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Ethical Considerations in Adolescent Participation in Vaccine Trials: Qualitative Perspectives on Family Decision-Making from a Human Papillomavirus Vaccine Trial in Tanzania

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Abstract

Research involving children is crucial for ensuring they benefit from scientific advancements, yet participation must be balanced against potential risks. In many regions, legal frameworks mandate parental consent for medical research until the age of eighteen, while guidance on obtaining children's assent is often vague. Despite this, there is limited evidence on how families navigate these decisions and the ethical considerations involved. This study examines the ethical issues surrounding decision-making for children and adolescents participating in a human papillomavirus (HPV) vaccine trial. Semi-structured interviews were conducted with Tanzanian girls aged 9–16 who had enrolled in an HPV vaccine trial (n = 13), their parents or guardians (n = 12), and paired parent-child interviews (n = 6). Thematic analysis was used to interpret the data, which were drawn from a qualitative acceptability study nested within the Dose Reduction Immunobridging and Safety Study of Two Human Papillomavirus (HPV) Vaccines in Tanzanian Girls (DoRIS) trial. While parents were ultimately responsible for providing consent, both parents and girls favored collaborative decision-making. Girls expressed a desire for a more substantial role in these discussions. Consent decisions were influenced by multiple actors, including extended family, trial staff, healthcare professionals, and media, often leading to conflicts that needed resolution. Trust emerged as a central factor, shaping both how families made consent decisions and how they responded to rumors regarding trial participation. Current models of decision-making capture interactions between parents, adolescents, and researchers but overlook broader social influences and the critical role of trust. Children's participation can be understood through the lens of consent principles—autonomy, freedom, and access to information—while concepts such as relational autonomy provide insight into how families navigate complex consent processes. Although legal parental consent remains supported, researchers should develop child-centered consent procedures that respect and integrate the family's decision-making dynamics.

Keywords: HPV, Consent, Autonomy, Paediatrics, Relational ethics, Trial, Adolescent, Vaccine, Assent, Tanzania

Background

Balancing the protection of children's safety with respect for their autonomy remains a prominent ethical challenge in healthcare [1, 2]. This tension becomes particularly pronounced in research settings, such as vaccine trials, where uncertainties about potential benefits and risks exist. In many countries, legal frameworks require parental consent for medical research until individuals reach 18 years of age, while guidance on obtaining children's assent is often vague or inconsistent [3]. The ambiguous status of child and adolescent assent

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highlights the need to understand how families navigate decisions about research participation, including the degree to which children are engaged in the process and how their perspectives are considered. This study uses interview data from a human papillomavirus (HPV) vaccine trial in Tanzania to examine the decision-making processes within families regarding adolescent girls' participation. We begin by reviewing the ethical principles pertinent to adolescent vaccine trials and outline the central issues surrounding decision-making and assent. For terminology, see **Figure 1**.

There is a wide variation in terminology used to describe young people. The United Nations defines adolescents as 10 to 19 years old [4]. International and Tanzanian guidelines define children as those under 18 years [5–7].

- Participants in the DORIS trial were aged 9-14(6). Although this extends just below formal adolescent definitions, child participants in the study will be referred to using the term 'adolescent' for brevity and because the same issues remain relevant.
- We use the term 'child' when talking about ethical issues in general to describe anyone not deemed old enough to provide consent (usually because they are under <18) or to denote their relationship to a parent/carer who gives consent on their behalf.
- Similarly, the term 'parent' will be used to encompass parents and guardians, although it is acknowledged that there are many different family structures.

Figure 1. A note on terminology

Key ethical concepts relevant to adolescent participation in vaccine trials

Ethical considerations for children's involvement in vaccine trials are grounded in several fundamental concepts—autonomy, assent, and capacity—which are outlined below.

Autonomy is a central principle in medical ethics [8], referring to an individual's right to make informed decisions independently [1, 8]. It is often emphasized in Western ethics due to the individualistic orientation of these societies [9], though it has been critiqued for overlooking the social influences that shape decision-making [10]. Legally, autonomy is expressed through consent [11, 12], where a competent individual provides informed permission to undertake a specific action [13]. For minors, consent is typically provided by parents acting as surrogates [14], although some countries allow adolescents to consent themselves under specific conditions, such as demonstrated competence [1]. True consent requires that individuals are free to choose, sufficiently informed about their options, and possess the capacity to make autonomous decisions [15, 16]. Information must be tailored to the child's age and the context [1, 17]. In pediatric research and medicine, both parents and clinicians have fiduciary duties to safeguard the child's best interests, which may sometimes conflict with the child's expressed wishes [12]. Parents often consider both the child's and the family's welfare when making decisions [1].

Assent involves providing the child with an opportunity to express their informed opinion about a decision [1], serving both moral and practical functions [18]. Requirements for assent are generally less rigid, allowing for age-appropriate participation—for instance, a lack of strong objection may be interpreted as assent in some settings [14]. Assent encourages children to take an active role in decision-making while recognizing their developmental vulnerabilities. However, this flexibility can also mean that assent is not always meaningfully sought, leaving the child's voice unheard.

Capacity refers to an individual's ability to make a specific decision and acts as a "gatekeeper" for autonomy and consent [19, 20]. It is sometimes used interchangeably with "competence" or distinguished between clinical and legal assessments [19]. Capacity is

evaluated on a decision-specific basis, making prior assessment essential before seeking consent. Concepts such as Gillick competence in the United Kingdom and the mature minor doctrine in the USA and Canada recognize that children may possess the ability to make reasoned decisions regarding their own health and medical treatment [11, 21].

