

"Opt out consent: the new frontier".

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research



advocacy



prevention



support



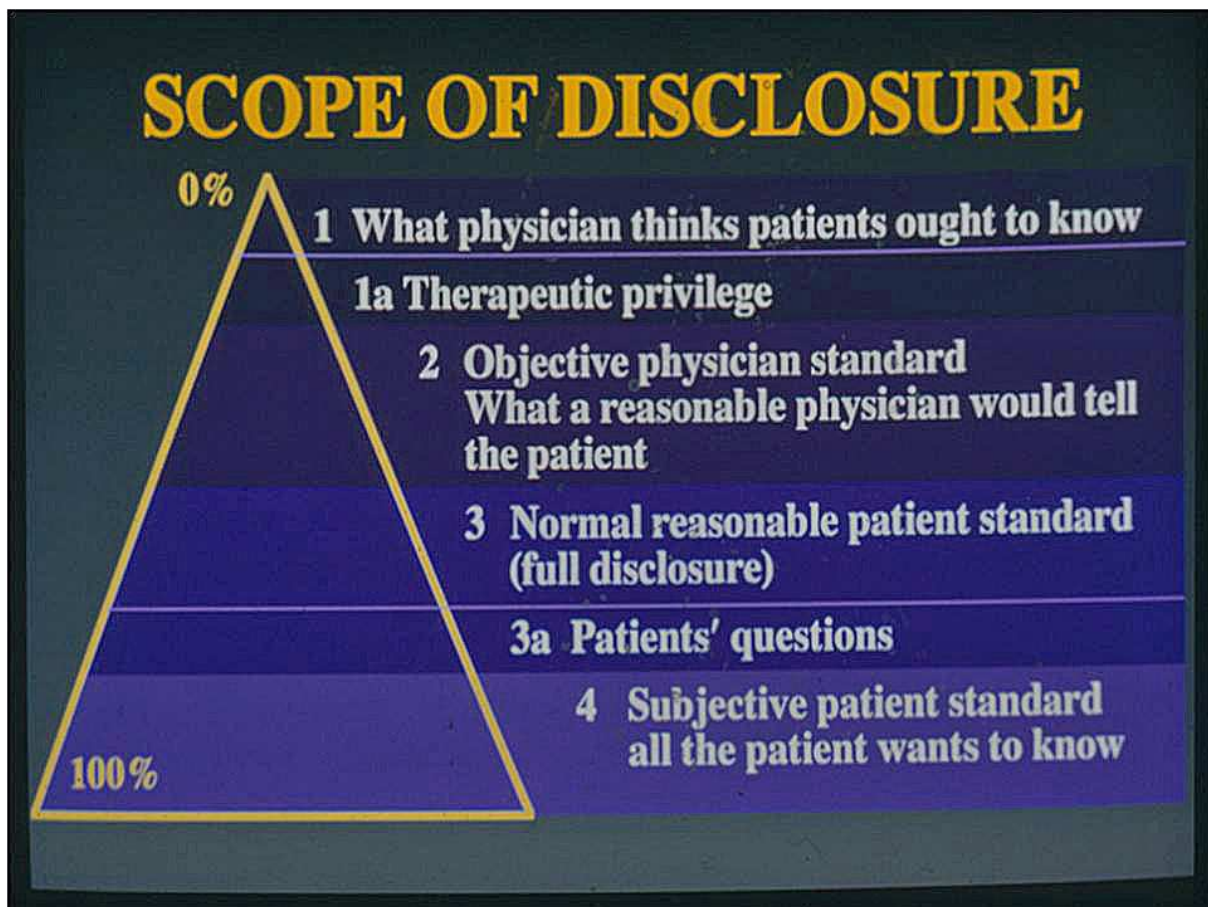
What do we mean by informed consent?

- **Institutional requirement to obtain legally valid consent before proceeding to a therapeutic intervention**
- **Autonomous authorization by the patient to an intervention**



Definition of Informed Consent

- **Can satisfy the institutional requirement without shared decision-making or true autonomous authorization
(Depends on information given)**
- **Can be autonomous authorization without satisfying the institutional requirement
(e.g. minors)**



Reasonable Person Standard

What is adequate information? (Rogers v Whittaker)

Information which would be expected to materially influence the decision of a reasonable patient

- Common side effects
- Serious side effects even if rare
- Response to specific questions



Informed Consent

- Adequate information
- Ongoing information
- Patient comprehension
- Voluntary
- Adequate documentation



When not to tell

- **Therapeutic privilege**
- **Emergency**
- **Incompetent to make the decision**
- **JW children and blood transfusion**



Framing

- **Half full, half empty distinction**
- **Information can be presented to influence a decision**
- **Language can be part of this e.g.**
 - Incision vs slash
 - % alive rather than % dead



Principles for Ethical Conduct of Research

Non-malificence – “do no harm”

Respect for persons

- **Informed consent**
- **Confidentiality**
- **No financial inducement to coerce patients**

