Putting research ethics in context: Rethinking vulnerability and agency within a research ethics case study on HIV prevention for young girls in South Africa

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ABSTRACT

We investigated conceptual shifts around vulnerability and ethical issues arising in research using a case study embedded within an HIV intervention project targeting adolescent girls and young women (AGYW) in a rural district, South Africa.

We recruited 77 participants. Sixty-five people participated in focus group discussions (FGDs); nine in in-depth interviews (IDIs) and three in key informant interviews (KIIs). Data were analysed iteratively using thematic framework analysis. Themes were determined by the study aims and an inductive development of codes emerging from the data. We investigated ethical issues arising at the intersection between the vulnerabilities and agency experienced by research participants. Our findings show that AGYW's ability to exercise agency is dependent on the social, economic and political context. Understanding the social structures is crucial for interventions seeking to improve the health and social well-being of AGYW.

1. Introduction

There is a tension between the concepts of justice namely, including everyone irrespective of their power and vulnerability to participate in research and have the benefits, and the protection of human participants in research. At the same time, real power differences and social and political vulnerabilities underscore the ongoing need for the protection of participants in research, ensuring that persons who are susceptible to physical or psychological harm, exploitation, or coercion, are recognized as such and safeguarded while entitled to meaningful engagement and respect. (ten Have, 2015; Zion, Gillam, & Loff, 2000). Biomedical research in low-income countries often involves participants who are vulnerable to a complex range of risks in their daily lives such as food insecurity/hunger, unemployment or job insecurity, exposure to and experience of violence, illness, disability, or premature death. Further, those living in extreme poverty navigate these challenges and make choices, albeit constrained by difficult circumstances.

However, population-based accounts of vulnerability in research have come under scrutiny for failing to reflect diverse global contexts, and for failing to account adequately for the agency of vulnerable people (Levine et al., 2004; Rendtorff, 2002; Rogers, Mackenzie, & Dodds, 2012; ten Have, 2015). This lack of balance and sensitivity to context limits the usefulness of research ethics protections to guide research practice. The manner in which vulnerability is operationalised in research ethics is often shaped by stereotypes and reinforces stigma about entire categories of individuals, over ascribing vulnerability to some and failing to capture hidden vulnerabilities in others (Bracken-Roche, Bell, Macdonald, & Racine, 2017; Luna, 2009; Luna & Vanderpoel, 2013; Rodriguez, 2017). For designated groups, such as young people and pregnant women, this more protective, paternalistic approach has inadvertently led to their exclusion from potentially beneficial research (Lyerly, Little, & Faden, 2009; Macklin, 2010).

Vulnerability is relational, and characterized by power asymmetries between participants, research staff, and socio-cultural and political institutions (Lange, Rogers, & Dodds, 2013; Luna, 2019; Luna & Vanderpoel, 2013; Lyerly et al., 2009). Conceptually, it has been argued that research ethics guidance may better serve otherwise vulnerable participants by encouraging measures that would empower and promote their agency in the research context (Bracken-Roche et al., 2017; Lange et al., 2013). Empirical studies have begun to examine and challenge how vulnerability is conceptualized in research and clinical trials and serve as a tool for building the evidence for improved interventions targeting vulnerable groups (Sengupta, Lo, Strauss, Eron, & Gifford, 2011). However, we still lack a context-specific understanding of how participants' vulnerabilities, agency and social relationships manifest in the research encounter, and how practical ethical guidance for researchers might be improved. To contribute to addressing this gap, we conducted an ethics case study using qualitative methods, embedded within an evaluation of a real world scale up of combination HIV prevention intervention for adolescent girls and young women (The DREAMS partnership) in a rural district in KwaZulu-Natal, South Africa (Birdthistle et al., 2018; Chimbindi et al., 2020; Gareta et al., 2021). We explored and highlighted the complex sources of vulnerability and the ways in which researchers and study participants navigate ethical obligations in this contentious landscape.

2. Material and methods

2.1. Theoretical background

To investigate recent conceptual shifts in thinking around vulnerability and the ethical issues that arise in research practice, our choices of setting, population and study design were informed by recent work on vulnerability and agency in feminist bioethics (Lange et al., 2013; Rogers et al., 2012). Accounts within this tradition share several important features in common, underscoring the importance of relationality and power, considerations of agency or choice, and situating ethical obligations within social, political, and cultural contexts. As Luna has argued, vulnerability as an ethical concept is "layered", often representing multiple susceptibilities to specific harms. These layers interact and often reinforce one another – as in cases of poverty, limited education, or living in a conflict zone (Luna, 2009). This view resonates with earlier work on intersectionality in feminist social science, which argues that the intersectional nature of social categories – such as gender, age, socioeconomic status, and race – converge to both exacerbate and hide deprivation and discrimination for marginalized persons (Kapilashrami, 2019). Rogers, Mackenzie and Dodd (2012) have further argued for the importance of not only considering how we ought to mitigate the vulnerability of others but do so in such a way that does not diminish individual autonomy or agency (Rogers et al., 2012). For example, policies that attempt to address gender-based violence (GBV) may exacerbate a woman's vulnerability if the level and quality of services are poorly designed, resulting in a sense of powerlessness and diminished agency (Nkosi et al., 2020). Responses to vulnerability should respectfully facilitate individuals' capacity and desire to make choices and have control over important decisions in their life, even when that capacity is severely limited by circumstances.

This normative obligation to balance protection and respect for agency, in turn, generates a need to carefully consider the broader context and sources of vulnerability, as we need rich descriptions of someone's situation to get the balance right. The additional attention to context helps refine our ethical obligations to respond in a way that minimizes the full range of risks and harms (Lange et al., 2013; Rogers et al., 2012). Taken together, and considered in social context, vulnerability and agency are relational and deeply social in nature. We all depend on other people, support systems or institutions, and these can either constrain or enable a person's agency and mitigate or worsen a person's vulnerability.

For this analysis, we adapted a feminist framework for identifying intersectional, overlapping sources of vulnerabilities in daily living and exploring how these raise ethical challenges and opportunities in the research encounter. We draw on this model to explore how researchers balance protection with respect for participants' agency, avoiding both stereotyping and paternalism. We refer to 'intersectional' sources of vulnerability, drawing on a socio-ecological layering which highlights the interconnectedness of the sources of influence which shape vulnerability (Hankivsky et al., 2014). In addition, by acknowledging the ways that different sources and types of vulnerabilities will yield different moral and political obligations, we are able to target ethical obligations to be more responsive to the complex sources of vulnerability – a critical conceptual tool for improving practical research ethics guidance.

