Ethical Issues in Adolescents Sexual and Reproductive Health Research in Nigeria

Morenike Oluwatoyin Folayan,

Department of Child Dental Health and the Institute of Public Health, Obafemi Awolowo University, Ile-Ife, Osun State, Nigeria

Bridget Haire,

Centre for Values, Ethics and the Law in Medicine, University of Sydney, New South Wales, Australia

Abigail Harrison,

Behavioral and Social Sciences with the Population Studies and Training Centre, Brown's University, USA

Morolake Odetoingbo,

Positive Action for Treatment Access, Lagos, Nigeria

Olawunmi Fatusi, and

Department of Oral and Maxillofacial Surgery, Obafemi Awolowo University, Ile-Ife, Nigeria

Brandon Brown

Program in Public Health, Department of Population Health & Disease Prevention, University of California, Irvine

Abstract

There is increasing interest in addressing the ethical dilemma related to engagement of adolescents in public health research – especially in sexual and reproductive health. This points to the need to design and implement research that addresses the needs of adolescents including STDs and HIV, adverse pregnancy outcomes, violence and mental health.

Decisions on when an individual has adequate capacity to give consent for research most commonly use age as a surrogate rather than directly assessing capacity to understand the issues and make an informed decision on whether to participate in research or not. Unfortunately, there is perception that adolescents participating in research are more likely to be coerced and may not fully comprehend the issues related to the risk they may be taking when engaged with research.

This paper examines the various potential ethical issues that may impact stakeholders' decision making when considering engaging adolescents in research and makes a case for lowering the age for consenting by adolescents. While some experts believe it is possible to extrapolate relevant information from adult research, studies on ethical aspects of adolescent participations in research are still needed, especially in the field of sexual and reproductive health where there are often differences in knowledge, attitudes and practices of adults when compared with adolescents. The particular challenges of applying the fundamental principles of research ethics to adolescent research, especially research about sex and sexuality, will only become clearer as more studies are conducted.

INTRODUCTION

Adolescents are generally considered to be individuals between childhood and adulthood who are in the process of reaching physical, psychological and sexual maturity though there is no agreement among experts about its precise definition. They represent one fifth of the world's population in general but constitute a larger proportion of the population of low and middle income countries (LMIC) compared to developed countries.¹ Individuals aged 10 to 19 years constitute 11% of the population of the more developed countries, 18.1% of middle income countries and 23% of the least developed countries (US Census Bureau).

The Nigeria Adolescent Health policy accepts the adolescent age range as the second decade of life, 10–19 years² in line with the definition by the World Health Organization³. However, it must be recognized that adolescence is a combination of physical, psychological and social changes that manifest differently in different cultural settings.

There are several justifications for conducting research on adolescents' reproductive and sexual health especially in Nigeria where there is limited data to inform national planning on sexual and reproductive health for adolescents. These include the need to understand the determinants of specific patterns of sexual behavior and practices, predictors and age of onset of active sexual life, life-long impact of sexual behavior on adolescents' physical and psychological health, and the health and psycho-social needs that results from these issues. These are all currently poorly understood.

One of the several rationales for biomedical or socio-behavioural research is that it may lead to discovery of information that can guide the implementation and delivery of appropriate preventive and therapeutic services to the particular population studied. Therefore, research on adolescents' reproductive health can lead to development of interventions that can maximize adolescents' health potentials. The omission of such research can perpetuate inadequate understanding of the particular reproductive health needs of adolescents and result in failure to deliver adequate services to this group.

Under the Nigerian constitution, a person under 18 years is defined as a minor.⁴ Therefore the law considers that such persons have limited legal capacity and in many situations require a legally authorized surrogate decision maker (parent, guardian or family member) to act on their behalf. The constitution also recognises married adolescents who are below the age of 18 years as emancipated minors. The Child Rights Act⁵ however, provides that a child who has attained the age of 16 years has the right to give consent for scientific investigation without parental consent. In practice, adolescents aged 15 years are regularly engaged in national surveys on HIV prevalence.⁶ While it is recognized that a constitutional pronouncement supersedes all other ordinances and pronouncements, these disparities in pronouncements and practice all recognize a particular need of older adolescents when it comes to health care research.