Justice – share the knowledge



Autonomy

- **In most human research, potential participants are provided with detailed information so that they can make a fully informed choice about whether to participate in the project.**
- **The requirement for explicit consent reflects the value that our society places on individual autonomy.**



National statement on ethical conduct in human research 2007 (updated Dec 2013)

http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_131211.pdf

- **Qualified the need for explicit consent by allowing human research ethics committees (HRECs) to approve limited disclosure**
 - Low-risk research where no practical alternative exists and
 - Where the potential benefits of the research justify it
- **An example is research that involves observing people's behaviour, where disclosing the nature of the research may change the behaviour being studied**



Waiver of Consent

- **The other option offered to HRECs is waiving the requirement for obtaining explicit consent**
- **E.G. analysis of the data from population disease registries, which may contain 1000's of people**
 - The research must be low risk,
 - of significant benefit to the population
 - on a scale where it is impractical to obtain consent from such large numbers of people
- **Often the data are de-identified and the privacy of those whose data are used in a study is adequately protected.**



Opt-Out Consent

- The 2013 National Statement neither included nor specifically excluded opt-out consent
- Opt-out consent is when, following dissemination of information about a research project, consent is presumed unless an individual actively withdraws it
- Challenged as not consent but more allows more autonomy than waiver
- Opt-out consent may better balances autonomy with research, because it demands a stronger intention not to participate, as withdrawal requires action, whereas opting in inflates non-consent



Requirements for Opt-Out Consent

- Must ensure appropriate respect for potential participants
- Define the spectrum of activities for which participants could be recruited or their information accessed
- Protect individual privacy.



Must Communicate to Populations

- **Opt-out consent requires that information about the process be provided to populations e.g.**
- **Information collected in clinical registries may be communicated by a brochure**
- **A media announcement may inform about a research project to use the data**
- **A quality improvement program in a hospital may be notified to patients in their admissions packages**
- **Some jurisdictions e.g. South Australia, have a Code of Fair Information Practice, which gives guidance about providing such information**



Difference of Explicit Consent

- **Unlike explicit consent, there is no guarantee that each individual has read the information**
- **Even with explicit consent the adequacy of the information given is questioned since recall can be poor**
- **It is often participant anxiety about the underlying disease and treatment that prevents assimilation of information at the time it is provided**



Studies of consent forms

We performed 2 studies:

Olver IN, Turrell SJ, Olszewski NA, Willson KJ. Impact of an information and consent form on patients having chemotherapy. Med J Aust 1995, 162: 82-83

Olver IN, Buchanan L, Laidlaw C, Poulton G. The adequacy of consent forms for informing patients entering oncological clinical trials. Ann Oncol 1995, 6: 867-870



Study of Recall of Consent Form

- **One hundred consecutive patients undergoing routine chemotherapy were given a standardised consent form**
- **At their next visit for chemotherapy 3 or 4 weeks later they were tested for recall**



2: Assessment of 100 patients' recall of the information and consent form

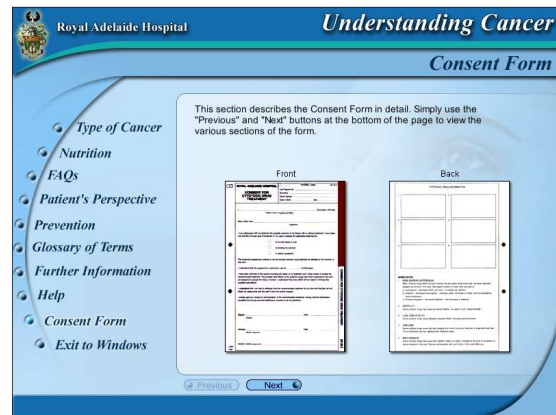
Know number of drugs	
Yes	37
No	62
Unspecified	1
Ability to name drugs	
All	20
≥ half	3
< half	1
None	75
Unspecified	1
Know length of treatment	
Yes	46
No	53
Unspecified	1
Know goal of treatment	
Yes	65
No	26
Unspecified	9
Recall of four side effects	
0	17
1	25
2	19
3	21
4	15
Unspecified	3

How much of the information had they read?

- 37 patients had read the whole form
- 9 had read part of it
- 22 skimmed it
- 10 did not read it
- 21 could not remember how much they had read
- 1 did not answer

A RANDOMIZED CONTROLLED TRIAL OF A WRITTEN FORM VERSUS AN INTERACTIVE MULTIMEDIA CD-ROM TO PROVIDE INFORMATION PRIOR TO CONSENT TO CHEMOTHERAPY

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- **This study determined whether recall of pre chemotherapy information can be improved using an interactive CD ROM compared to written informed consent and what impact psychological factors make on recall**
- **101 patients randomised were tested for immediate and delayed recall, thematic recall, short-term memory, concentration, IQ, anxiety, depression, coping styles)**
- **Recall of the consent form information was tested when they returned for the next cycle of chemotherapy**