The notion of relational capacity moves beyond overly individualistic interpretations of autonomy by situating decision-making within a social context. It emphasizes dialogue and the sharing of information, helping families navigate conflicting perspectives without simply overruling the child's viewpoint [20].

Application of ethical principles to the trial context

The Nuremberg Code emphasizes that "the voluntary consent of the human subject is absolutely essential" in medical research [16]. Similarly, the Declaration of Helsinki and World Health Organization (WHO) guidelines recommend that children's assent should be sought in addition to the legally required parental consent [22, 23]. Notably, WHO guidelines suggest that, while legally considered assent, adolescents' agreement may be treated ethically as "co-consent" alongside parental permission [23]. Unlike clinical practice, where consent is primarily procedural, assent is mandatory in research contexts [1].

Although children generally gain competence as they grow, this development is neither linear nor uniform across individuals or cognitive domains [1, 24, 25]. Research in the USA indicates that children as young as nine can engage in consent processes, with competence comparable to adults by age 14 [26]. This is directly relevant for HPV vaccine trials, which often target girls aged 9–14 years [7]. However, other studies suggest that even older adolescents may have difficulty fully understanding assent, the purpose of research, and research procedures sufficiently for informed decision-making [12, 27, 28]. Guidelines therefore need to balance respect for emerging autonomy with protective measures, particularly given adolescence is a period of higher and sometimes inconsistent risk-taking [1]. Research contexts require additional caution compared with clinical practice due to uncertainties about risks and benefits, the voluntary nature of participation, and the complexity of some research concepts [12, 29].

Adolescent self-consent for vaccination has been widely studied [30, 31] and is implemented in some established immunization programs worldwide, including HPV vaccination [32, 33]. This concept has been extended to research contexts, yielding mixed conclusions about its appropriateness [24, 34]. Some researchers advocate dual consent models, requiring agreement from both parent and child [35], while others suggest assessing each child's capacity on a case-by-case basis and involving parents only if the child lacks sufficient capacity [18, 36]. These latter approaches often critique traditional assent models as poorly structured and implemented, with unclear accountability.

Decision-making processes in adolescent trial involvement

WHO research guidelines distinguish between the legal act of consent and the decision-making process itself, emphasizing the importance of involving children in decisions about study participation. This involvement should consider the child's age, prior experiences, maturity, cognitive development, and family and social context [23].

Snethen *et al.* outlined four levels of child involvement in consent decisions [37]:

- Exclusionary: The child is not involved.
- Informative: The child is informed but cannot influence the decision.
- Collaborative: The child participates actively, but parents make the final decision.
- Delegated: The child makes the decision independently.

The authors noted that parents' goals, perceptions of their roles, and their view of the child's involvement significantly shape the balance of power in decision-making. They also highlighted the often-overlooked influence of extended family and wider social networks [37]. Additionally, family structure and cultural norms profoundly affect decision-making strategies [38].

Understanding what participants value in decision-making is also crucial. A study of an HIV vaccine trial in South Africa found that while some adolescents supported independent consent, many adolescents and parents preferred parental decision-making. For adolescents, this preference reflected a desire for reassurance and practical support, such as assistance with transport, alongside decisional support [39]. Other studies similarly report broad acceptance of parental consent models among both adolescents and parents [40].

Critics argue that many models of children's decision-making are framed narrowly, focusing primarily on cognitive abilities and portraying children as inherently less capable than adults [19]. Broader conceptualizations that incorporate beliefs, values, and the influence of adults on children's decision-making could more accurately reflect children's contributions. Practically, narrow cognitive frameworks assume adult capacity by default, whereas children must demonstrate competence to participate [20]. There is a growing call for decision-making models that integrate emotional and value-based considerations and situate capacity within its social environment [41].

Negotiating consent in a socio-cultural context

Decisions regarding adolescents' participation in clinical trials often involve multiple stakeholders, each navigating competing priorities and perspectives [42]. Research in The Gambia by Geissler *et al.* highlighted that ethical practices in such trials are relational rather than rigidly codified [43]. Instead of strictly following formal international ethical standards, families and researchers relied on familiarity, dialogue, and flexible negotiation to manage power dynamics and complex social interactions.

Evidence from vaccine trials in Kenya has shown that engaging the broader community is essential for facilitating individual consent [44]. Community opinions and collective concerns can significantly affect both willingness to participate and retention in trials, sometimes fueled by rumors or local disputes [44]. Tanzanian ethical guidance similarly recognizes the influence of elders, community leaders, and husbands in family and community decision-making. In these situations, researchers are advised to emphasize decisions grounded in participants' best interests rather than strictly adhering to individual autonomy [45].

The notion of a single, universal standard for consent has been questioned, with calls for approaches that reflect local social and cultural norms [46]. For instance, Western models of autonomy, which prioritize individual decision-making, may not align with cultural practices in other regions, potentially affecting how ethical principles are understood and applied [47]. Much of the research on child assent and parental consent has been conducted in high-income settings, which may overlook important factors in low- and middle-income countries. Cheah and Parker, for example, observed challenges in Bangladesh where cultural expectations made it difficult for children to dissent from parental decisions [18]. Other context-specific challenges include varying literacy levels, generational differences in education, early maturation, limited exposure to medical research, non-nuclear family structures, and regulatory constraints. Despite these challenges, research in The Gambia demonstrates that culturally sensitive implementation of internationally recognized consent principles—emphasizing voluntary, informed decision-making—can be effective [15].