In this paper, we will consider whether the need for more information about adolescent sexual and reproductive health justifies a lowering of the legal age of consent in Nigeria. In making this assessment, we will consider the level of demonstrated need for evidence-based

sexual and reproductive health programs for younger adolescents, whether extrapolation from other populations is adequate, and issues of capacity, coercion, and risk assessment in and by younger adolescents.

SEXUAL AND REPRODUCTIVE HEALTH NEEDS OF ADOLESCENTS IN NIGERIA

A large number of adolescents initiate sex early with the median age of sexual debut being 15⁷. Less than 70% of the population in Nigeria use contraceptives, including condoms.⁸ Factors influencing the low use of contraceptives amongst adolescents include lack of detailed knowledge about the use of different contraceptive methods and their safety profiles.⁹ Emerging evidence shows that the use of hormonal contraceptives may increase the risk for HIV infection transmission from a HIV positive to HIV negative partner, as well as increase the risk of acquisition of new HIV infection.¹⁰ This evidence might complicate contraceptive decision-making. Accordingly, it will be important to understand how and when adolescents make decisions about choices on contraceptive options, points of access to these contraceptive tools, and how appropriate information on contraceptive choices related to their sexual and reproductive health needs can be shared in an accessible manner.

Early sex initiation also increases the prospect for multiple sex partnering. Data from Nigeria show that adolescents 15 to 19 year engage in high sexual risk behaviour: 64.7% of sexually active boys and 71.4% of sexually active girls had had unprotected sex with a sexual partner who was neither spouse nor co-habiting partner in the last 12 months of the survey.¹¹ This high risk behaviour – including unprotected sex during transactional sex – was comparatively higher than other age groups. While this evolving evidence has implications for planning sexual health education for adolescents, there is currently little known about factors that drive choice of sexual practices and sexual behaviours in adolescents in Nigeria.

Adolescents also face sexual violence; a recognised growing problem and a leading sexual and reproductive health issue. Adolescents face and have to deal with sexual abuse and sexual coercion in their daily lives. The prevalence of sexual violence ranges between 15 to 40% in sub-saharan Africa¹² with studies showing rates of sexual coercion and abuse among adolescents in Nigeria ranging between 11 to 55%.¹³ The report of rape ranges between 4% and 6%.¹⁴ A recent study conducted amongst 1,601 adolescents in Nigeria shows that 12 (0.05%) male and 69 (31.4%) female adolescents reported forced sex. Significantly more female adolescents who reported being HIV positive had experiences forced sex when compared to female adolescents who reported being HIV negative ($p = 0.008$).¹⁵

The Nigerian population is young with well over 55% of the population below 29 yrs.¹⁶ There is therefore the need to pay particular attention to the health needs of this population. These data above on age of sexual initiation and rates of sexual violence make it apparent that a lot more adolescent-specific research needs to be conducted to construct an evidence base for the planning and implementing adolescent-specific sexual and reproductive health programmes in Nigeria. As we shall elaborate later in this paper, data cannot be extrapolated from other populations because adolescent experiences are particular to their societal

context, shaped by factors including gender expectations and the socialisation processes at family levels¹⁷. Development of guidelines that would support and promote the conduct of ethically valid researches among adolescents in Nigeria is therefore essential.

ETHICS AND REPRODUCTIVE HEALTH RESEARCH

There are no clear ethical justifications for excluding adolescents from research. There are a number of reproductive health problems that are restricted to, or occur also in, adolescents which cannot be solved with existing knowledge. As a result, there is an ethical duty of beneficence and justice to conduct appropriate research to address these problems.

The sexual and reproductive health needs of adolescents differ from those of adults in three critical respects: firstly, physical immaturity that can make young women more biologically vulnerable to infection; secondly, dependency upon parents or other caregivers can make health based decision-making more difficult; and thirdly, their risk perception may be under-developed. The data on adolescent rates of STIs and experiences of sexual violence show that their sexual and reproductive health needs are inadequately served. Research is needed to help understand what adolescents need and how best to reach them in order to design appropriate interventions focused on safe sexual behaviour and to protect and promote their sexual and reproductive health.

Many adolescent health challenges are closely interrelated and successful interventions in one area can lead to positive outcomes in other areas. Adolescent health data is important to develop evidence-based policies and programmes that support adolescent health; to increase access to and use of health services for adolescents; and to strengthen contributions from the education, media and other sectors to improve adolescent health.

