

Balancing roles and responsibilities

a qualitative study on experiences and perspectives of members of a Dutch Medical Research Ethics Committee

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Introduction

- The first responsibility of MREC's is the protection of the human subject
- Apart from protecting human subjects, MREC's have other responsibilities as well, eg relating to the progress of medical science
- Different responsibilities can bring along moral tensions^{1,2}
- Insight is needed in the different roles and responsibilities of MREC members



Aim and research question

- To gain in-depth insight into the perspectives of MREC members on their individual roles and responsibilities and on possible moral tensions within and between these roles
- *What is the perspective of MREC members on their roles and responsibilities? Which tensions are experienced in and between these roles and how are these dealt with?*



Methods

- Members of a Dutch MREC, attached to a large University Medical Center recruited with help of the Executive board of the MREC
- 12 members selected, taking into account variety in professional background
- Semi-structured interviews using topic list
- Saturation reached after 10 interviews, last two interviews did not yield new results



Methods

- Focus group with all MREC members in order to get feedback on preliminary results and further in-depth insight
- Data analysis hand in hand with data collection^{3,4}
- Data coded, categorized and clustered by two researchers, independent from one another



Ethical considerations

- Protocol was submitted to MREC which officially declared that the study is outside the scope of the Dutch law on medical scientific research in human subjects.



Results

Five roles were identified:

1. Protector
2. Facilitator
3. Educator
4. Advisor
5. Assessor



Protector

- The central responsibility of the MREC is to protect the rights, security and well-being of subjects who participate in medical scientific research.

Two tasks:

- assess and minimize risks and burdens for the subjects.
- Ensure valid informed consent



Protector

- *"You often imagine what is actually done to the subject. And what impact this can have."*
- *"But there is often discomfort in me. ... Is our interpretation of the informed consent equal to the informed consent as it is experienced by this potential patient group?"*



Tensions regarding the protector role

- Tensions were perceived between protecting subjects on the one hand and giving them room to choose to participate on the other (paternalism vs autonomy).
- *"... Can you still do that to someone in the final phase of life? (...)The discussion about this quickly ends and goes like: 'yes, but people can decide for themselves'."*



Facilitator

- Creating room for researchers and thinking along with them in creative ways.
- *"You want to help science progress, don't you? (...) Not take the position of 'nothing goes'. (...) after all, we are an academic clinic ."*



Tensions between facilitator and protector

- If the risk-benefit ratio is considered unfavorable for the subject, researchers are instructed to amend the protocol
- *"In this way it does not work, but try to solve it in a different way because as ... you are going to do it now, it can turn out bad for the subjects."*



Educator

- Making researchers aware of the risks and burdens for the subjects
- Helping researchers improve the quality of their protocol
- Researchers are encouraged to contact individual MREC members and vice versa



Tensions between educator and facilitator

- Researchers may not be interested in education but want their study to move on.
- *"So there are researchers with whom you occasionally have a bit of an annoying conversation. (...) And then I always try to explain, well, that if the protocol is not methodologically sound ... yes then the burden for the patients is not ethical anymore."*



Advisor

- Bringing in knowledge and expertise of individual members during the evaluation process.
- Based on individual expertise, the protocol is assessed on completeness and accuracy.



Tensions within this role

- Specialist expertise may lead to the experience that one's own role is limited.
- *"Yes, my role is very limited in the sense that when (...) things come up in my area, that I am then supposed to talk about it."*



Assessor

- Judgement formation as consensus building
- Members depend on one another:
- *"Everyone is there with his own field of expertise. One cannot judge such a study on one's own, that is just a combination of all ideas. And there you need one another."*



Tensions within the role of assessor

- Respondents observe that discussions focus on technical aspects, instead of the ethical aspects
- *"I think the statistical considerations and also the medical considerations are discussed very well ... But sometimes I miss the ethical discussion. (...) The discussion just runs very fast. I think, yes, I would need more ethical discussion about things."*



Tensions within the role of assessor

- Assessment of protocols remains implicit:
- *"And that very explicit weighing of benefit versus burden either happens implicitly and is therefore invisible, or does not happen at all. My opinion on this field of tension is that we should make consensus formation more explicit and thereby increase quality."*



Discussion

- MREC members experience various roles and responsibilities that may cause moral tensions within and between roles
- MREC members not only aim to approve or disapprove but also to improve studies⁵
- MREC work is guided by different values that may come into conflict with one another
- Making explicit moral tensions between values can foster MREC work



Recommendations

- MREC's should be aware of various roles and responsibilities
- Making explicit moral tensions between conflicting values may contribute to the review process
- Well developed tools such as moral case deliberation may be useful for fostering reflection on roles and responsibilities and thus improving MREC's work^{6,7}



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Further information

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