2.2. Integrated ethics case study design

This case study focused on adolescent girls and young women (AGYW) vulnerable to multiple risks to HIV including social, economic, behavioural and biological (Chimbindi et al., 2018). The boundaries of the case were defined by the experiences and perspectives of research staff and participants involved in the (evaluation study, but many of the ethical issues raised and experiences shared go beyond the intervention and refer to broader experiences. Here we report overall findings related to participant vulnerabilities and agency in daily life and as experienced in research participation.

2.3. Setting

This study took place in uMkhanyakude district, a predominantly rural area with a high HIV prevalence among 15–24 year old of 19% among young women and 5% among young men, as well as a high burden of poor sexual and reproductive health among this age group (Francis et al., 2018). The dominant social determinants of health include unemployment (>80% among out of school people and lack of basic services (Gareta et al., 2021).

The Africa Health Research Institute (AHRI) has been carrying out population-based health and demographic surveillance in the district for over a decade (28). This surveillance includes an annual population-based HIV surveillance since 2003; and residents aged 15 and over were eligible for participation in the surveillance from 2007. AHRI's Public Engagement team and the Community Advisory Board (CAB) members build and foster partnerships between researchers and local study communities by enhancing the ability for a constructive, interactive and integrated engagement with local communities.

2.4. Recruitment and data collection

We used a qualitative approach to conduct focus group discussions (FGDs), in-depth interviews (IDIs), and key informant interviews (KIIs). The manuscript adheres to the COREQ (Consolidated criteria for reporting qualitative research) guidelines for reporting qualitative studies (Tong, Sainsbury, & Craig, 2007). **See Supplementary file 1: COREQ 32 item checklist.**

The sampling framework was designed to gain insights from the research ecosystem that surrounded the study. Participants were recruited face to face in the schools, community and via email using purposive sampling. We explained the study aims and rationale during recruitment, and during the consent process. We recruited seventy-seven participants, sixty-five people participated in focus group discussions (FGDs); nine in in-depth interviews (IDIs) and three in key informant interviews (KIIs). Participants were recruited from three categories from the linked study (DREAMS') Implementing Partners (IPs), AGYW, and caregivers; 2) ethics committee members, who provided perspectives on research involving vulnerable populations, and ethical dilemmas; and 3) community stakeholders who provided the broader community context and wider perspectives about research in their community. Only AGYW,

and adolescent boys and young men (ABYM) were recruited based on age and gender pre-set during the HIV intervention program. Participants were recruited from rural and peri-urban areas. We did not ask participants for specific ages, but categorised participants according to age ranges. (Table 1: Data collection methods and study sample). There were five refusals, the reasons given were time constraints (n = 3) and lack of interest (n = 2).

Piloted interviews were conducted with ten participants, six AGYW, 2 research assistants and 2 community members. Data obtained during pilot interviews were excluded in the analysis but helped informed subsequent interview tools and our understanding of the context.

Data collection was conducted from December 2017 to July 2018. Interviews were conducted by BN, experienced in health and social science research (PhD), and two research assistants, male, and female, trained in social science and qualitative research methods. The interviews were conducted at the participants' homesteads, community halls, AHRI offices, and by telephone in isiZulu and English. FGDs with AGYW and ABYM were stratified based on age (10–14 years) and (15–17 years) respectively and gender. We used semi-structured interview guides, and audio-taped interviews lasted from 45 to 60 min. **See Supplementary file 2: Interview guides**. The interviews were conducted until data saturation was reached. We did not conduct repeat interviews. BN conducted weekly debrief sessions with the fieldworkers and reviewed interview summaries and field notes to capture and reflect on the interview context. JS and MK attended some debrief sessions.

Following initial analysis, study findings were presented to the PE officers and CABs to enable peer validation of findings and collective reflective learning. We did not use incentives for participation in the study, participants were reimbursed for transportation, and refreshments were provided during the interviews. We obtained informed consent prior to interviews and participation was voluntary.

Table 1
Data collection methods and study sample.

Group 1: Participants from the intervention linked study			
Participants (years)	**Age**	**Data collection method**	**Sample (n=)**
Adolescent girls and young women	10–14	Focus group discussion	6
Adolescent girls and young women	18–24	Focus group discussion	7
Adolescent girls and young women	18–24	Focus group discussion	7
Caregivers	30–40	Focus group discussion	4
Implementing partners	30–40	In-depth interviews	5
Frontline researchers	20–30	Focus group discussion	8
Researchers	30–40	In-depth interviews	2
Group 2: Ethics committee members, Public Engagement officers; Community Advisory Board members			
Ethics committee members	50–60	Key informant interviews	3
Public engagement officers	30–50	Focus group discussion	6
Community advisory board members	20–50	Focus group discussion	5
Community advisory board members	20–50	Focus group discussion	6
Community advisory board members	20–50	Focus group discussion	6
Group 3: Community members and stakeholders			
Community members	40–60	In-depth interviews	2
Adolescent boys and men	10–14	Group discussion	3
Adolescent boys and young men	18–24	Group discussion	2
Community caregivers	30–40	Focus group discussion	5
Total:			77

2.5. Analysis

We used thematic framework analysis to examine perspectives of the study participants, highlighting similarities and differences, and generating unanticipated insights (Aronson, 1995; Nowell, Norris, White, & Moules, 2017). Transcribed interviews were translated into English and analysed iteratively for themes using thematic framework analysis. The study team met regularly to reflect and to revise emerging codes and themes throughout the analysis process. BN, MK and JS conducted initial open coding independently. Themes were determined by the study aims and content of the interview guides combined with an inductive development of codes as they emerged from the data. BN developed a codebook which the study team revised and modified to reflect emerging themes throughout the analysis process, adjusting some codes in the process.

Once the themes were identified, connections across themes were sought through ordering and re-ordering using NVivo 12 (QSR International) (Bernauer, Lichtman, Jacobs, & Robertson, 2013). We explored these themes with reference to the framing of vulnerability, agency and resilience as well as research and ethical dilemmas. Differences and discrepancies were discussed until a consensus was reached (See Table 2: Coding process example.). A descriptive narrative approach is used to present the findings.