One of the key ways that adolescents below the age of legal majority have gained access to sexual and reproductive health services is through assessment of competence – specifically, whether the young person can demonstrate an understanding of the nature and implications of the proposed treatment, including the risks and alternative courses of actions.¹⁸ Applying a similar test in the research context would remove a major objection to enabling greater participation of minors in research – the objection that minors might not understand their range of choice and thus be more vulnerable to coercion. Applying specific and individual test of competency, and documenting it, has a clear advantage over age-specified restrictions in that it recognises the developmental and cognitive differences that exist within groups of young people who mature at different rates.

The need for distinct data on adolescents

Adolescents represent a critically important user group for reproductive health products as they bear a disproportionate share of the global health burden of STIs and HIV, in addition to risks of unplanned pregnancy. The claim that it is reasonable and sufficient to extrapolate safety and effectiveness data derived from those over 18 years to younger adolescents is flawed on two levels – the physical and the social. A Global Campaign for Microbicide report notes that the biologic and behavioral differences between young adolescents and older women justify separate safety and effectiveness data on younger adolescents on sexual

and reproductive health products.¹⁹ The cervixes of younger female adolescents are not fully mature, making them biologically more susceptible to STIs. Adolescents' menstrual patterns also differ from adult women, as some 80% of adolescents will have cycles without ovulation within four years after menarche. Without ovulation, adolescents lack progesterone, which may influence the vagina's local immune responses. These biological differences make it important to conduct health research amongst adolescents as it is equally important to under geriatrics and their health related problems.²⁰

At the social level, younger adolescents differ from adults in significant ways that could eventually affect how they will use sexual and reproductive health products. Such distinctions could become incredibly important when considering how to introduce and promote such products to teens.

In Nigeria, despite the stipulated legal age of consent of 18 years, a large proportion of adolescents are sexually active. The 2008 NDHS shows that 23% of women age 15–19 have begun childbearing, 18% have had a child and 5% are pregnant with their first child. Also, 12.4% of male and female respondents were married by 15 years, 15.3% of women and 6.2% of men had their first sex experience by 15 years, and 29.7% of female and 6.8% of male 15–19 year old respondents had had sex within the last 4 weeks of the survey.²¹ These data emphasises the need for early engagement of adolescents in sexual and reproductive health research that can help in the development of products and the design of programmes that addresses their sexual and reproductive health needs.

ADOLESCENCY AND RESEARCH

Adolescents have unique intrinsic and extrinsic challenges that face them when considering participation in research. Intrinsic ones include developmental considerations in physiology, pharmacology, and behaviour. Extrinsic considerations are those in the community, ethical, legal, and regulatory arenas and those in the design of clinical trials for adolescents to feasibly participate.²²

Adolescence is divided into 3 broad developmental periods: early (11–14 years), middle (15–17 years), and late (18–19 years) recognizing that there will of course be individual variation as to when there periods begin and end. Each of these periods is defined by unique cognitive and physical developmental attributes that are on a continuum: early adolescence is cognitively dominated by concrete thought processes, with limited ability to comprehend potential consequences of risk behaviors while middle adolescence is characterized by the emergence of abstract cognitive processes, which revert to concrete thinking during stress.²³ By mid adolescence (normally around the ages of 14 to 16), the cognitive abilities of adolescents are roughly the same as biologically mature adults. Adolescents' behavioural code is frequently defined by their peer group with major conflict developing between the adolescent and parent as they strive for greater autonomy.²⁴ Late adolescence is defined by well-developed abstract cognitive processing with the peer group being replaced by more adult type close personal relationships.²⁵ It is important to understand this dynamic developmental trajectory as Rudy et al defines it, so as to be able to contextualize the variety of adherence behaviors adolescents display when it comes to their health care.