Contribution of this study

Understanding how families negotiate decisions about adolescent participation in clinical trials remains limited, particularly across diverse social and cultural settings. Conceptual frameworks that integrate ethical and social perspectives can help clarify the factors that shape family decision-making and enhance understanding of key ethical issues in adolescent research. Such insights have practical implications for designing more ethically robust and culturally appropriate research practices.

This study uses qualitative data from the Dose Reduction Immunobridging and Safety Study of Two Human Papillomavirus (HPV) Vaccines in Tanzanian Girls (DoRIS) trial. The DoRIS trial was an unblinded, randomized study evaluating the safety and immune response of one, two, or three doses of two HPV vaccines in healthy schoolgirls aged 9–14 years in Mwanza, Tanzania, a city on Lake Victoria surrounded by rural communities. The main trial included 930 participants, followed for up to 36 months post-vaccination, with blood samples collected at multiple time points to measure immune response. Girls in the two- and three-dose arms continue to be monitored for long-term outcomes up to nine years.

An ancillary qualitative study explored two aspects: (a) the acceptability of the vaccine and dosing schedule (reported separately [49]) and (b) how families made decisions about participation, including consent and assent. The current paper focuses on the latter, examining ethical considerations in family decision-making processes for adolescent participation in the HPV vaccine trial.

Methods

The study employed semi-structured interviews with adolescent girls, with separate interviews conducted for

parents, as well as paired interviews involving both girls and their parents. In total, 31 interviews were completed and analyzed using thematic analysis. To stay closely grounded in the data, no pre-existing theoretical framework was applied at the outset; instead, theory was iteratively developed throughout the analysis, guided by insights drawn from the interviews and a conceptual model that evolved during the process.

Participant selection and data collection

Data were gathered as part of a qualitative sub-study embedded within the DoRIS trial between November 2017 and December 2018 [7]. The sub-study focused on the acceptability of different HPV vaccine dosing regimens, and methods have been detailed elsewhere [49]. Participants were eligible if they had completed their assigned vaccine schedule and attended a six-month follow-up visit. Random sampling was conducted within two age groups (9–11 and 12–14 years at the time of vaccination) and across each trial arm (one, two, or three doses of Cervarix® or Gardasil-9®), with further review to ensure diversity in factors such as religion, ethnicity, and geographic location.

Potential participants were initially contacted by the DoRIS trial team, followed by a qualitative researcher who arranged meetings to discuss the sub-study. If both the adolescent and their parent or guardian agreed to participate, a subsequent interview date was scheduled. Written parental consent and participant assent were obtained before interviews commenced [48].

The interview guide was developed by the Acceptability research team, initially in English and then translated into Swahili and back-translated by a Tanzanian member of the DoRIS trial team. Questions were designed to address acceptability issues outlined in the main vaccine trial.

Data analysis

Anonymized interview transcripts were imported into NVivo for coding. Thematic analysis followed an inductive, reflexive approach as outlined by Braun and Clarke [50], with six stages:

1. Data familiarization: Reading transcripts to understand content and identify emerging patterns and concepts.
2. Code generation: Developing codes derived from the data.
3. Theme construction: Identifying provisional themes by grouping codes based on shared or significant ideas.
4. Theme refinement: Reviewing and adjusting provisional themes for clarity, depth, and coherence, including examining deviant cases that did not fit initial themes.
5. Defining themes: Clearly outlining the scope and content of each theme.
6. Report production: Finalizing analysis by writing up themes and comparing findings with existing literature.

The total of 31 interviews provided substantial coverage for qualitative research, with recurring themes suggesting proximity to data saturation—where additional interviews yield few new insights [51]. Anonymized quotes were used to illustrate findings, enhancing transparency and reliability in theme development.

Ethical considerations

The qualitative sub-study received ethical approval from the London School of Hygiene and Tropical Medicine Ethics Committee (ref: 11972) and the National Health Research Ethics Committee of Tanzania (ref: NIMR/HQ/R.8a/Vol.IX/2682).

Informed consent

Consent for participation was obtained by a qualitative researcher who explained the study, provided written information, and addressed participants' questions. Written parental consent and written assent from the adolescents were collected. For parents or guardians who were illiterate, consent was witnessed and documented via thumbprint. Researchers were trained to recognize signs of reluctance during recruitment or interviews. No financial incentives were offered; parents were reimbursed for travel expenses, and transportation to the study clinic was provided for the girls when needed.

Confidentiality

All interview data were processed and stored in anonymized form, ensuring that no identifying information was included. While the possibility of deducing participant identities was minimal due to the type of data collected, special care was taken to present illustrative quotations in a way that eliminated this risk. The data were kept on a secure network drive, adhering to the data management requirements of both the University of Glasgow (the lead institution for this qualitative study) and the London School of Hygiene and Tropical Medicine (LSHTM).

Results

In total, 31 interviews were completed. This included 13 interviews with adolescent girls enrolled in the DoRIS trial, 12 with parents or guardians, and 6 paired interviews involving a girl and her parent or guardian (distinct from those who took part in the individual interviews). Participant demographics have been described previously and are summarized in **Table 1** [49]. Interviews were conducted either in participants' homes or at the study clinic, depending on individual preference. A semi-structured interview guide (see Supplementary Files 1–3) was used to ensure consistency while allowing participants to share their experiences freely. All interviews were audio-recorded with consent, then transcribed and translated from Swahili into English for analysis.