- **There were no significant differences between the groups on these variables**
- **The written information group read more of the information than the multimedia group read the contents of the CD-ROM $p = .06$**
- **50% patients with written information looked at it after their consults**
- **38% patients given the CD-ROM didn't use it again**
- **28% CD-ROM patients reported they were not computer literate, but literacy did not impact on satisfaction with the CD ROM**

- **33% pts had borderline scores of anxiety**
- **25% pts had borderline scores of depression (HADS)**
- **The non-anxious group had lower IQ scores $p = .01$**
- **The non-depressed group had greater concentration $p = .05$**
- **Intention-to-treat analyses showed no significant differences in recall between written information and CD-ROM**
- **Although no individual predictors were significant, depression was the strongest predictor of inaccurate recall**
- **The CD-ROM did not decrease patient anxiety ($p = .96$) or depression ($p = .65$) during treatment, although anxiety did significantly decrease over treatment time**

What type of research suits opt-out?

- **Interrogating and linking large digital databases to inform clinical practice and answer research questions**
- **Opt-out consent could apply where research or the improvement of health care standards would be critically compromised without it**
- **Epidemiological studies where it is not practical to obtain explicit consent e.g. an investigating an occupational exposure may need access to health records collected some years previously where it may be difficult to trace ex-workers to obtain explicit consent.**



Examples of the Use of Opt-Out

- **Clinical quality registries that collect and analyse information from groups of patients with the aim of enhancing the quality of care**
- **Opt-out consent is currently used by three-quarters of the clinical registries in Australia which collect individually identifiable or reversibly anonymous information on individuals tracking across institutions and post discharge follow-up for outcomes**
- **The accuracy of the outcome depends on the completeness of the sample.**



Where accuracy requires a complete sample

- Research on explicit consent shows that it is generally associated with a recruitment rate of 30%–50%
- It is highly likely that with this level of recruitment, the participants will be unrepresentative of the whole population, and the data therefore will have little credibility for quality improvement, benchmarking or policymaking
- the Victorian State Trauma Registry, with > 15 000 people, uses opt-out consent and has a high recruitment with a less than 0.5% patient withdrawal rate



Comparisons

A randomised trial in Australia comparing opt-in with opt-out parental consent for childhood vaccine safety surveillance using data linkage is ongoing



The research benefits individuals

- **Registries benefit individuals by providing them with information about outcomes of their diseases and allowing them to benchmark outcomes with other jurisdictions.**
- **It is not just about benefit to the community or to researchers at the expense of some individuals autonomy**



Needing HREC Approval for Registries

- **The establishment of clinical registries not intended for research does not require the approval of an HREC**
- **However, the data may subsequently prove valuable for research and an opt-out approach may be sought**
- **It would therefore be prudent to apply for opt-out consent at the establishment of such data collections**
- **This aligns with the Australian Commission on Safety and Quality in Health Care principles for clinical quality registries**



Criteria for Opt-Out Consent

- Research should be low risk
- Result in substantial public benefit
- Require near to complete participation
- There must be a reasonable strategy to widely disseminate plain language information
- A mechanism for potential participants to obtain further information or to opt out.
- Strict procedures in place to ensure the privacy of an individual's information as stated under s 95A of the *Privacy Act 1988*, both during the study and in subsequent reporting of results



A survey of Patient's Attitudes Towards the Use of Their Health Data

Beeke CF, Olver IN, McLaughlin KJ. *J Registry Manage* 2007, 34: 119-122

- 911 consecutive patients attending Med Onc at RAH completed structured questionnaires
- Agreed that Govt had a duty to collect data
- Most agreed that de-identified and confidential their data could be used
- Just over half wanted to give permission for use of their de-identified data, 40% were undecided
- Just under half responded that their identified data usage depended on their consent and on third did not
- Trusted use by researchers



Summary

- **Explicit consent remains the most desirable method of obtaining consent**
- **The option for opt-out consent would provide ethical review bodies with an additional tool to apply to types of low-risk research that result in important benefits to the community, but only if near to complete participation is achieved**
- **Ethical review bodies would be responsible for interpreting the general guidance provided by the National Statement and applying it to specific research proposals.**



Combine with Other Consent

Situations will arise where it is possible to combine waiver and opt-out consent — for example, a research study wanting to use information from a tissue bank or registry may apply opt-out consent to those still contactable and a waiver for the others.



Including Opt-Out Consent in the National Statement

- **The *National Statement on Ethical Conduct in Human Research, 2007* (the National Statement) has been updated to provide guidance for the use of the opt-out approach**
- **This guidance was tabled in Parliament on 27 March 2014.**



Quality Assurance Activities

- **As the National Statement only applies to research, it was determined that the best way to present guidance for an opt-out approach in both research and non-research contexts, was to develop guidance for research in the National Statement, Chapter 2.3 and guidance for quality assurance activities in a separate document: *Ethical Considerations in Quality Assurance and Evaluation Activities*.**