Intellectually, by mid adolescence, adolescents are generally able to understand issues such as long-term risks and the benefits of research. Adolescents of the same age are also frequently inclined toward risk taking, and are acutely sensitive to peer influence. These factors can affect their understanding of risks and their capacity to make consistently sound judgments about their long-term best interest. This is important as research participants who consent (or whose consent is sought) to participate must be able to understand the implications of information provided about the study. Ethical guidelines have however, traditionally treated adolescents as “vulnerable,” meaning their capacity to give consent without duress may be easily compromised and therefore requires special protection as a group. This challenge requires a balance between recognizing the emerging autonomy of adolescents, their differential rates of development and their not yet fully mature response to personal risk. Potential risk needs to be weighed against the potential benefits derivable from participating in the research. Research involving adolescents needs to be designed to ensure it takes into account these characteristics, including their tendency toward altruism,²⁶ rebellion, and peer pressure, as well as their increased sensitivities around body image,²⁷ privacy, and confidentiality.²⁸

INFORMED CONSENT

Informed consent is a fundamental principle in research ethics. It is obtained through a dialogue that respects the individuality of each prospective participant and allows ample opportunity for the prospective participant to ask questions, which the research team member must answer fully. Every research protocol will need to clearly explain how the researchers and research team members intend to ensure understanding and comprehension of all legally required information given to research participants.

The ethical requirement is that informed consent must be voluntarily obtained and devoid of undue inducement and coercion. It is also described as the principle of ‘respect for persons’²⁹ which acknowledges that individuals with capacity have to right to make autonomous decisions. While the capacity for autonomous decision-making varies considerably across cultures and stages of adolescence it is important to consider that the involvement of parents (and guardians) in an informed consent process may jeopardize the autonomous decision-making of the adolescent, in addition to possibly compromising confidential information about the adolescent.

Paediatric Regulations and Legislation

As noted in the introduction, the Nigeria Constitution³⁰ and the section 277 of the 2003 Child Rights Act³¹ define a minor as a person under the age of 18. This implies that people under the age of 18 years have limited legal capacity and are vulnerable to decision making that is not fully competent. They therefore need a legally authorized surrogate decision maker-usually a family member to act on their behalf. The Section 64(2) of the Child Rights Act however provides that an adolescent who has attained the age of 16 years has the right to give consent for scientific investigation without parental consent. The 2011 (version 7.0) National Health Research Ethics Code also contains provision for soliciting consent from parents or legal guardians and for obtaining assent from minors participating in research. It explicitly states in the section F(c) that minors should not be excluded from research without

explicit reasons for doing so.³² Unfortunately, the code is not explicit about age for consent and assent. However, the working principle upheld by the National Health Research Ethics Committee is that assent needs to be given by adolescents between the ages of 12 and 17 years while their parents give consent for those who are not considered matured minors.³³ This is partially in line with the requirement of the Section 29(4b) of the constitution of the Federal Republic of Nigeria which states that *'any woman who is married shall be deemed of full age'*. Children below 12 years are not however, required to give assent (personal communication, Prof Clement Adebomowo, National Health Research Ethics Committee Chairperson). The above shows clearly that for Nigeria, the age for consent for participation in research is still very unclear. These all have far reaching implications for the development of regulation and legislation governing adolescent engagement in research in Nigeria.³⁴ As at date, research regulatory guidelines on adolescents' engagement in research is yet to be developed³⁵

Parental Consent

Parental consent alongside that of the adolescent is a major concern. Within the Nigerian legal context, parental consent and assent for adolescents below the age of 16 years are needed before participation in any form of research – except for mature minors. This clause raises multiple ethical dilemmas.

First, there is also the legal dilemma of who provides parental consent. Singh et al³⁶ noted that mature minors live with surrogate caregivers who are not formally appointed or recognised as the adolescents' legal guardian. In these instances, it is practically impossible to seek parental consent or to determine who, if anyone, is the legal guardian to authorise an adolescent's participation in a study. In Nigeria, this legal dilemma poses challenges for the conduct of research in the field. In many communities, young people have surrogate caregivers who are not formally appointed as legal guardians. Legally, these caregivers may not be recognized as the legal guardian. The 2008 NDHS showed that 9% of those under the age of 15 years were not living with biological parents.³⁷ A recent analysis of a data collected on adolescent studies showed that 18.9% of adolescents aged 10 – 19 years reside with guardians.³⁸ Research practice however limits parental consent to recognized legal guardians. The implication for adolescents' resident with surrogate caregivers is exclusion from research which could be of benefit both to the participants and the broader population. This action negates the principle of justice which promotes fair selection of study participants. Participants' exclusion should be on the basis of their ineligibility due to scientific parameters, those who may undermine the scientific validity of the study, and those who may face significantly higher risk through participation in a study. Secondly, there is also another dimension to parental consent which adds a later of challenge to parental consenting. For many communities in Nigeria, parents may want to talk with their families or respected people in their community before reaching a decision about providing consent for an adolescent to participate in a sexual and reproductive health research, especially when such research involves invasive procedures such as regular blood draws and vaginal examinations. This is particularly likely to occur if the research involves discussing sex with young people in communities where discussions of sexual subjects with adolescent are usually taboo. This consultation is also likely to occur if there are no clear therapeutic