Given the interest in exploring the themes of vulnerability, agency and resilience at the outset, the topic guides were based on working definitions of vulnerability and agency from the social science and research ethics literatures. We avoided use of these specific words as they did not translate directly in local language, isiZulu and relied on the participants' own descriptors. Vulnerability was characterized as a participant's sense of being or feeling more susceptible to harm, exploitation by others, and risks of any kind (health, social, psychological), or third person descriptions of the same range of feelings. The study also probed for specificity and sources and causes of vulnerability from the participant's perspective wherever possible, considering, "vulnerable to what?" as opposed to a general state of being. Furthermore, we reflected on power relations in our setting, not just gendered but also intergenerational and structural power relationships such as researchers-participant relationships, and the relationships between research institution and communities, and how power structures influence access to employment (for researchers) as well as access to health among study participants.

3. Results

We have organised our results to illustrate the intersection between the vulnerabilities and agency experienced by participants' in their daily lives, how these manifest in the research encounter, and ethical dilemmas and lessons. These are synthesized in Fig. 1 which illustrates how overlapping primary sources of vulnerability — poverty, age, gender, health and social situation give rise to ethical challenges and opportunities in research. We also show how individuals and institutions can constrain or enable participants' agency and autonomy, and illustrate the unintended consequences of focusing on specific disease and population groups. Finally, we describe issues around consent, power and voluntariness, as well as frontline researchers' ethical dilemmas and empathy during the encounter with the participants.

3.1. Intersectional sources of vulnerabilities and the research encounter

This theme focused on the ways social, political, and economic vulnerabilities in daily living manifested in research participation. This was particularly striking in the relationship between research participants and members of the research team who witnessed the daily struggles of participants. For example, inherent characteristics, such as age and gender, intersected with poverty; with children and younger women being described as easy prey for older men for their survival.

Table 2
Example of the coding process.

Code	Category	Subcategory	Meaning unit
Vulnerabilities	Poverty	Unemployment	… I think it's worse for women who are unemployed, who are unable to financially support their children. There is that emotional weight and it makes it difficult for them to talk about it. [FGD, Public engagement officer, female].
		Financial resources	It's not every parent who will have money to provide for their [children's] needs. Some older of the men lure girls as young as 10 years and buy them fast food and have sex with them. [IDI, community member, female].
	Age	Children	There are young [women] who live alone, without any adult taking care of them. Eventually most of them end up in trouble because there is no adult to look after them and protect them. They must fend for themselves and this puts them at risk because some people take advantage of them, especially the young girls. [FGD, Community advisory board member, female].
		Elderly	We help old people like grannies and grandfathers, those who are very poor and living alone. We help them by donating money and buy them something. [FGD, Adolescent girls and young women, 10–14 years, females].
	Gender	Girls, boys, women, men	It's definitely true that girls fifteen to twenty years who are mostly affected. Why, does a fifteen-year-old teen date a person who is over thirty-five years, an old person. For some (of the girls) it is for survival, to get money and food. [Group discussion with males]
	Stigma		When people see us, they think of HIV … are afraid of being seen by other people. As young people, yes there are those who engage in risky behaviours and have the HIV virus. It's not all of us. But we are all cast in a negative way just because we are females and young … [FGD, adolescent girls and young women, 18–24 years old].
Support	Sources of support	Family, friends, researchers	In most cases I talk to my cousin sisters and their mother. Then I feel like something that has been taken off of my shoulders. I sometimes go to my sister and talk to her, it makes me feel better. [FGD, Adolescent girls and young women, 18–24 years].
	Lack of support	Institutions: economic, political	Like participant #6 over there, number and #5 they are very good with doing people's hair. They need networks and people who can help them develop their business. [FGD, adolescent girls and young women, 18–24 years old].
		Family	A lot of kids would say 'my uncle once raped me' … One of the young girls gave birth to two kids by her step-father … The mother will ask 'If you say the step-father must go to jail then who is going to support the family?' [IDI, Implementing Partner female].
Ethical issues in research	Consent, power and voluntariness		People feel indebted and think that refusal might negatively influence (potential) return of the mobile clinics down the line. This blurs the concept of voluntary participation and, on the surface, it might seem like participation is voluntary when in fact it is not. [FGD, CAB, male]
			I don't know how far does the issue of 'voluntary participation' go because you can see that a person is not interested. The participant will participate because maybe they feel sorry for you or they just want to get this over with, So, no matter how we put it, it's the same, we're Africans. [FGD, frontline researchers, male].
			I think that for the poorest and indigent, they enrol their participation not because they understand the study, but because of the incentives in form of R50 vouchers. When they hear about the vouchers, they are calculating 'ok I will be able to buy something to eat, or make ends meet'. [FGD, Public engagement officer, female].
	Compensation		Many in the community chase [institute's] vehicles demanding to participate 'hey you did not visit my house, who qualifies to receive this (R50).' It creates problems because they want to participate because of the R50 [reimbursement]. [FGD, Community advisory board member, female].

It's definitely true that it's girls fifteen to twenty years who are mostly affected. Why, does a fifteen-year-old teen date a person who is over thirty-five years; an old person? For some (of the girls) it is for survival, to get money and food. [Group discussion with males].

It's not every parent who will have money to provide for their [children's] needs. Some older men lure girls as young as 10 years and buy them fast food and have sex with them. [IDI, community member, female].

Programme Implementing Partners (IPs), CAB members and PE officers described how, through their research roles, they learned that many children were victims of physical and sexual abuse. In many cases, parents, and often mothers, 'were covering up' because they were economically dependent on the perpetrators.

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Research staff and PE officers observed that poverty and unemployment were engendered, often reinforcing male dominance, as many women depended on men for financial support. Consequently, many women were trapped in abusive relationships, and shared with research staff that they felt ashamed talking about their situation.

… I think it's worse for women who are unemployed, who are unable to financially support their children. There is that emotional weight and it makes it difficult for them to talk about it. [FGD, Public engagement officer, female].

Researchers described community members' motivation to participate in research as a means to ameliorate situational vulnerabilities through access to health care, and food vouchers to cover basic needs. For many, receiving vouchers in a form of reimbursement, albeit small, provided opportunities to supplement their income. The annual demographic surveillance at the institute provides vouchers valued at R50,00 (about $2.64 at the time of the study) per household, and/or airtime vouchers.

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The PE staff reported that community members did not understand concepts of sampling or targeted recruitment therefore there was an expectation that all community members would all be invited to participate in new studies.

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this (R50)?' It creates problems because they want to participate because of the R50 [reimbursement]. [FGD, Community advisory board member, female].

Participants understood that the benefits of research were realised at multiple levels, such as influencing policy, publications, and informing health intervention programmes. However, many raised concerns that they rarely obtained tangible benefits at the individual level. Health related needs were not always regarded as the priority, and they suggested that the institute must align its research with other needs.