Table 1. Participant characteristics

	GIRLS (*n* = 19)	**PARENTS (*n* = 18)**
Type of interview		
Individual	13	12
Paired	6	6
Age in years, Median (range)	12 (9–16)	44 (28–72)
Gender		
Male	0	4
Female	19	14
Residential setting		
Urban	15	17
Peri-urban	4	1
Religion		
Christianity	16	14
Islam	3	4
Current school level		
Primary school	12	–
Secondary school	7	–
Education Level of parent		
Primary School	–	14
Secondary school	–	2
Vocational training	–	1
University	–	1
Occupation of parent[a]		
Vendor, salesman/woman	–	6
Farming, agricultural work	–	4
Housewife	–	3
Business man/woman	–	3
Unemployed	–	1
Other	–	5
Number of HPV vaccine doses received	Girls	Daughters
Empty Cell		
3 doses	5	7
2 doses	7	5
1 dose	7	6

a Some parents gave more than one occupation

Among the parental interviews, participants included seven mothers, one father, one stepfather, one aunt, one cousin, and one guardian. In the paired interviews, three mothers and three fathers participated, with one father joining partway through the discussion.

Both parents and adolescents described the decision-making process for DoRIS trial participation as involving a tension between parental authority and aspirations for collaborative involvement. Parents valued their central role in making the final decision, whereas girls expressed a desire for more substantial involvement and employed various strategies to participate meaningfully. Families navigated a wide range of information sources, and judgments about whom to trust played a central role in shaping the decision-making process. These dynamics were embedded within social relationships and broader family and community contexts.

Contested and uncontested autonomy

Primary decision-making practices

Nearly all participants, with the exception of two adolescent girls, recognized that parents ultimately held the final authority to consent. The two girls who felt more decision-making control acknowledged that their role was exercised alongside their fathers' authority. Often, the girls' opinions influenced the official parental decision:

Paired 4 (father): "Before participating I came with the girl here at Medical Research; she was asked questions by the doctors, and they asked me too. So we agreed. The girl was asked and she agreed; if she had refused, she wouldn't have participated."

Understanding that parents had final decision-making authority shaped family dynamics, making adolescent involvement appear optional, as parents' authority was generally assumed. Girls explained why it was

appropriate to defer to their parents, citing reasons such as parents' seniority, life experience, legal authority, and the practical support parents could provide.

Girl 7: "It is my duty to listen to my parents and if I go against their wishes they would curse me, and the curse of a parent is strong."

Instances where parental authority was questioned were rare. One girl argued for self-consent, emphasizing personal agency in deciding for herself: "You are creating yourself in deciding if whether you want it or you do not want it" (girl 2). Similarly, one parent suggested that their role should be advisory rather than determinative:

Paired 3 (father): "The best way is [not for] the parents to decide but to discuss and involve the [girl] because the parent's task is only to advise."

Despite these exceptions, most adolescents preferred that parents remain involved in the consent process, seeking reassurance and acknowledging parents' rights to make such decisions. Some parents strongly opposed the idea of adolescent-only consent, framing it as potentially unethical:

Paired 1 (father): "Why vaccinate the child without [parent's consent]? Ee, if it were so, we would conclude that this study is a fraud and unethical."

Parents generally saw their role as coordinating the decision-making process—determining who should be involved, in what capacity, and evaluating the information provided. Adolescent participation was more variable: almost all girls expressed a desire to have a role in decisions affecting them, though experiences ranged widely. Some were merely informed of pre-made decisions, while others took part in family discussions where they could voice their preferences:

Paired 3 (girl): "He was giving me his views and I was giving him mine until we decided to take part."

Some participants also noted the influence of gender on decision-making, although patterns were not consistent. In certain families, mothers collected and synthesized information, offered recommendations, and guided the father's final decision:

Parent 6 (mother): "I was the one who made the decision. After attending the seminar and having detailed information about the vaccine, I then decided all alone and later discussed it with her dad, and he had no problem with that."

Similar dynamics were observed in other household decisions, such as purchasing new school uniforms, although this was not universal. In some families, fathers took an active role by attending seminars, addressing concerns from other family members, and engaging directly with the trial team.

Only two cases involved exclusion of one parent from the decision-making process. In one instance, the mother—living with the child and father—was not included, and in the other, the father—who did not reside with the child and mother—was excluded. The girls involved were unsure why a parent had been left out of the process. Extended family members, particularly female relatives who lived in the same household, were often consulted. This included grandparents, aunts, siblings, and cousins, who acted as advisors or, at times, surrogate parental figures in the consent process.

Expressions of adolescent autonomy

Girls found ways to participate in decision-making, such as reminding parents about meetings, raising trial-related issues strategically, or enlisting support from other family members. For example, one girl sought her aunt's help before approaching her father about the trial.

Adolescents in non-traditional family structures—where both biological parents were not present—often experienced greater agency. Guardians who were not biological parents tended to adopt a cautious approach, allowing girls more influence over decisions. One guardian explained her reluctance to assert an opinion:

Parent 3 (guardian): "I said that because this vaccine is a trial one, what if it affects her and she is not mine…what will I do?"

Parents also described how age shaped their weighting of girls' opinions, reflecting assumptions about cognitive development and maturity:

Paired 1 (father): "It is because she is still in the foolish age. She is not in any position to get to decide until we first get to decide."

Girls were aware of the boundaries of their influence, acknowledging that they could not override parental refusal:

Girl 11: "You cannot force parents who have refused."