benefits accruable from participation in such studies, as it is the case for many HIV prevention research. This kind of discussion obviously compromises the adolescent's privacy. It is however possible that ethics review committees waive a requirement for parental permission for adolescent participation when there are compelling reasons warranting this action. Such justification for a waiver must however establish a case for ethical duty of beneficence and justice for the conduct of the research on this group with evidence to show the research is appropriate for the group. In Nigeria, ethics committees may have to act based on their informed discretion as the Section F(f13) of the National code provides limited guidance on this subject matter. The code states that: '*Consent in other situations, including research involving children, persons with diminished autonomy, vulnerable populations and other extraordinary situations, including waiver of consent, are described in other guidance documents issued by NHREC*'.³⁹ The documents referred too, including that that provides guidance on research involving children and adolescents, are still in development.

Implications of parental consenting for all adolescent research

Privacy and confidentiality are considered critical for adolescent enrollment in research.⁴⁰ Where parents give consent for an adolescent to participate in research, the researchers will need to struggle to strike a balance between parental involvement and the need to protect the adolescent's privacy and confidentiality especially with regards to sex and sexuality. Adolescents are unlikely to want parents to know about his/her sexual activities. This becomes complex when enrolling teenagers who are below the legal age for sexual consent. While the parent may have given consent to the adolescent's participation in research, the onus is on the researchers to keep all information provided by the adolescent confidential. The principles of ethics require that researcher's respect study participant's autonomy and right to confidentiality. The assurance of data security is likely to promote adolescents' engagement in sexual and reproductive health research. Requiring adolescents to seek parental consent for their participation in the study may nullify this obligation to assure confidentiality⁴¹ and may compromise the quality of generated data. In extraordinary circumstances, however, there may be a need to disclose information divulged by a minor during research to the 'legal' caregiver. For example, a 12 year old who tests HIV positive and needs to be enrolled for ARVs will need to have information disclosed to the parent in order to provide access to treatment. It will be necessary and important to discuss any instances where such a requirement might occur with the adolescents prior to such disclosure, even where the law requires disclosure.

The guideline 14 of the Council for the International Organisation of Medical Sciences Guidelines tries to address the potential challenges that may arise with parental consent when adolescents are enrolled in research. It states that: "*Some studies involve investigation of adolescents' beliefs and behaviour regarding sexuality or use of recreational drugs; other research addresses domestic violence or child abuse. For studies on these topics, ethical review committees may waive parental permission if, for example, parental knowledge of the subject matter may place the adolescents at some risk of questioning or even intimidation by their parents*" (CIOMS, 2002).⁴²

Zuch et al also further highlighted the challenges associated with parental consent for all forms of research engaging adolescents. They clearly argued that strict adherence to the implementation that require active parental consents will deter from the conduct of school based adolescent sexual and reproductive health studies for a number of reasons including introduction of significant sample bias into the data.⁴³

The complexity of obtaining parental consent however hinges on balancing the requirement of the law and compliance with ethical principles because it is required that the norms and standards (both legal and ethical) that govern adolescent research in any country must be complied with. Unfortunately, there is little clarity on how to manage confidentiality in research involving adolescents. In research where parents give consent, complex privacy issues arise. As noted, a parent may give consent for enrolment, but adolescents may expect confidentiality for some components (such as their risk behaviour). There is also tension around how to manage confidentiality when the setting has laws about disclosures that must be reported to authorities e.g. adolescent sexual activity before the age of consent that meets the legal requirement for disclosure, but which is occurring with consent of the adolescent. In Nigeria, the National Health Research Ethics Code provides limited guidance on this. While it recognises the need to protect research participants' privacy it is not explicit address the implication of this with respect to adolescents engaged in research. The onus therefore currently rest with the researcher and the ethics committees to ensure that the study design ensures the privacy of any adolescent engaged in research within the ambit of existing legal frameworks while ensuring the scientific validity and the ethical integrity of the study conduct.