… what about us? People are concerned about young people that 'our kids have finished school, and are still at home, what is the [institute] doing about that because they are getting something from us. This means they should also try to support us here and there'. [FGD, Community advisory board member, female].

CAB members, PE officers and frontline researchers reported that participation in research was often shaped by community members' previous experiences and history of the research institute. For example, in a previous cluster trial the research institute had provided community-based HIV testing and deployed mobile clinics within the communities. Reflecting on that experience, participants expected that research would alleviate their needs, not always realising that tackling their daily needs and vulnerabilities was beyond the research project's remit.

3.2. Sources of support and constrained agency

While there is often a perception that those who are highly vulnerable lack choices or agency in their own lives, the young girls in this study demonstrated strategies for navigating challenges in their daily lives and through participation in research. Although their range of opportunities were constrained by circumstances, choices and plans were nearly always described in relational terms. Support from social networks and peers and institutions including family, church, and the intervention programme reinforced participants' resilience and coping mechanisms. For most participants, emotional support helped them through difficult times.

In most cases I talk to my cousin sisters and their mother. Then I feel like something that has been taken off of my shoulders. I sometimes go to my sister and talk to her, it makes me feel better. [FGD, Adolescent girls and young women, 18–24 years].

Most AGYW portrayed themselves as proactive and demonstrated agency by being agents of change in the community. Many reported that they sustained their families from the social grants, and income generating activities they were involved in. Younger adolescent girls and young women (10–14 years) reported that because of participating in the HIV intervention programme they developed the skills and empathy to care and support the elderly.

We help old people like grannies and grandfathers, those who are very poor and living alone. We help them by donating money and buy them something. [FGD, Adolescent girls and young women, 10–14 years, females].

Whereas for other AGYW, life choices were severely limited by difficult living conditions, lack of basic resources and lack of protective social systems. For these girls, subjection to social, emotional and financial harm constrained their choices in profound ways and put them at risk for exploitation.

There are young [women] who live alone, without any adult taking care of them. Eventually most of them end up in trouble because there is no adult to look after them and protect them. They must fend for themselves and this puts them at risk because some people take advantage of them, especially the young girls. [FGD, Community advisory board member, female].

As illustrated, research staff observed and young women described a range of situations faced by AGYW with some facing situational challenges with resilience through the support of social networks, and others struggling to survive. While staff tended to focus risks and vulnerabilities, the young girls also described choices and strategies for navigating their lives.

3.3. Focusing on vulnerability can have unintended consequences for vulnerability

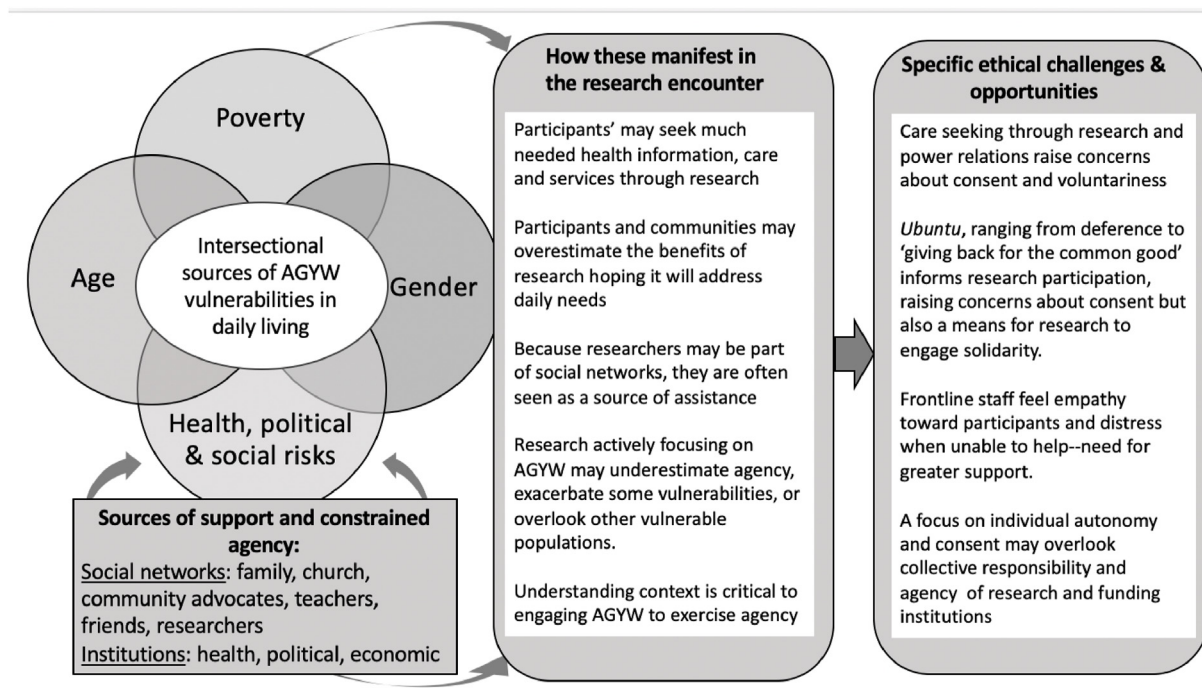As described, the linked evaluation study was assessing a package of

Fig. 1. How intersectional sources of vulnerability and constrained agency in daily living manifest and raise ethical considerations in the research encounter.

interventions for HIV-prevention specifically targeting young girls susceptible to HIV. As we learned, even programmes focused on advocating for one group or targeting a specific, serious health vulnerability may inadvertently worsen other vulnerabilities. Participants in our case study discussed several limitations and unintended consequences of this otherwise well-intended approach. We identified three sub-themes on the unintended consequences for vulnerability of programme focus, 1) targeting AGYW as a vulnerable group may have worsened their vulnerability; 2) focusing on one vulnerable group in a context of wider social deprivation will likely leave out other groups who consider themselves vulnerable, and 3) the tensions in legal requirements and ethical guidelines may worsen adolescents' vulnerability in research.

3.3.1. Targeting AGYW as a vulnerable group may have worsened their situation

In discussions, AGYW reported their weariness in being targeted for HIV interventions. And for many AGYW, the focus on HIV prevention targeting AGYW did not have the desired effect, as one participant stated, "the problem is that we are all seen as HIV positive." They argued that this compounded the HIV-related stigma in this age group. As many were single parents and taking care of ill family members, they reported that their most pressing needs were employment, opportunities to further education and support from health and social services.

> When people see us, they think of HIV … are afraid of being seen by other people. As young people, yes there are those who engage in risky behaviours and have the HIV virus. It's not all of us. But we are all cast in a negative way just because we are females and young … [FGD, adolescent girls and young women, 18–24 years old].

