RESEARCH ETHICS

Children, Gillick competency and consent for involvement in research

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This paper looks at the issue of consent from children and whether the test of Gillick competency, applied in medical and healthcare practice, ought to extend to participation in research. It is argued that the relatively broad usage of the test of Gillick competency in the medical context should not be considered applicable for use in research. The question of who would and could determine Gillick competency in research raises further concerns relating to the training of the researcher to make such a decision as well as to the obvious issue of the researcher's personal interest in the project and possibility of benefiting from the outcome. These could affect the judgment of Gillick competency if the researcher is charged with making this decision. The above notwithstanding, there are two exceptional research situations in which Gillick competency might be legitimately applied: (1) when the research is likely to generate significant advantages for the participants while exposing them to relatively minor risks, and (2) when it is likely to generate great societal benefit, pose minimal risks for the participants and yet raise parental objection. In both cases, to ensure that autonomy is genuinely respected and to protect against personal interest, Gillick competency should be assessed by an individual who has no interest or involvement in the research.

In clinical practice in the UK, patients over the age of 16 years are treated as autonomous adults. They are permitted to give their consent to or to refuse treatment without parental involvement. The case of patients under the age of 16 is not as clear. In general, such patients are not deemed to be autonomous adults. Hence, any decisions requiring consent are made by parents or guardians. However, some recognition has been given to those under 16 years of age who may be mature enough to make competent decisions for themselves.

The case of *Gillick v West Norfolk & Wisbech Area Health Authority and Department of Health & Social Security* (1985)[1] led to the law introducing the concept of the Gillick competent child as one who is under 16 and is deemed mature enough to understand the nature and implications of a clinical treatment or procedure. A Gillick competent child can give consent to medical procedures as an autonomous adult. The subjectivity of the concept arises because the law leaves the decision about whether a child is Gillick competent to the individual practitioner.

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While guidelines are available for dealing with children in terms of healthcare decisions, there are no objective guidelines to assist with decision-making. Once it is decided that a child is Gillick competent, the practitioner is expected to respect the autonomy of the child as for any adult patient. Difficulties are further compounded in cases of teenage pregnancy, where fear of parental reaction may be a major determinant in a young girl's seeking termination. The volatility of such a decision was seen in the UK when a 14-year-old sought help from a school health worker to have an abortion but, after her mother's outrage at not having been consulted, became pregnant again to avoid maternal displeasure.[2] It would appear to be questionable whether this child was mature enough to decide about an abortion.

There is always a risk associated with deciding whether a child is Gillick competent, and this is particularly concerning when dealing with refusal of a treatment. In such instances, however, the medical or healthcare practitioner has recourse to the law, and often the court will decide whether the decision to refuse should be respected. Regarding children less than 16 years old, the lack of clarity regarding their consent as patients is minimal compared with the absence of any substantive guidance for validity of their consent for scientific research.[3]

GILLICK COMPETENCY IN RESEARCH

The application of Gillick competency to research requires consideration of whether the minor is capable of understanding the nature of the research, the rights of the child as a subject, and the risks and benefits of participating in the research.

Given that an alarming proportion of adults do not comprehend basic aspects of medical treatment to which they have agreed, do not comprehend the information sheets describing studies to which they have consented, or have even not read the consent form before signing it, the situation with children needs to be even more closely monitored.[4–7] That certain adult participants do not understand what they are consenting to does not necessarily mean that the capacity of children to understand should be underestimated. There will always be children who possess greater intellect and understanding than some adults. It is merely worth remembering that just because individuals appear to understand does not always mean that they do understand. This is particularly pertinent to children. Difficulties can also arise when simplifying the explanation for children,

because this may result in the presentation of inaccurate or incomplete information.

