NIA IMPACT COLLABORATORY
TRANSFORMING DEMENTIA CARE

Grand Rounds

The Ethical Value of Notification Without Consent



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Housekeeping

- All participants will be muted upon entry
- Enter **all questions** in the Zoom **Q&A/chat box** and send to Everyone
- Moderator will review questions from chat box and ask them at the end
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Don’t Ask, Do Tell

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Conflicts

I have no conflicts of interest with respect to the present presentation.

Informed Consent

Informing individuals about research is frequently understood as having one goal:

Describe the study in question so they can decide whether to participate.

Purpose of Informing

This suggests the value of informing individuals about a study is limited to helping them to decide whether to participate.

If that is right: no reason to inform participants when research consent is waived.

Example

Taking Your 10 Year-old to the Hospital

Lesson

Informing individuals about an activity can promote goals independent of their deciding whether to participate in the activity.

Challenge: Identify what other goals might be promoted by informing individuals in the context of research.

Implementation

When research is conducted under a waiver of consent: consider whether these other goals apply.

If so: what information should be disclosed to promote the other goals?

[Also relevant when obtaining research consent!]

Benefit #1

Respondents who regarded pragmatic trials as valuable and did not think they pose additional risks still want to be informed.

https://pmc.ncbi.nlm.nih.gov/articles/PMC5573142/

Respondents prefer to be asked to participate in observational research on usual practice, but accept less elaborate approaches to consent.

https://pubmed.ncbi.nlm.nih.gov/25868119/

Benefit #1

Promotes Respect:

Many individuals want to know they are in research

Disclosure helps to respect this preference

Benefit #2

Promotes Participant Understanding:

What is happening
The nature of one's relationships
The goals to which one is contributing

Benefit #3

Facilitates Expressing Any Concerns

TiME Trial

Pragmatic trial of hemodialysis session duration: enrolled 7035 patients at 266 sites in 38 states.

Discontinued due to inadequate uptake of the study intervention (increased duration).

“Developing strategies for effective engagement of clinicians and patients is a critical component of research embedded in routine clinical care delivery.”

Benefit #4

Promotes Participant Engagement

Benefit #5

At least half of respondents said that no prior notification decreased their trust.

General notification was associated with greater distrust than other more active forms of notification and authorization.

https://pmc.ncbi.nlm.nih.gov/articles/PMC5640464/

Benefit #5

Maintain Trust

Consult

Team identifies a clinically relevant finding in a sample that was obtained in a study for which consent was waived.

Contact individual to determine whether they want to receive the finding?

Benefit #6

Facilitate Return of Secondary Findings

Benefit #7

Keep the IRB on Your Side

Application

The presence and importance of these goals varies across studies.

Promoting understanding and engagement when:

Research on left-over samples
vs
Longitudinal study of nurses monitoring patients

Alterations

We argue that empirical data bolster normative arguments that alterations of consent should be the default in pragmatic research; waivers are appropriate only when the pragmatic research would otherwise be impracticable and has sufficiently high social value

https://pubmed.ncbi.nlm.nih.gov/33840104/

Alterations

Rather than considering standard written consent or waivers, researchers and research ethics committees could consider alternative consent approaches that may facilitate the conduct of pragmatic trials while preserving patient autonomy and the public's trust in research.

https://pubmed.ncbi.nlm.nih.gov/34782417/

Alter Rather than Waive

Potential to promote these other goals suggests disclosure should be the default for trials that waive research consent.

But: the content and process should be tailored to the individual study.

Brief

Patients in this study wanted to be told about research and have a choice, but were very open to such disclosures being streamlined.

https://www.tandfonline.com/doi/pdf/10.1080/23294515.2016.1156188

Opt-Out

Patients tended to believe that being informed about research was more important than the actual mechanism of consent, and most were content with being able to opt out from participating.

https://pubmed.ncbi.nlm.nih.gov/27833931/

No Signature

Respondents generally supported prospective involvement in enrollment decisions in the setting of acute myocardial infarction and were particularly supportive of brief verbal consent.

https://pmc.ncbi.nlm.nih.gov/articles/PMC6218277/

Possible Approaches

Posted notices: respect? understand? trust?

Notices to patients: respect; understand? trust?

Information sheet to participants: respect; understand?; trust; express concerns

Discussion with participants: respect; understand; trust; express concerns; engage

Brief Disclosure

It’s research

Goal/value of study

(No) extra burdens or risks

Questions?

Solicit cooperation

Potential Costs

Takes some time and effort.

Participants who are informed may object.

They may withdraw.

Future Research

We need research to assess whether different disclosure methods result in participant understanding or confusion.

We also need to assess whether disclosure leads to more or fewer individuals leaving/withdrawing.

Summary

When consent is waived, there can be value in providing information to participants.

What and how to disclose should be tailored to the individual study.

Typically, it can be very brief.

Future research should assess the potential costs of disclosure, and ways to minimize them.



Questions?

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