> Like participant #6 and #5 they are very good with doing people's hair. They need networks and people who can help them develop their business. [FGD, adolescent girls and young women, 18–24 years old].

Despite the HIV intervention programme being comprehensive and designed to empower adolescent girls and young women, participants felt that the implementation was focused on the individual level, raising questions about underlying structural and gender dynamics driving risk. They viewed men as having innate power or dominance over women.

3.3.2. Focus on one group may overlook needs of other vulnerable groups

In interviews with the CAB members, although PE officers and frontline researchers appreciated the burden of HIV among AGYW, they expressed concerns that "there is too much focus on women and HIV". The interviews showed that in the context of broad socio-economic deprivation, focusing on one group overlooks the needs of other groups. For example, they pointed out that elderly persons are vulnerable to economic, and health risks, and that, they too, require support.

Similarly, participants expressed strong views about the exclusion of young boys. They indicated that excluding young boys from HIV intervention programmes was counterproductive, especially in a patriarchal setting, and failed to address the status quo and the entrenched gender power imbalances. They felt strongly that young boys are equally critical in the fight against HIV and AIDS.

As participants' experiences show, there can be unintended consequences of applying group-based vulnerability involving young women, resulting in unnecessary exclusion of other individuals in the vulnerable population categories, such as young boys or older adults.

3.3.3. Tensions between justice and protection in legal requirements and ethical guidelines may worsen adolescents' vulnerability in research

Interviews with the research ethics committee (RECs) members highlighted the complexities in the legal norms, National Health Act, Section 71 which contain protections for adolescent participation in research. RECs indicated that in the process of protecting adolescents from exploitative or undesired research, is a tension between their

protection, and excessive regulation may undermine their emerging autonomy, or result in adolescent research being unfeasible. For example, the blanket requirement of parental consent for all research involving adolescents' risks disclosing sensitive information to the parents, and may result in adolescents refusing to participate. RECs members indicated that adolescents may be vulnerable because of certain choices therefore 'there are some instances where older adolescents could give consent on their own'.

> … In some instances children live with the parent or legal guardian, but they are older, they might be 16 or 17 and they do not want to involve their parent or legal guardian because of the nature of the research. The research might be for example, adolescent MSM (men who have sex with men), sexual orientation, or ToP (termination of pregnancy). Sometimes the behaviour is illegal e.g. drug, sex worker and that's why you do not want to tell your parents. KII_3, [Research Ethics Committee member, female].

Furthermore, RECs argued that mandatory parental consent, may unintentionally exclude adolescents who do not have the parent or guardian.

> Many vulnerable children in the communities where we are doing research do not have a parent or legal guardian. So, if you apply the legal guidelines, then that group is excluded from research participation. [KII_2, Research Ethics Committee member, female].

These contradictions make it ethically difficult to conduct research with adolescents. Interviews also showed that mandatory parental consent is likely to compromise adolescents' confidentiality, thus making it hard for them to participate in research that would benefit them.

3.4. Ethical issues, lessons and opportunities

Beyond considering the unintended consequences of the programme design, focus, and inclusion, other specific ethical issues were raised that offer lessons and opportunities for implementation research engaging vulnerable persons.

3.4.1. Consent, power and voluntariness

This theme highlighted the complexity of voluntary participation in light of participants' vulnerabilities and power relationships between the participants and the research institute. The narratives with frontline researchers, PE officers and CAB members suggested that voluntariness could be compromised by authority figures who can exert undue influence and coerce the young people to participate in research.

> … there are also cases where you'll get into a household and find a child sitting along with his/her parent – obviously you won't start explaining to the child and ignore the parent. So, you start with the parent, explain everything about the research; and then you ask to explain it to the child too … So, if the parent agreed, then child will feel like 'just because the parent has agreed, I am also forced to agree.' [FGD frontline researchers, male].

As in many African settings, obtaining consent involves various gatekeepers with power and influence in the community, such as tribal authorities. The tendency to entrust one's well-being to an authority figure makes it difficult to ensure voluntariness. Narratives of PE officers and researchers suggested that there might be unintended coercion to participate in the study if the local chief had given permission for the study in their jurisdiction.

The interviews with CAB, PE officers, researchers and community members also suggested that research created certain expectations of direct benefit and a sense of obligation among community members. For example, a clinical trial previously conducted by the institute deployed the much-needed mobile clinics in the community. Narratives with PE officers, CAB members, and researchers suggested that this created a

sense of obligation from the community with the hope that their participation might result in the institute reinstating the mobile clinics to mitigate weak health systems.

> That has impact in the community. People have that idea that 'if I participate maybe I might help in bringing the mobile clinics back in the community.' [FGD frontline researchers, male].

This sense of obligation raised questions about voluntariness, illustrated in the excerpt below:

> People feel indebted and think that refusal might negatively influence (potential) return of the mobile clinics down the line. This blurs the concept of voluntary participation and, on the surface, it might seem like participation is voluntary when in fact it is not. [FGD, CAB, male]

We also identified the notion of '*ubuntu*', a system premised on a collective responsibility and obligation to participate for the good of the community. So some community members took pride in participating for the greater good of the community. Interviews with the CAB members, PE officers and frontline researchers indicated that rural communities are generally socialised to believe that it is impolite to say no when asked to help outsiders, and study participants were no different. Frontline researchers acknowledged that some of the community members participated in the study "because maybe they are feeling sorry for you".

Frontline researchers explained the nuances in obtaining informed consent. The following narratives illustrate the complexity of consent, power and voluntariness.

> I don't know how far the issue of 'voluntary participation' goes because you can see that a person is not interested. The participant will participate because maybe they feel sorry for you or they just want to get this over with, So, no matter how we put it, it's the same, we're Africans. [FGD, frontline researchers, male].

3.4.2. Frontline researchers' empathy with participants created ethical dilemmas

This theme focused on a range of ethical dilemmas facing frontline researchers and PE officers and the emotional distress they experienced due to their inability to help. Some of the frontline researchers reported that it was emotionally difficult for them to hear anecdotes of young girls being sexually active. Others reported feeling sad that many AGYW were not able to find employment nor pursue their studies due to financial difficulties.

> There was a learner who did well in matric [senior] high school, and she wanted to further her studies. She asked if [the institute] since [information redacted to maintain the integrity of the review process] works with young people. I told her that unfortunately, [the institute] does not have an educational program for young people who want to further their studies. These re the difficulties that we face. You just try to recruit or conduct interviews and leave them like that.