The other major concern when deciding about the competency of a subject under the age of 16 years is the question of who is sufficiently qualified and impartial to make the decision. This is of over-riding importance. In clinical practice, the clinician trained to administer the treatment and deal with adverse consequences is treated by the law as able to decide on the maturity and competency of the child.[1] The expertise and training of the researcher, however, does not necessarily provide for development of skills for dealing with the consequences of the procedure, nor for assessing the competency of a subject aged under the age of 16 years. Deciding on the partiality or otherwise of the researcher can be even more difficult. In clinical practice, the doctor applies the ethical principles of beneficence or non-maleficence when deciding whether a treatment or procedure should be applied. In research, these ethical principles may be indirect objectives, but even with the best will, the quest for results may mar or distort the ethical viewpoint, rendering impartiality at best questionable. Whether Gillick competency to consent to medical treatment should similarly be applied when obtaining consent from minors to participate in a research study is therefore worthy of question.[8] We argue here that Gillick competency can be applicable to research, but only under certain conditions.

RESPECT FOR THE PERSON AND THEIR AUTONOMY VERSUS NON-MALEFICENCE

While bioethical literature has included among its major principles that of respect for autonomy,[9] Ross argues that this has replaced the earlier principle, established in the Belmont report, of respect for the person.[10] This latter principle incorporates respect for the autonomy of those who can make their own choices, but also includes an obligation to protect those who are not sufficiently autonomous to make such choices.[10] Omitting the aspect of protecting those who lack autonomy means that decisions are not always taken in the best interests of such individuals.[10] Ross's argument is applicable if the best interests of those who lack autonomy are indeed being neglected. Fortunately, in the UK, the courts typically rule that doctors and other healthcare professionals who make decisions for patients are obliged to act in the best interests of the patients.

The primary moral argument for the application of Gillick competency in the arena of research is that this would better respect children under 16 who would be able to consent on their own behalf and who wish to participate.[11] The primary argument against the application of Gillick competency in the case of research is that it might expose children to harm, by being inappropriately applied.

In essence, then, this is a conflict between the principle of respect for the person and the person's autonomy and the principle of non-maleficence. This conflict occurs in several other areas where society considers children capable of making certain potentially harmful decisions by virtue of attaining a certain age. These include decisions about smoking, drinking alcohol, gambling, joining the army and taking part in sexual intercourse. In each of these areas, the same ethical dilemma between autonomy and non-maleficence arises. The application of a chronological age of consent to all inevitably means that some children who may be competent to make these decisions earlier are denied the right to do so. There is no equivalent to the Gillick competency test for circumstances that do not deal with obtaining consent to medical treatment.

In the situations mentioned, society appears to have decided that protecting young people from harm is more important than respecting their autonomy. If this is the case, why is a greater respect for autonomy allowed when giving consent to medical treatment?

There seem to be two possible answers to this. First, given the legal stance in the UK and the importance placed on autonomy with regard to consenting to medical treatment since the Gillick case[1], it may be that respect for autonomy is becoming increasingly more important than respect for non-maleficence. (This would appear to be the opposite of trends in the USA, where patient welfare is placed before autonomy.[10]) If this is the case, then the position with regard to consent to medical treatment is likely to be the thin edge of the wedge, with other consent laws expected to change accordingly. Thus, Gillick competency should be transposed into research without further ado, and respect for the autonomy of minors should be treated as more important than non-maleficence. With the introduction of the Sexual Offences Act 2003 into UK law, current arguments about lowering the age of consent may, in the future, result in greater and wider decision-making powers being given to minors.[12]

