Protecting and promoting the interests of patients and the public in health research

The ShED: learning from each other's review to address the quality and consistency of our debate:
a programme in the UK

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What is the Shared Ethical Debate (ShED)?

A process of ethical review of a single application, previously approved, undertaken by a number of RECs with the following purposes

- *reviewing consistency in decision making*

- *considering and analysing issues raised at meetings,*

- *encouraging ethical debate across committees.*

- *looking for trends in decision making*

- *relating decisions made and issues raised to guidance and published evidence.*

RECs are asked to record the decision and the broad reason for that decision, and any ethical concerns and comments and requests for additional information/clarification under defined headings.

Response forms are collected into a report and key ethical themes identified for discussion at a workshop and fed back to RECs

ShED 9

Sharptalk

A6–1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. This summary will be published on the website of the National Research Ethics Service following the ethical review.*

Self–harm is a serious and growing health problem among young people in the UK. Young people who engage in self–harm do not readily consult health professionals and appear to rely heavily on the peer–to–peer advice and support that is available through online discussion groups and bulletin boards. While well moderated self–harm sites are mainly supportive, there are concerns about the safety of the health advice that young people give each other online.

This study will explore the potential for NHS professionals to work in and with online communities and to collaborate with young people in the production of health information that is safe but is also relevant to and trusted by the young people themselves. We will recruit young people aged 16–25 who engage in self–harm, healthcare students and recently qualified health professionals to participate in exploratory online discussion groups. Participants will be allocated to one of three separate groups of approximately 24 participants, made up of 'lay' young people, healthcare students and recently qualified health professionals in different proportions. Each group each be given the same set of discussion topics relating to self–harm. Transcripts of their online discussions will be analysed using Computer–Mediated Discourse Analysis to explore online behaviour and the content and style of verbal (written) interaction. By examining differences between the groups we will assess the acceptability and impact of student and professional involvement in online health discussions.

The project could bring about a significant change in the way in which the NHS manages the production and delivery of online health information, representing a shift from sole reliance on a top–down model, in which evidence is synthesised by teams of experts and delivered via glossy portals, to a more collaborative model that overcomes the patient/professional and provider/consumer divide. It may also provide a model for proactive health promotion in hard–to–reach groups. We anticipate that the findings will be applicable to many other health conditions and to the NHS more widely.

Summary I

36 RECs contributed and to them – thanks.

The standard of minutes was excellent in general with some examples of particularly well laid out descriptions of REC discussion and concerns. In some cases articles for reference were included.

In our analysis we couldn't identify comments that seemed inappropriate, outside RECs' remit or in contravention of guidance

Summary II

A complicated study to review as it combined "research on the net" with a clearly vulnerable yet inaccessible subjects

Vigorous debate took place and several RECs took a vote.

Dissenting voices registered

Summary III

Benefit, harm and science dominated REC comments

Difficulties of internet research were identified and often accepted

Divergent views between RECs

Summary IV

Some RECs felt a lack of expertise

Training needed – a role for the Health Research Authority and National Research Ethics Service

Criticisms of ShED

REC opinion (for this and other ShEDs)

	ShED9 (this one!)	ShED8	ShED7	ShED6	ShED5
Favourable	7	1	2	1	0
Provisional	18	14	15	7	2
No opinion	4	3	4	1	0
Unfavourable	7	3	3	8	18

REC comments: "top ten domains"

1. The research purpose
2. Risk and harm
3. Risk, harm and the difficulty of intervention
4. Study methods
5. Confidentiality and anonymity
6. Participant Information
7. Suitability of research team
8. Verification of participants
9. Support for researchers
10. Standard of the application

An analysis of the 7 RECs that delivered an unfavourable opinion

The possibility of harm (risk/benefit matrix) topped concerns of these committees (5/7 RECs), along with the fact that these were perceived to be vulnerable subjects. Three RECs criticized the research purpose and whether the chosen method could answer the question posed. Two criticized the application, one commented there were other ways to address this problem, one felt deception was involved, one was concerned about confidentiality and anonymity on the web and one was concerned that the researchers had no indemnity to cover any response they might make.

However such criticisms were also made by some RECs that approved the study

Domain	Number of comments (n=528)	Number of RECs (n=36)	Difference of views evident	Comment
The research purpose	**52**	**26**	**Y**	A major domain and it's clear that science does concern RECs. (22 positive comments, 15 negative comments) "excellent study" / "Brave approach" "unfavourable opinion for following reasons : social or scientific value" /"unclear what actual research question is"

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Domain	Number of comments (n=528)	Number of RECs (n=36)	Difference of views evident	Comment
Risk and harm	**43**	**25**	**Y**	Eight RECs accepted the possible risks inherent in this area and made positive comments about the study, however six made negative comments, one recording "...not satisfied that the applicant has suitably identified the risks and benefits"

Domain	Number of comments (n=528)	Number of RECs (n=36)	Difference of views evident	Comment
Risk, harm and the difficulty of intervening	**37**	**28**	**Y**	Seven RECs (8 comments) made positive comments either recognizing the limitations of possible help or commending the researchers for their provision of support, resources and contacts. Fourteen expressed concerns about arrangements or made a criticism. 4 RECs made negative comments.

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Domain –	Number of comments (n=528)	Number of RECs (n=36)	Difference of views evident	Comment
Study methods	**35**	**24**	**Y**	Diversity of views evident. One said:- "Committee thought that this study is an excellent model for future similar studies" but another "thought this was a potentially dangerous study which was not designed properly"

Domain	Number of comments (n=528)	Number of RECs (n=36)	Difference of views evident	Comment
Suitability of the research team	**25**		**N**	Four RECs were positive about the expertise of the team but 4 felt unable to assess this with the information they had.

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Domain	Number of comments (n=534)	Number of RECs (n=36)	Difference of views evident	Comment
Standard of the application	21	18	Y	Divergent opinion evident "Committee would like to congratulate the researchers on a well written application" "application is confusing and difficult to understand"

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Conclusions and discussion

Is this a meaningful process?

Is the variation in opinion expected and acceptable?

How can we best exploit our findings from this ShED?

Is it worth the effort?

Is there value in a "ShED lite"?