Girl 13: "I would not pursue my own wishes because dad said so."

Negotiating disagreements and reaching consensus

Decision-making around trial participation often mirrored other family decisions, such as those related to schooling. Girls who had historically been involved in household decisions reported feeling similarly included

in trial-related choices, whereas those less involved in previous decisions felt excluded in both contexts.

Disagreements between parents or between parents and children were common but typically addressed through dialogue aimed at reaching consensus. Parents often framed efforts to persuade others as "educating" or "explaining" rather than imposing:

Parent 12 (stepfather): "After I went to school […] I came back home and involved my partner, but due to her fear, I had to educate her […] she understood, received it well, and I signed the form."

Non-confrontational approaches were preferred, with few references to conflict or punishment. In some hypothetical scenarios, parental authority could override the child's wishes:

Girl 11: "On the day they were coming for me, dad would have said that my mother has refused, and I should not take part."

Nonetheless, achieving consensus was almost universally viewed as the most desirable approach:

Paired 4 (father): "Sometimes there can be misunderstandings between the mother and the father. But if you love each other, you sit down together."

Influence and trust

Deciding how to be influenced

Both adolescents and their parents actively managed how they engaged with information and opinions from individuals outside the immediate decision-making circle. At times, they sought outside advice to help inform their choice, while at other times, they deliberately avoided external input to prevent confusion or the spread of misleading information:

Parent 4 (mother): "In some families you will get crazy opinions such as 'these vaccines are this way or that way, they will do this or that to your daughter' […] Before involving someone, you must first understand them, even if it is your relative."

Information came from a wide array of sources, including the trial team, healthcare professionals, media, community and religious leaders, school lessons, friends, neighbors, and family members. Many participants highlighted that knowing others were also taking part in the trial encouraged their own participation:

Girl 2: "Another reason is that I wasn't the only one who went to be vaccinated. We were many of us and all of us saw how important it was to be vaccinated."

Being part of a larger group helped overcome fears, including concerns about potential risks. Written materials provided by the DoRIS team were frequently mentioned as particularly influential. These materials served as a reference point, sparked discussion, and helped participants navigate conflicting opinions:

Parent 4 (mother): "I asked her whether she would like to go on; and I gave her the pamphlet to read; after reading it I asked her if she still wanted to go on."

While both parents and adolescents drew on multiple sources, girls tended to rely most heavily on their parents and the DoRIS team, whereas parents collected and considered information from a broader range of inputs. When asked about her decision-making process, one girl explained:

Girl 3: "I was just listening to mum's opinions."

Despite some gaps in understanding, particularly among the girls, participants generally felt they had enough information to make an informed decision. Any misunderstandings did not seem to cause concern, suggesting their informational needs were sufficiently met. This uncertainty may have been influenced by the time elapsed since consent, even though all participants and their parents had passed a 'test of understanding' prior to enrollment [48].

Parents demonstrated a solid grasp of the consent process and unanimously acknowledged that participation was voluntary:

Parent 9 (aunt): "It wasn't compulsory. It was an optional thing. It just depends if you like it and no one was forcing you."

Most participants expressed satisfaction with the information provided:

Girl 1: "[We had enough information] because they had explained to us and told us that, 'if you do not understand, you ask a question.'"

When additional clarification was needed, participants employed various strategies. Many referred back to the written materials, and some parents actively sought further explanations from researchers. One father described persistent engagement to ensure full comprehension:

Parent 2 (father): "We wanted explanation on that, and I actually asked about it twice. Then that guy told me, 'You have already asked about that question,' but I told him that I have not clearly understood it."

In contrast, several girls reported that they refrained from asking questions they had, and one mother had hoped that

her daughter's peers might raise the question on her behalf:

Parent 9 (aunt): "I didn't understand, I wanted to ask, but then I thought I'd wait, maybe one of my peers thinks like me, so I didn't ask."

Trust and its role in decision-making

Trust emerged as a central factor in determining which external inputs were considered relevant in family decision-making. Families used trust to filter out rumours circulating about the trial—such as claims that the vaccine caused infertility, was linked to terrorism or Freemasonry, involved excessive blood draws, or introduced bacteria into the body. Participating in the trial required more than weighing risks and benefits cognitively; it demanded confidence in specific people and institutions. Opinions from sources deemed trustworthy carried greater weight.

Girls consistently viewed their parents as highly trustworthy, often respecting their guidance even when they disagreed:

Girl 4: "[I value Mum's opinion most] because she was the one that gave birth to me and the one I listen to the most."

Extended family members' views also mattered, though opinions from neighbours, friends, or broader community members were considered more uncertain. While some participants felt it was important to gather as much information as possible, others believed that consulting uninformed individuals could be misleading:

Parent 3 (guardian): "You know that there are some friends that you can tell them and they end up misleading you. Such a serious matter requires independent thinking."

Exceptions existed for people with direct experience of illness or vaccination. For instance, a girl who had received the HPV vaccine and later had a child was cited as evidence that fertility-related rumours were untrue. Likewise, stories of individuals affected by cervical cancer helped reinforce trust in healthcare providers and the trial:

Parent 7 (mother): "There is a girl who was once vaccinated in this study […] and she gave birth, so after meeting her I realized these rumours are just words circulating in the streets."

Healthcare professionals—both within and outside the trial—were widely regarded as reliable sources. Some parents actively sought guidance from trusted doctors, such as an employer or a church member, to verify information:

Parent 1 (mother): "I went to that doctor and asked her […] She told me it was fine, there was no problem […] when the doctor assured me, I felt at peace."

