs the evaluation of an existing therapeutic service, with low risk for harm, and with appropriate strategies providing information clients can rely upon to understand the content, purpose, and consequences of participation.

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[9] Ibid