

Gatekeeping in pediatric clinical research: An undesirable practice

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Gatekeeping by professionals in recruitment of pediatric research participants: Indeed an undesirable practice.

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ABSTRACT

Professionals should not be reluctant to ask young people to participate in clinical trials; overly doing so is known in the literature as gatekeeping (not approaching all eligible research participants).

Our research into participation in pediatric clinical trials identified reasons why professionals engage in gatekeeping; these are e.g. protection of child and prejudice beliefs about the choice the child will make.

Although gatekeeping might be understandable, we argue it is not desirable because of the negative implications this practice entails (e.g. denies children a choice, might introduce inclusion bias and introduces unfair distribution of risk and benefit).

We call upon pediatric health care and research professionals to be aware of the many negative implications of their reluctance and in principle to refrain from the problematic practice of gatekeeping.

PREAMBLE

The article, on which this chapter was based, was an open peer commentary on a target article by Luchtenberg and colleagues in *The American Journal of Bioethics*.¹ Although this chapter is a commentary it can be read and understood without reading that specific target article.

Luchtenberg and colleagues interviewed 25 young people aged 10 to 23 years of age who were invited to take part in clinical trials. They had a similar goal as we had for our interview study: to understand the experiences and motivations of people participating in pediatric clinical research. There is a difference also: we mainly interviewed parents, whereas they interviewed adolescents. They found that personal benefit and helping others were the main motivators for the adolescents, and that these factors were more complicated than they expected. Similar to our results, discussed in chapter 5, they also found the altruistic motives of participants to be reciprocity-based.

Another important similar finding they showed was the fact that the interviewed adolescents wanted to be asked to participate in clinical research and they concluded their article with the statement that research professionals should not be reluctant to ask young people to participate in clinical trials. We agree with that statement. In this commentary, we elucidate our views about gatekeeping by professionals in pediatric clinical research.

INTRODUCTION

Luchtenberg and colleagues bring their interesting article to a close with the concluding statement that professionals should not be reluctant to ask young people to participate in clinical trials. They substantiated this recommendation with results from their interview study with young people about their experiences with and motivations for participation in clinical trials. The young people they interviewed welcomed the opportunity to contribute to medical research and wanted to learn from it. Unfortunately though, the interviewed young people also mentioned that they had wanted to take part in clinical trials before, but had not always been offered a chance to contribute.¹

We recognize this reluctance of professionals to ask children, and consequently their parents, to participate in clinical trials. Being overly reluctant is a practice known as gatekeeping. Definitions of gatekeeping in a research context differ in the literature. For instance, Hudson and colleagues define gatekeeping as the process by which people's

capacity to be invited into a research project, or to make an informed decision regarding research participation, is inhibited by others.² The definition of Sharkey and colleagues focuses on the health care professional who prevents the researchers access to eligible patients for research recruitment.³ These definitions have in common that eligible subjects are not approached to participate in research. Therefore, we define gatekeeping by professionals in a research context as follows: having implicit in- and exclusion criteria that lead to not approaching all *eligible research participants*. This gatekeeping by individual professionals adds a third layer to the assessment of acceptability of pediatric research (the protective measures in legislation concerning research with children being the first layer and evaluation of the protocol by a research ethics committee (REC) the second).

During our own empirical research concerning participation of minors (and their parents) in clinical research this practice of gatekeeping kept cropping up. We have encountered it ourselves: we were dependent on other professionals to approach their patients (children and their parents) for participation in our interview study, and noticed eligible children and their parents were selectively approached. The issue also rose in discussions, focus groups and personal talks we had with other researchers, physicians and (research) nurses about participation of children in clinical research.

In this commentary we want to share some of the reasons these professionals mentioned to justify their gatekeeping behavior. These reasons show why gatekeeping can be an understandable practice. Moreover, we want to point out that there are negative implications and argue that, however understandable, it is not a desirable practice.

REASONS FOR GATEKEEPING

So, why are professionals reluctant to approach children and their parents for participation in clinical trials? In all probability the core of their justification lies in the fact that children are a vulnerable population susceptible to harm and exploitation in research and need to be protected. For this reason precisely, ethical and legal documents concerning research with humans, such as the Declaration of Helsinki, set specific protective measures for children in research.⁴ However individual professionals might feel they need to be more protective than the legislation and/or REC prescribe.

The explicit intention to protect the child from burden and risk associated with trial participation is a reason we were frequently given by professionals for not approaching eligible children (and their parents). This reluctance to burden patients can result in not

approaching the sickest children, and lead to inclusion of a non-representative study population.