Religious leaders, however, were not considered credible sources regarding the trial due to perceived lack of expertise:

Parent 3 (guardian): "He is not a professional in health; he is a religious leader and doesn't know what's going on."

When trusted individuals offered conflicting advice, recommendations against participation often carried more influence.

A conceptual framework for decision-making

The decision-making processes described by participants can be represented diagrammatically **(Figure 2)**. This model highlights the wide array of factors affecting consent decisions, from trust in government to intimate family discussions. Although parents—typically one primary parent—hold ultimate authority, the decision-making process frequently involves cooperative input from the child and other family members. Evaluations of different opinions are shaped by complex negotiations involving power, social proximity, and trust. Both parents and adolescents actively participate, asking questions and strategically deciding how much information to seek and from which sources.

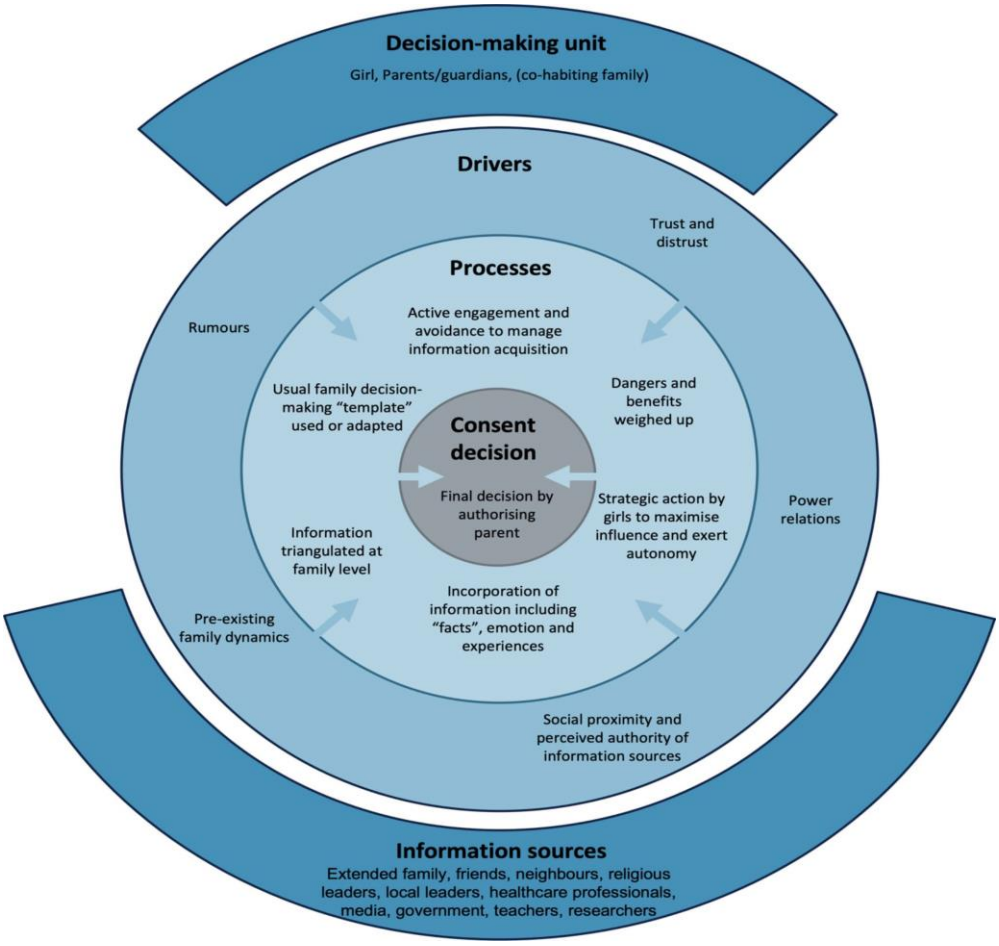

Figure 2. Conceptual model of family decision-making for adolescent trial involvement

This conceptual model expands on previous frameworks by situating decision-making within a broader social landscape and highlighting how power dynamics and trust influence the handling of information. It emphasizes that information flows are not one-directional; rather, decisions emerge through ongoing negotiation among multiple actors over time. The model also integrates aspects of relational autonomy, acknowledging that decision-making is inherently interpersonal and shaped not only by logical assessment of risks and benefits, but also by emotions, experiences, and social power [10, 20, 52]. While developed using Tanzanian data, the framework has potential applicability across cultural contexts, though the relative importance of different factors—and potentially additional influences—may differ elsewhere.

Discussion

Findings from the DoRIS qualitative interviews showed that both girls and parents valued each other's perspectives in the decision-making process. Parents generally assumed ultimate authority, whereas girls described a more negotiated and sometimes contested role. Both parties navigated the decision collaboratively, although it was commonly agreed that parents would make the final choice. Decision-making was not solely based on objective facts; rather, it was grounded in trust, pre-existing family dynamics, and the surrounding social context. These insights raise important ethical questions regarding the interpretation of autonomy for adolescent participants, what constitutes genuinely informed consent, and how such consent should be negotiated in research involving minors.

Positioning the findings within existing decision-making models

Many elements observed in these interviews align with findings from other studies. The notion that parents hold

ultimate decisional authority is common, though not universal [15, 37, 53]. Age is frequently considered a factor in both access to decision-making and responsibility, yet developmental research suggests that age alone does not determine decision-making capacity and may not correlate linearly with maturity [12, 25, 53, 54]. Seeking consensus through some level of parental and child involvement is a widely reported approach [55].