The evaluation study team expressed moral distress and helplessness about their inability to respond to the participants' immediate needs, as opposed to the research contribution which seemed further off in the future. Some expressed concerns about research being a burden given participants' time spent during interviews, often with little 'tangible' benefits to the individuals.

> Research can be a burden. A lot of people's time is being consumed, but there is no benefit, it is like they are being exploited in a way. So, it's like 'you're exploiting me if you want my information, but I don't benefit anything now'. [FGD, frontline researchers, male].

The staff, including PE officers, HIV programme staff, and CABs were often the source of support for the many participants. For example, lack of primary documents, such as identity documents or birth certificates, posed insurmountable challenges as these are linked to accessing social

grants. So, the staff advocated for expedited services on behalf of the participants, often under intense resistance from the government departments.

Frontline researchers had to navigate their roles as community insiders and researchers. These roles became blurred as they increasingly received requests for support and advice on a variety of problems. They passionately advocated for the institute to put systems in place to support and improve families' and communities' living conditions. They felt moral distress as they walked away from impoverished families.

> It's difficult to talk to someone who tells you that they are hungry, and there is nothing you can do about it. You just try to recruit or conduct interviews and leave them like that ... [FGD frontline researcher, male, 20–30 years].

Narratives with the frontline researchers, CAB members, PE officers, IP, and AGYW (17–24) showed that many women and children in the community were subjected to interpersonal violence. However, most women were reluctant to report these incidents for fear of retribution by family or community members. Frontline researchers were reluctant to report these cases to the study supervisors despite Standard Operating Procedures (SOPs). This was primarily to protect the participants because reporting these cases could do more harm than protect the participants. For example, there were concerns about confidentiality, fear that the perpetrator/s might retaliate, and sheer lack of sensitivity in handling GBV. Secondly, as members of the community, the frontline researchers stated that they did not feel safe about reporting these issues because "*we also live in the same communities*". As a result, frontline staff often referred AGYW to health facilities for HIV counselling and testing.

3.4.3. The role of research in strengthening young people's collective autonomy and the community members' power to inform research

Interviews with CAB members and PE officers highlighted the limitations and benefits of research. One of the serious limitations of current research programmes from their perspective was the limited role for communities' voices in setting the research agenda. They expressed a growing sense of what research the community wanted. This was reflected in participants' concerns that the research mainly focused on HIV and excluded other health problems such as non-communicable diseases.

> (community members) ask us 'why don't you do research on cancer, because it's devastating our community, or why don't you do research on chronic illnesses such as BP, diabetes. The community feels that there is a high rate of mortalities resulting from chronic illnesses. [FGD, Public engagement officer, female].

Similar views were echoed during informant interviews with ethics committee members, who were critical about using ethical guidelines as a check list rather than attending to the challenging ethical issues facing vulnerable groups. They advocated for meaningful research that directly benefits those deemed vulnerable.

> Doing research with young people is challenging. I think the onus is on all of us as researchers and people working in research ethics to rethink where there are major gaps on the specific guidelines to motivate for their revision ... There needs to be a culture of trying very hard to make sure that research is tailored to answer questions of central interest to them [vulnerable groups]. [KII, Ethics committee member, female].

However, interviews with PE officers showed that persistent community research education and engagement campaigns were starting to make a difference. PE officers observed a shift in communities' attitudes towards research.

> ... the community now understands research better than they used to in the past. Now they do not just respond to the questions asked, but they want to know why certain questions are included. They ask

questions such as 'what is the purpose of the study, what is the impact of the study? [FGD, public engagement officer, male].

Frontline researchers also shared ways that research can be used to 'give back' to the communities. Some of the direct benefits highlighted included linking participants to health care services and provision of seamless health care compared to public health facilities. Suggestions pointed to use of data to inform public health programmes and strengthen the public health system to address widespread health problems in the area.

The publications are used by experts to identify the gaps and develop interventions accordingly. In the long run, the health system improves. [FGD Frontline researchers, male].

Furthermore, discussions with the CAB members and PE officers showed that research could help community members deal with HIV-related stigma. The community might ultimately become comfortable talking about HIV and their [HIV] status as community members increasingly discussed and participated in HIV studies.

… I remember at first, nobody would listen to us as soon as we wanted to talk about HIV and AIDS, they would say 'oh do not start with that diseases, that plague' … Now I look at how far we have come, and people are not afraid to talk about their [HIV] status as they used to be. This shows how the attitudes change when we work together. [FGD, PE officer, female]

4. Discussion

Our study findings illustrate how overlapping primary sources of vulnerability — poverty, age, gender, health and social situation give rise to the ethical challenges and opportunities in research … and we also show that understanding the social structures is crucial for interventions seeking to improve the health and social well-being of AGYW. The study also challenges how vulnerability has been characterised in long-standing research ethics guidance, and how this in turn creates ethical blindspots for research staff and institutions, and confirms more recent characterisations of vulnerability as complex and layered Council for International Organisations of Medical Sciences (CIOMS, 2016; Luna & Vanderpoel, 2013). Specifically, our study reveals gaps in how research ethics accounts for structural vulnerability and participant's resulting needs in the research encounter. Drawing on our conceptual framework (Fig. 1), we have shown that participants' vulnerabilities in daily life are intersectional and multi-layered and shape the research encounter between frontline researchers and participants. Yet, research ethics obligations tend to focus more narrowly on the boundaries of research projects and aims. Our data also reveal the importance of constrained agency among those who are vulnerable. This confirms accounts of vulnerability in theoretical research ethics but further grounds these concepts in participants', researchers' and community members' direct experiences (Luna, 2009; Rogers et al., 2012). In doing so, we can better appreciate the difficulty of navigating such complex needs in the relatively narrow confines of a research study.

Furthermore, the formulation of the HIV problem and the resultant focus of international and local attention with respect to AGYW also overlooked the opportunity to understand the unique needs of other vulnerable sub-populations, including adolescent boys and young men, and older adults. Although the intervention programme was comprehensive and designed to address behavioural, structural and bio-medical interventions, focusing on AGYW raised ethical concerns including the exclusion of 'other' vulnerable groups and the subsequent power structures which constrain AGYW's agency. This study therefore raises three important issues: firstly, the importance of how researchers can use research to navigate the complexities of conducting research in constrained settings. Secondly, how the research encounter can strengthen AGYW's ability to navigate the intersectoral vulnerabilities. Thirdly, how

the research encounter can strengthen AGYWs' individual autonomy and importantly strengthen collective agency and create power to influence research strategy.