Also, although it would be assumed that the legality of guardianship serves as a protection for the adolescent because affection and close family ties make parents/legal guardians most likely to reach decisions based on the child's best interest, for those children without 'legal' guardians, additional safeguards will need to be put in place. Such safeguards will protect them from potential abuses due to their increased vulnerability, rather than exclude them from research. The onus therefore lies on the ethics committee to ensure that safeguards are in place to protect the rights of all adolescents – with or without legal guardians – enrolled in research.

PARENTAL CONSENT: REALITY IN THE FIELD

Independent of the laws and guidelines, there are cultural and social issues that may promote and support the need for parental consent prior to adolescents' engagement with research. These cultural and social issues may become the main consideration in the question on the morality of not obtaining parental permission prior to adolescent engagement in research. For example, enrolling adolescents without parental permission could alienate communities at the cost of losing support for the study. In Nigeria, the perceptions and opinions of many policy makers, public opinion leaders and gatekeepers are sometime not supportive of discussion of sexual issues among adolescents-it is assumed adolescents will be more promiscuous if they learn about sexuality and prevention of HIV/AIDS. Open discussions about adolescents and issues that related to them are limited and conservative.

To succeed at enrolling adolescents in research, it may be important to extensively engage adolescents, youth and parents in research design and implementation to promote recruitment and retention of adolescents in the research. Consultation and engagement of the community prior to research protocol submission to the ethics committee creates the opportunity to discuss the rationale underpinning the inclusion of adolescents in the research, as well as the reasons for not making parental consent for an adolescent's participation in a study a requirement where such is the case. Education about the benefits and risks of research for adolescents and the possible challenges with such research design must be carefully examined and discussed in such a way that makes them understandable, and can facilitate community investment in actions to address them. In addition, the inclusion of adolescent perspectives into every stage of the research development process, especially in clinical trials is essential. Scientific experts also need to clarify the differences in adolescent and adult sexual and reproductive health issues thereby justifying adolescents' engagement in sexual and reproductive health research. To date, scientific justification for adolescent enrolment in any research has not been articulated in a way that key stakeholders, like community representatives, can continuously appreciate.

CONSIDERATIONS FOR INFORMED CONSENT BY ADOLESCENTS IN NIGERIA

In summary, the informed consent process should take into consideration the capacity of the adolescent to consent; the role of surrogate decision-makers who should be able to consent when adolescents do not have capacity; and possible restrictions on the autonomy of adolescents or their proxies to consent. Unfortunately, while the National Childs Act specifically specified the age limits for consenting in research, evolving evidence points to a need to lower the current age for consenting to enable younger adolescents engage in research that can inform programme development and programming apt to address their needs.

One major concern about adolescents is their ability to comprehend. As medical evidence shows, cognitive development of the adolescents is near that of the adult by 14 years such that *'decision making and reasoning ability is as good as that seen in adulthood and involves the flaws'*.⁴⁴ It may therefore be important to advocate for changes in the law so it can permit adolescents 15 years and above with proven evidence of sufficient maturity, and with the mental capacity to understand the benefits, risks, and social and other implications of the outcome, to participate in research in general and sexual and reproductive health research specifically, without parental consent. The onus now lies on the ethics committees to be competent enough to calculate the risk-benefit calculus for the research and adjudge that the implementation of such research would not expose the adolescent to undue risk taking cognisance of age and cultural peculiarities.

In addition, sexual and reproductive health research protocols that would engage adolescent who are 14 years old should critically appraise the informed consenting processing and evaluate for perceived threats to consent like inadequate education and developmental characteristics of adolescent decision-making. It may be inappropriate to assume that all 14 year olds in Nigeria should be excluded from parental consent prior to engagement in sexual

and reproductive health research. Rather, researchers may need to always develop tools and processes to impart information, assess understanding, and enhance the voluntariness of decisions for sexual and reproductive health research conducted in adolescents that require therapeutic interventions. Researchers should ensure the adolescent demonstrates capacity for comprehension and required actions.