Snethen *et al.* outlined four models of child involvement in decision-making: exclusionary, informative, collaborative, and delegated [37]. These models differ according to parental goals, the child's degree of participation, and the parents' perception of their role. Families' chosen approaches often reflect pre-existing relationships and the significance of the decision at hand [37, 38]. Applying these models to the DoRIS data suggests that informative and collaborative strategies were most common, with occasional exclusionary practices. However, the interviews indicate that girls actively envision and pursue ways to participate in decisions—a role not accounted for in Snethen's model, which also does not address how conflicts between parental and child perspectives are negotiated.

Pre-existing family dynamics strongly shaped trial-related decision-making. Families accustomed to collaborative decision-making in other areas of life were more likely to adopt a similar approach for trial participation, a pattern supported by prior research [37, 56].

While the data did not allow for in-depth conclusions about gendered dynamics, some patterns were noted. Mothers tended to engage more in the information-gathering and discussion processes, whereas fathers often provided the final authorization. Similar findings were reported in The Gambia, where mothers were more process-oriented in decisions without necessarily holding ultimate authority [15].

Other research has also shown that parents often rely on advice from extended family while maintaining decision-making control themselves [15]. In the DoRIS interviews, extended family members living with the nuclear family frequently contributed substantively to decisions, whereas those living separately were consulted more as advisors. Previous studies have emphasized that the influence of extended family members is often under-recognized in research on parental consent [37].

Who provides consent?

In some regions, adolescents are permitted to self-consent for vaccination programs [31, 57], and the suitability of self-consent in research contexts has also been explored [24, 34]. In these interviews, however, the girls neither wanted nor felt comfortable providing legal consent independently of their parents. Considering that some participants were as young as nine years old—below typical thresholds for cognitive readiness to make healthcare decisions [26]—the findings suggest that self-consent for the HPV vaccine trial was neither appropriate nor desired. Nevertheless, both parents and adolescents expressed a strong preference for meaningful dialogue regarding participation. Exploring adolescents' perspectives on informed consent therefore offers a more nuanced understanding of their actual role in decision-making and highlights opportunities to design future trials that better support their involvement.

Ethical frameworks generally define valid consent as requiring autonomy, freedom, and sufficient information [16]; these elements are considered in turn.

Autonomy: individualistic or relational?

Interviews indicated that decisions were co-constructed between adolescents, their parents, and sometimes extended family. Traditional models of autonomy, such as the in-control agent framework described in core ethics texts, emphasize the individual's ability to logically assess information and make independent choices [8, 9]. Critics argue that this approach is excessively individualistic and rationalistic, neglecting the influence of social context, emotions, and embodied experience [10]. Adolescents' lives are deeply embedded in family and community networks, and expecting purely independent decisions risks creating an artificial and potentially harmful separation. The interviews highlighted that adolescents often struggled to delineate their own opinions from those of their parents, a phenomenon documented in other research [9]. Factors such as fear and trust, particularly in relation to rumors or authoritative figures, influenced decisions not just cognitively but emotionally, shaping who was perceived as "trustworthy."

A relational autonomy approach frames adolescents as legitimate autonomous agents within their social environment. This model recognizes their contributions as essential to decision-making while acknowledging that parental or social influence can be both supportive and, in some cases, potentially exploitative [9]. Relational

autonomy allows for the involvement of parents and family members in the process. In pediatric decision-making, choices can affect the whole family [37], and parents often play crucial roles in nurturing children's understanding and judgment [58]. Traditional in-control agent models tend to overlook these dynamics. The degree to which parents engage children in general decision-making influences the child's ability to participate in research decisions [12], aligning with the study findings that family decision-making patterns shaped trial consent practices. Additionally, relational approaches help address concerns about adolescents' tendency toward higher-risk behavior [1].

Freedom of choice in adolescent trial consent

The notion of freedom in adolescent consent is nuanced and complex. Legally, adolescents cannot provide independent consent, as this authority rests with parents—a reality that shaped discussions around "choice" in the interviews. Beyond the legal framework, the idea of being truly "free" is complicated by children's dependence on their parents. This dependence is both practical—relying on parents for housing, food, education, and healthcare—and emotional, encompassing the need for love, guidance, and approval [59]. The interviews reflected this reality; many girls cited living at home as a key reason for following parental decisions regarding trial participation. The influence of parental authority was particularly strong when parents were assertive or did not communicate that they would respect the child's decision [37, 60].

What constitutes sufficient information for consent?

By the time interviews were conducted, participants' understanding of the trial was generally limited, for both girls and parents. It is unclear whether this reflects comprehension at the moment of consent or whether knowledge faded over the months following participation. Both groups demonstrated better awareness of procedural aspects of the trial—such as voluntariness and practical requirements—than of its purpose or the vaccine's function, a pattern consistent with other studies [61]. This raises questions about how children's ability to grasp information for consent is assessed. Often, children are assumed incapable of fully understanding the relevant information [12, 27, 28], although exceptions exist [26, 62]. By contrast, adults are presumed to have this capacity, yet in these interviews, both adults and children exhibited similar gaps in understanding.

Adults also play a crucial role in helping adolescents interpret information [37], highlighting the implications when adults themselves are relatively "uninformed." Despite these gaps, most participants felt adequately informed to make a decision and were confident in their choice. Previous research has shown mixed views on whether participants feel sufficiently informed: some who declined participation reported feeling that information was biased or insufficient [53, 15], suggesting that trust and the perceived adequacy of information may be closely linked.