Second, it is possible that there is some morally relevant difference between consent to medical treatment and the other types of consent that warrants treating medical consent differently. The difference is that, fundamentally, healthcare is aimed at benefiting the recipient. This provides a natural damper on concerns about the abuse of the Gillick competency test within the context of healthcare because, even if it is wrongly applied, the aim, at least, is the child's benefit. A similar argument has been made with respect to consent laws and regulations in the USA.[13] Ross points out that the respect for the autonomy of the ''mature adolescent'', permitting the adolescent to consent to participate in research, arises because of the extrapolation from such consent to medical treatment. Statutes that permit the latter, however, were written to accommodate public health issues and were not concerned with the minor's competency to consent.[13] There is thus a substantial reason, based on non-maleficience, to treat the use of Gillick competency in consenting to medical treatment as a special case. Although non-maleficience usually rules that we err on the side of caution before we allow someone to consent on their own behalf to things that involve significant risks to themselves, in the case of medical decision-making, erring on the side of caution may well lead to a greater degree of harm. While placing greater emphasis on non-maleficence than on respect for the person and their autonomy may apply with regard to medical treatment, because of the benefits that can be obtained for the patient, the argument is not as strong when one tries to apply it to participation in research. Here benefits are not as obvious and indeed may not exist.

RISKS AND BENEFITS

Gaylin [14] argues that the risk and benefit of a procedure to both recipient and society should be taken into account. However, while he considers different levels of risk and benefit, he does not make a separate analysis for consent to medical treatment and consent for participation in research. A clearer distinction between the two forms of consent is needed. The legal age of consent will always take into account the effect on society, because laws are intended for social good. In the case of Gillick competency, the case concerned the rights to contraceptives, without parental consent or knowledge, for girls who are under the age of consent to sexual intercourse. One of the main arguments made in the Gillick case in support of the Health Authority was based on consideration of societal benefit and the perceived need to reduce the number of teenage pregnancies.[1] Such a benefit could also be directly applicable for the sexually active teenager who is prescribed the contraceptive pill.

However, with regard to participation in medical research, the risk:benefit analysis needs to be looked at from a different perspective. The beneficiaries of medical research may be many or they may be few, and which it is to be may not be known at the time consent is sought. Time is needed for the experiments to produce results and for these to be further tested and long-term effects and side effects to be observed and noted. A risk/benefit analysis may therefore not be possible when consent to participation in research is being sought. This may make a decision about whether to participate more uncertain for an autonomous adult. It is further complicated when the consent is needed for involvement of a child under the age of 16.

The emphasis on assent rather than dissent has been questioned with regard to legislation in the USA.[13] Clark cautions about the granting of decision-making powers to the minor, because this can leave the child lacking necessary protection and lead to an abandonment of parental responsibility.[15] Gaylin argues that to dismiss the importance of parental authority would be immoral.[14] However, there are findings that provide evidence that parents may not always be aware of their children's reservations towards participating in the research and may grant permission for procedures which cause discomfort to the child.[13]

The aim of research is not to benefit the participants directly, but to answer some research question. A successful research project will convey obvious benefits to the researcher, such as more grant money and publications. The researcher will be aware of this at the inception and this could be construed as a vested interest. This will apply to any project, whether participants are adults or children, and hence ethical approval always needs to be sought before such projects are permitted. The consent issue is addressed by informing the participant, and it is assumed that a mentally competent adult is able to give this consent. When dealing with children, the determination of competency may require application of the Gillick competency test, and great care must be taken that any vested or personal interests do not cloud judgment. Because the potential exists that interest in the project and its outcomes may indeed result in too ready a determination of Gillick competency, the extension of this from medical treatment to research participation should be limited and permitted only in two exceptional circumstances.

The first and least controversial exception is when the research is likely to bring direct benefits to the participants and poses minimal risks for them. A study aimed at improving the eating habits and exercise routine of children and that involves a basic questionnaire and measures of height, weight and heart rate would fall into this category. Research that trials the comfort and benefits of a newly designed chair to look at the improvement in posture is another such example. In these cases, the consent to be involved in the research becomes relatively similar to obtaining medical consent, because participating is likely to benefit the children involved. If requiring parental consent is likely to bar some of the children from participating and thus garnering the benefits, Gillick competency can justifiably be applied. However, the minimal risk aspect of this exception ought to be treated very seriously. This is reflected in the Medicines for Human Use (Clinical Trials) Regulations 2004[16], which allow children to be enrolled in clinical trials only if they stand to benefit directly—and, crucially, even then only with parental consent or that of a guardian or legally recognised representative.[16] This legislation indicates that where there is more than a minimal risk, the consent of an adult to the child's participation is required.