Furthermore, sometimes professionals think the informed consent procedure itself is too burdensome for certain eligible children and their parents. They decide not to approach children and their parents to protect them from the burden of being asked.

A third reason we encountered is that professionals sometimes refrain from approaching certain eligible children and their parents in order to protect the researcher. For example: a clinician does not approach an eligible child that has shown non-compliance with a prescribed drug before, in order to protect the researcher from the possibility of drop-out.

Prejudiced beliefs of professionals about the choice children and their parents will make regarding trial participation can be considered yet another reason for gatekeeping behavior. This may happen, for example, if in the past parents did not consent to participation of their child in a similar study, and the research nurse therefore assumes they do not want to participate in this new study and refrains from approaching them.

It can also be the case that the health care professional responsible for recruitment (e.g. the treating physician) does not support the rationale or methods of the study and therefore decides not to approach his/her patients eligible for the study.

Finally, practical concerns can influence reluctance of professionals to approach eligible research subjects. Especially when the professionals responsible for recruitment are not involved in the research project themselves (e.g. lack of time or resources to approach eligible children).

NEGATIVE IMPLICATIONS OF GATEKEEPING

Although gatekeeping is understandable in pediatric research, it is not desirable because of the negative implications this practice entails. Luchtenberg and colleagues already addressed an important one: it denies children the opportunity to contribute to medical research.¹ However, gatekeeping has many more negative implications.

First of all, gatekeeping by professionals involved in pediatric research denies parents (and children who have the capacity to co-consent or assent) a choice. Thereby, gatekeeping in recruitment for research violates the principle of respect for persons.³

In pediatric clinical trials, respect for persons is operationalized by the informed proxy consent of parents for the participation of their child and when possible the co-consent or assent of the child itself.⁴ In general children's right to express their views is arranged in the United Nations Convention on the Rights of the Child.⁵ It is therefore problematic that the young people interviewed in the target article stated they had not been offered the chance to participate. Essentially, with gatekeeping, it is the professional who makes the choice (one of non-participation), not the child and his/her parents, which is a paternalistic practice.

Second, by not approaching eligible children and their parents with an offer for participation in the trial, professionals could deny children a possible beneficial treatment. This argument is not applicable to so called non-therapeutic research (e.g. observational studies and phase 1-drug trials). However professionals need to be aware that there are studies from which children may directly benefit (e.g. randomization in intervention arm of phase III drug trial); and by withholding the opportunity to participate from children and their parents, they might withhold a beneficial intervention.

Third, gatekeeping practices of professionals decrease inclusion rates in trials. This can become problematic when this decrease means that the needed sample size is not achieved. This endangers the scientific and social value of the study. A large international review study showed that one third of randomized controlled trials in the Pediatric Intensive Care Unit (PICU) is terminated before the needed sample size is achieved, often due to recruitment problems.⁶ We suggested in a previous article that these recruitment problems in the PICU could be caused by gatekeeping of professionals.⁷

Fourth, gatekeeping does not only *decrease* inclusion, it can also cause *selective* inclusion. The selective approaching of eligible children introduces bias. This selective approach can create a non-representative study population, which endangers the generalizability of the results. A recent study by Crocker et al. showed that this threat is not hypothetical at all. They found evidence of gatekeeping behavior (they call it selective invitation practices) that can bias research findings in pediatric palliative care research.⁸ The effects of gatekeeping bias on the representativeness of the study population are more difficult to assess than other biases. For instance: non-response bias can be assessed by comparing responders with non-responders. But with bias due to gatekeeping this is generally not possible as the eligible patients who are not approached, are not known.

Finally, gatekeeping by professionals involved in research could create an unfair distribution of burden, risk and benefit among children and thereby violates the principle of justice.³

GATEKEEPING IS AN UNDESIRABLE PRACTICE

Although gatekeeping might be understandable in the context of pediatric clinical research, there are also negative implications. Gatekeeping should therefore be avoided. Luchtenberg and colleagues already concluded their target article with the statement that professionals should not be reluctant in approaching young people for participation in research.¹ They base their recommendation on their finding that children welcome the opportunity to contribute to medical research.

We presented some additional arguments to support their recommendation. To control gatekeeping practices in pediatric clinical research, it is of crucial importance that professionals involved in the recruitment process are aware of their behavior and the negative implications of their gatekeeping.

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