Several strategies have been suggested to enhance comprehension among young participants. These include the use of technology to present information [53, 61], reminder or follow-up notifications [53], and comprehension checks similar to those implemented in the DoRIS study [1, 48]. Information sheets remain a critical tool [15]. However, much of this guidance originates from high-income countries, indicating a need for further research to determine effective approaches for improving understanding in other socio-cultural and resource-limited settings.

Balancing trust and distrust in decision-making

A central theme that arose from discussions around decision-making was the role of trust and perceived trustworthiness. Consistent with prior research, trust emerged as essential for participation in research [15, 38, 63]. Trust can be actively fostered by trial teams, including by delegating authority to fieldworkers from central research offices [63]. However, it is also shaped by factors less amenable to direct intervention, such as prior experiences with research teams [43, 63]. Geissler and colleagues highlighted that, in a malaria vaccine trial in The Gambia, ethics were deeply embedded in social relations, reflecting an intertwining of researcher and participant roles that contrasts with the formal divisions assumed by international ethical codes [43]. This was described as 'relational' ethics, emphasizing the significance of "knowing each other" and the fluid nature of these relationships. This framework provides valuable insight for understanding the DoRIS interviews, showing how researcher-family interactions contribute to building trust.

The data also indicated that successful decision-making required not just trust in researchers, but also a healthy

skepticism toward others, allowing families to navigate rumours. Families weighed the trustworthiness of researchers, governments, and healthcare providers against that of community members and potentially misleading opinions. Family members themselves often occupied an intermediate position—trusted, yet not entirely immune to believing false information. Interestingly, Fairhead *et al.* noted that research staff emphasized narratives of trust, whereas parents tended to focus on weighing potential risks and benefits [64]. In these interviews, parents and adolescents evaluated short-term risks such as pain, long-term concerns including fertility rumours, and potential benefits like cervical cancer protection [49]. Trust served as the foundation underpinning how these risks and benefits were prioritized.

Implications for adolescent trial consent

Both parents and adolescents expressed reluctance toward self-consent models. While this may reflect familiarity with parental consent practices, it aligns with research on adolescent cognitive development and decision-making capacity [12]. Applying a best interests perspective highlights the value of alternative consent models, particularly when autonomy is limited. For instance, allowing adolescents without sufficient capacity to consent independently could expose them to potential harm [65]. Assent models can protect young people by calibrating involvement to their preferences and abilities [12, 66], focusing on meaningful contribution to decision-making irrespective of full capacity.

Models that consider parents or adolescents in isolation are unlikely to facilitate the collaborative decision-making both groups desired. While assent provides a channel for children to express their opinions appropriately for their developmental stage, it has been critiqued for lacking clear standards and still leaving the final decision with parents [1, 35]. Dual consent models could strengthen recognition of the child's emerging autonomy while retaining parental protection, though challenges remain when disagreements arise [35].

Strengths and limitations

This study incorporates the perspectives of both adolescent girls and their parents, with paired interviews offering a platform for unique discussions. These discussions generated rich insights into how families approach decision-making and perceive their roles within it. The study bridges ethical considerations surrounding adolescent participation in vaccine trials with the practical realities of decision-making, offering guidance on how adolescent trials can be conducted ethically. Many of the findings may also have relevance to broader adolescent research contexts.

Several limitations should be acknowledged. First, the primary focus of this qualitative study was the acceptability of dose reduction [49], with the exploration of decision-making mechanisms and the degree of adolescent involvement being secondary objectives. Consequently, the data were more informative for some aspects than others, restricting the depth of conclusions on certain elements. For example, there was limited exploration of how disagreements were resolved or precisely what "involvement" entailed.

Second, the interviews were only conducted with participants who had consented to the DoRIS trial. Therefore, findings should be interpreted in this context. Research including non-consenters could provide valuable insights into variations in decision-making processes and increase the generalizability of results. Accessing this group may be challenging due to their prior lack of research engagement, so strategies to maximize comfort and willingness to participate would be important. Additionally, since the DoRIS trial involved only girls, it is unclear how perspectives might differ if boys were included in vaccination programs.

Finally, while interviews are a powerful tool for understanding experiences and perspectives, they may not fully capture actual behaviors. Decision-making practices, particularly in complex or conflict-laden situations, may differ from what participants describe. Nonetheless, interviews offer a pragmatic method to explore private family decision-making, which would be difficult to observe directly. They provide insight into participants' thought processes, interpretations, and feelings about the consent process. Further research comparing adolescent decision-making experiences in research and clinical practice could support translation of these insights into broader contexts.

Conclusion

The interviews revealed diverse decision-making approaches, highlighting the complexity that models of consent must accommodate. Girls actively seek

opportunities to exercise autonomy, while family dynamics—both between children and adults and among adults themselves—strongly influence outcomes. Consent should be reframed as a relational, negotiated process over time rather than a single act of signing a form. Relational autonomy offers a framework to understand how adolescents exercise agency within their family context, integrating both emotional experience and rational deliberation.

These findings carry significant implications for public health. Research trials underpin the development of public health interventions, including vaccination programs. Understanding who is involved in decision-making and how these decisions are made can help support families, promote ethical practice, and potentially improve trial recruitment. Ensuring adolescents have meaningful involvement through supported mechanisms, such as assent or dual consent, can validate their perspectives, encourage family discussions, and foster the development of decision-making skills for future health-related choices.

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