The more controversial case where the use of Gillick competency might be appropriate is if requiring parental consent would hinder or seriously bias very important research.

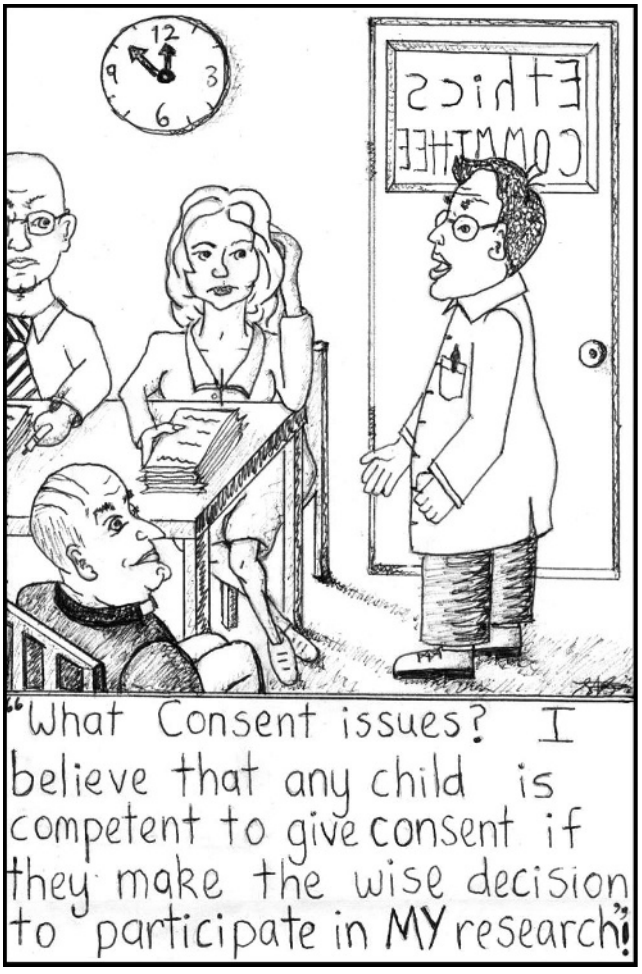

Figure 1 "The deliberation". Copyright Simone Hunter.

The risks of harm to participants would have to be minimal and the research such that it would potentially generate very important results unachievable in any other manner. Examples might be research on the incidence of sexually transmitted diseases, drug usage or abortions by those under 16. Parents might consider it offensive to have their children participate in such studies. This is more controversial, because the aim of the research is not to be of direct benefit to the participants, but instead to provide information that may be of wider benefit. Obviously the judgment of what will count as a sufficiently large societal advantage needs to be weighed against the size of the risk to participants, and it is imperative that an individual who is not associated with the research is responsible for doing this. This applies also to the Research Ethics Committee that assesses the application. A body that is external to the institution where the research will be conducted should review such applications. This provision is in place in the USA.[17] In the UK there is no such stipulation for non-medical research.

CONCLUSIONS

It is not appropriate in most cases to apply Gillick competency to obtaining consent for research participation. This is because generally research seeks answers to specific questions; any benefits for the participants can be considered incidental rather than a primary aim. In two exceptional situations, Gillick competency might be legitimately applied. The first is where the research is likely to generate significant advantages for the participants while exposing them to relatively minor risks. The second is when the research is likely to generate greater societal

benefit, pose minimal risks for the participants yet raise parental objection. In both cases, to ensure that autonomy is genuinely respected and to protect against personal and vested interests clouding judgement, Gillick competency should be assessed by an individual who is not involved in the research.

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