Our study also demonstrates tensions between individual autonomy versus collective responsibility and agency. By placing the collective responsibility and obligation on the relationships which the individual has with others in community, the worldview of 'ubuntu' may inadvertently place limits on the individual autonomy, especially for young women who are low in the order of intergenerational and gendered power. This raises concerns about whether the young women feel obliged/coerced to participate to please their elders, the community leaders, or to get the compensation. Therefore, AGYW's ability to exercise agency is dependent on the social, economic and political context. Understanding the social structures is crucial for interventions seeking to improve the health and social well-being of AGYW.

Appreciating how intersectional sources of vulnerability manifest during research studies has important implications for ancillary care planning (authors, 2020). Our case study showed how well-meaning plans to respond to gender-based violence in the research context in fact generated new vulnerabilities stigma among AGYW, despite an HIV intervention programme designed to help them.

While the literature on vulnerability often presupposes that the concept of vulnerability stands in contrast to the concept of autonomy, our study shows that the two concepts are intertwined. In our study, AGYW perceived themselves as the agents of change in the community. This is in contrast with the literature on young people's agency which risks casting them as passive recipients of development and health interventions (Lorimer, Knight, Shoveller, Lorimer, & Knight, 2020). We also show that limiting vulnerability to diminished individual autonomy masks addressing other dimensions that keep groups vulnerable (Levine et al., 2004).

Consistent with the literature on vulnerability, our findings revealed that research ethics protections and guidance, and even the academic discourse, can become unduly paternalistic when enforcing institutions do not take into account the capacity for agency amongst those who are vulnerable in other ways (Grabovschi et al., 2013; Rodriguez, 2017; Zagorac, 2017). Targeting young women's vulnerability to HIV, as in our case study, we can see that even well-meaning research ethics policies and practice rely on implicit assumptions about the nature of a group's vulnerability—in this case, adolescent girls living with HIV, and often without taking into account the context (Bracken-Roche et al., 2017; ten Have, 2015). We showed that despite AGYW being active agents of the community, sustaining and supporting their families, research staff, research ethicists and policy makers' focus on their vulnerability to HIV masked their priorities and stifled voices. This was true of our own team's assumptions at the start of this project. We heard from the CAB, HIV intervention Implementing Partners, and frontline researchers that AGYWs' age and gender rendered them vulnerable. We reflect that this silencing of the AGYW voice and speaking on their behalf is itself a form of protectionism.

By linking vulnerability and relational autonomy, the research ethics model supported by our data goes beyond the mere protection of vulnerable people, but also seeks social, economic and health support to promote autonomy and empowerment for the AGYW, and the community (Lotz, 2016). Studies in resource limited countries including South Africa indicate that this protectionist approach has resulted in adolescents being under-represented in HIV clinical trials (Bekker, Slack, Lee, Shah, & Kapogiannis, 2014; Strode, Richter, Wallace, Toohey, & Technau, 2014). The study illustrates the delicate balance between protecting vulnerable groups and being overprotective to the extent of obscuring rather than enabling their autonomy and agency, as well as denying them access to potential interventions.

This approach does not, however, offer a clear limit for our obligations to engage vulnerability and agency in the research context — as illustrated, participants' needs in low-resource settings are complex and vast. However, it offers an important first step for planning sensitively

designed research studies, and rethinking the role of research institutions, funders, and government partners in not only responding to structural sources of vulnerability but engaging the collective agency of communities to actively shape research strategy. The findings show that because biomedical research is not well prepared to deal with structural vulnerabilities and wider social determinants of health and because frontline staff are themselves part of these communities struggling with structural vulnerabilities, they feel they should respond to needs outside of research and feel distressed when unable to do so in a sustainable way, or by virtue of professional constraints (Beard et al., 2018; Kingori, 2015). This points to a need for guidance in post-research ethics approval for responding to intersectional, structural needs in the research context. Similar to the findings reported in Kenya, and South Africa, our findings raise concerns about participants' understanding of informed consent, compensation and voluntariness and the tendency to overestimate the benefits of research (Kamuya, Theobald, Marsh, & Parker, 2015; Ngwenya et al., 2020; Nkosi et al., 2020). Finally, our findings show the importance of considering vulnerability and our ethical obligations in research in context, not viewing vulnerability in a vacuum. Consequently, (institute) has moved beyond this approach, and has embedded participatory community led methods with the young people to co-develop youth-led interventions informed by AGYW's needs, priorities and support their agency (Bernays et al., 2021; Shahmanesh et al., 2021).

4.1. Strengths and limitations

Working with an ongoing research project enabled us to map and explore different sources of vulnerability from the participants' own perspectives and consider the research encounter against the backdrop of their daily lives. However, this advantage introduced potential limitations. Since our study was embedded within the HIV intervention programme, this could have influenced some of the participants to provide socially acceptable responses regarding the intervention programme. Further, the translation of ethical concepts such as agency and vulnerability was complex and sometimes technical for the participants. To mitigate this, the interviewers had prior discussions about the definitions and translations and an agreed upon lay explanation was used. These terms were explained in lay terms by the interviewers in the local language and all interviews were translated verbatim to retain original participant views and meanings as some of the terms could not be translated into the local language.

5. Conclusion

We illustrate how implementation research aimed at addressing specific health vulnerabilities around HIV prevention, targeted at a specific vulnerable population, raised complex ethical questions about the role of research in responding to health and social vulnerabilities in South Africa. Our study illustrates the delicate balance between protecting AGYW and being overprotective to the extent of obscuring rather than enabling their autonomy and agency. Finally, our study suggests greater meaningful engagement of participants throughout the research process.

Biographical note

BN, PhD (Family Social Science) is a Senior Research Associate at the Africa Health Research Institute. Her research interest includes bioethics research, and she has conducted research on ethical challenges and equitable representation of adolescents in global health research. JS is a faculty member at the Africa Health Research Institute and Professor of Anthropology and Health at the London School of Hygiene and Tropical Medicine.NC, PhD, (Epidemiology) is a post-doctoral research programme manager for the HIV prevention programme at the Africa Health Research Institute (AHRI) in South Africa, leading on major mixed-method evaluation and development of complex HIV prevention interventions among young people. TZ PhD (Public Health) is a Senior Research Associate at the Africa Health Research Institute's Social Science and Research Ethics Department. She is involved in developing and supporting peer-led interventions focusing on sexual health promotion and peer-mentorship to navigate resources and improve retention in HIV care among adolescents and young people. Her research interests combine public health, health promotion and health literacy, with a focus on how community-based participation in health promotion and health literacy can function as a progressive force on the road towards enabling community members to make informed health choices to manage their wellbeing. MK is a Professor of Bioethics at the Ethox Centre and Wellcome Centre for Ethics and Humanities at the University of Oxford.MS is a faculty member at the Africa Health Research Institute and Professor of Global Health at University College London.