Where ethics committees do not feel confident that the risk associated with the research are acceptably low, parental consent for research participation may be required. Thus, consent norms for adolescent research participation needs to reflect the reality that research is of varying complexity and risk. For simple and low-risk research, exceptions to the norm of parental consent may be appropriate, provided that other protections are in place, including competent ethical reviews. In addition, community endorsement of research plans should be a major factor in research ethics committee consideration on whether to allow adolescents to provide autonomous consent for participation in a study. The World Health Organisation provides comprehensive guidelines on engagement of adolescent in research which could serve as a useful guide for research protocol review.⁴⁵

While the ethical-legal framework for consent is specified in Nigeria, its understanding and application by ethics reviewers needs to be addressed through trainings. This is underpinned by the work of the New HIV Vaccine and Microbicide Advocacy Society (NHVMAS) which has been engaged for over 5 years in building the capacity of ethics reviewers in the country on the ethics of biomedical HIV prevention research. These trainings are conducted in a way that ensures knowledge and skills acquired are applicable to other research field.⁴⁶

EXISTING EXAMPLES

There is a growing body of evidence to show that adolescents can be ‘safely’ engaged in sexual and reproductive health research howbeit these examples are almost exclusively limited to USA. One successful example is the Adolescent Trial Network funded by the National Institute of Health (NIH). It conducts research, both independently and in collaboration, with existing research networks to explore HIV related issues in infected and HIV at-risk adolescents, age 12 through 24 years. Its activities encompass the full spectrum of research needs for adolescents including clinical management of HIV-infected youth and risk reduction. The Network also includes a leadership group that is responsible for defining and developing the research agenda.⁴⁷ There are also studies that engage adolescents in microbicide researches. Microbicides are potential sexual health products that should reduce the possibility of HIV infection through vaginal and or anal sex. There have been two such studies by the Microbicide Trials Network conducted in USA and Peru and funded by NIH.

The most notable study is that of the HPV vaccine which has resulted in the licencing of HPV to prevent cervical and anal cancers in adolescents. This is one successful story in the conduct of ethical trials that engage adolescents on health issues of particular concern to them.⁴⁸

Within the African continent, there are recognizeable efforts in South Africa focused at addressing adolescent engagement in sexual and reproductive health research. The engagement of 16 year old adolescents in the Carraguard study is a step in this direction.⁴⁹

The proposed engagement of adolescents in post CAPRISA 004 studies is also one effort in this direction.⁵⁰ Locally, adolescents have long been engaged in multiple social science and epidemiological researches. The Integrated Behavioural and Biological Sentinel Surveys, the National HIV/AIDS Reproductive Health Surveys and the National Demographic Health Surveys engaged participants 15 years of age.⁵¹ The studies capture issues relevant to sexual and reproductive health.

The authors feel that in view of the cultural sensitivity to open discussion about sex, the ethics of engagement of adolescents in sexual and reproductive health research may be an issue of debate for a while to come. A good starting point may be the conduct of a national youth sexual and reproductive health survey. This survey may provide the ground for starting to think through the ethics of engagement of youths in sexual and reproductive health research in the Nigerian environment more specifically taking cognisance of Nigeria's peculiar, diverse and sometimes contradictory traditional, religious, legal and social systems.

CONCLUSION

The ethical dilemma of engaging adolescents in research in general, and sexual and reproductive health research specifically, is intertwined with legal and regulatory issues. For example, the appropriateness of including adolescents in research when the risks are more than "low" or "minor increase over minimal" is a difficult and thorny ethical issue. For sexual and reproductive health research in which the risks are "low" or have "minor increase over minimal", consideration should be given to allowing adolescents to consent unassisted to such research so long as the parents or legal guardians or community at large are unlikely to object to the adolescent's participation and the protocol justifies why adolescents should be included as participants.⁵² Also, ethical guidelines in Nigeria should consider the feasibility of engaging adolescents 14 years and above (rather than the current consideration of 16 years and above) in research without the need for parental consent. The peculiar challenges of applying fundamental ethical principles for adolescents engaged in research especially in cultures sensitive to open and public discussions about sex and sexuality, and how to resolve them can only be learnt from practical field experiences. Ethics is an ever evolving field and ethical consideration of adolescents' engagement in sexual and reproductive health research shall continue to constitute central themes in many ethical discourses for a while to come.

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