Ethics approval and consent to participate

The Biomedical Research Ethics Committee, University of KwaZulu-Natal approved the study (Ref BE524/17) and Oxford Tropical Ethics Research Committee (Ref 573-17). Participants were provided with participant information sheets and were given an opportunity to ask questions and withdraw before participating in the study. Written informed consent was obtained prior to data collection. For participants <18 years in addition to obtaining their assent, their parents or a caregiver (where applicable) gave written consent.

Ethical statement

The Biomedical Research Ethics Committee, University of KwaZulu-Natal approved the study (approval number, BE524/17) and Oxford Tropical Ethics Research Committee (Ref 573-17). Participants were provided with participant information sheets and were given an opportunity to ask questions and withdraw before participating in the study. Written informed consent was obtained prior to data collection. For participants <18 years in addition to obtaining their assent, their parents or a caregiver (where applicable) gave written consent.

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Authors' contributions

JS and MK conceived and designed the study. BN conducted and supervised the data collection. BN, JS and MK conducted the analysis and interpretation of data; BN, JS and MK drafted the manuscript; MS, NC and TZ critically reviewed and revised the manuscript. All authors read and approved the final manuscript. All authors read and approved the final manuscript.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Consent to publish

Not applicable.

Declaration of competing interest

The authors declare that they have no competing interests.

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Appendix A. Supplementary data

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References

Aronson, J. (1995). A pragmatic view of thematic analysis. *Qualitative Report, 2*(1), 1–3.

Beard, J., Skalicky, A., Nkosi, B., Zhuwau, T., Cakwe, M., Simon, J., et al. (2018). Challenges of developing a district child welfare plan in South Africa: Lessons from a community-engaged HIV/AIDS research project. *Global Health Promotion, 27*(2), 1–11. https://doi.org/10.1177/1757975918774569

Bekker, L.-G., Slack, C., Lee, S., Shah, S., & Kapogiannis, B. (2014). Ethical issues in adolescent HIV research in resource. *-Limited Countries, 65*, 24–28.

Bernauer, J. A., Lichtman, M., Jacobs, C., & Robertson, S. (2013). Blending the old and the new: Qualitative data analysis as critical thinking and using NVivo with a generic approach. *The Qualitative Report How To Article, 18*(2), 1–10. Retrieved from http://www.nova.edu/ssss/QR/QR18/bernauer2.pdf.

Bernays, S., Lanyon, C., Tumwesige, E., Aswiime, A., Ngwenya, N., Dlamini, V., et al. (2021). 'This is what is going to help me': Developing a co-designed and theoretically informed harm reduction intervention for mobile youth in South Africa and Uganda. *Global Public Health*, 1–14. https://doi.org/10.1080/17441692.2021.1953105. ISSN 1744-1692, In this issue.

Birdthistle, I., Schaffnit, S. B., Kwaro, D., Shahmanesh, M., Ziraba, A., Kabiru, C. W., et al. (2018). Evaluating the impact of the DREAMS partnership to reduce HIV incidence among adolescent girls and young women in four settings : A study protocol. *BMC Public Health, 18*(912), 1–15.

Bracken-Roche, D., Bell, E., Macdonald, M. E., & Racine, E. (2017). The concept of ' vulnerability ' in research ethics : An in-depth analysis of policies and guidelines. *Health Research, 15*(8), 1–18. https://doi.org/10.1186/s12961-016-0164-6

Chimbindi, N., Birdthistle, I., Floyd, S., Harling, G., Mthiyane, N., & Seeley, J. (2020). Directed and target focused multi-sectoral adolescent HIV prevention : Insights from implementation of the ' DREAMS partnership ' in rural South Africa. *Journal of the International AIDS Society, 23*, 54–59. https://doi.org/10.1002/jia2.25575

Chimbindi, N., Id, I. B., Shahmanesh, M., Osindo, J., Mushati, P., Ondeng, K., … Seeley, J. (2018). Translating DREAMS into practice: Early lessons from implementation in six settings. *PLoS One*, 1–17.

Council for International Organisations of Medical Sciences (CIOMS). (2016). *International ethical guidelines for international ethical guidelines for health-related research involving humans*.

Francis, S. C., Mthiyane, T. N., Baisley, K., Mchunu, S. L., Ferguson, J. B., Smit, T., et al. (2018). Prevalence of sexually transmitted infections among young people in South Africa : A nested survey in a health and demographic surveillance site. *PLoS Medicine, 790*(October 2016), 1–25.

Gareta, D., Baisley, K., Mngomezulu, T., Smit, T., Khoza, T., Nxumalo, S., et al. (2021). Cohort profile update: Africa centre demographic information system (ACDIS) and population-based HIV survey. *International Journal of Epidemiology, 50*(1), 33–34. https://doi.org/10.1093/ije/dyaa264

Grabovschi, C., Loignon, C., Fortin, M., Masi, R., Smedley, B., Stith, A., et al. (2013). Mapping the concept of vulnerability related to health care disparities: A scoping review. *BMC Health Services Research, 13*(1), 94. https://doi.org/10.1186/1472-6963-13-94

Hankivsky, O., Grace, D., Hunting, G., Giesbrecht, M., Fridkin, A., Rudrum, S., et al. (2014). An intersectionality-based policy analysis framework: Critical reflections on a

methodology for advancing equity. *International Journal for Equity in Health, 13*(1), 119. https://doi.org/10.1186/s12939-014-0119-x

ten Have, H. (2015). Respect for human vulnerability : The emergence of a new principle in bioethics. *Bioethical Inquiry, 12*, 395–408. https://doi.org/10.1007/s11673-015-9641-9

Kamuya, D. M., Theobald, S. J., Marsh, V., & Parker, M. (2015). The one who chases you away does not tell you go " : Silent refusals and complex power relations in research consent processes in Coastal Kenya. *PLoS One*, 1–22. https://doi.org/10.1371/journal.pone.0126671

Kapilashrami, A. (2019). Intersectionality and why it matters to global health. *The Lancet, 6736*(February), 10–13. https://doi.org/10.1016/S0140-6736(18)31431-4

Kingori, P. (2015). The 'empty choice': A sociological examination of choosing medical research participation in resource-limited sub-saharan Africa. *Current Sociology, 63*(5), 763–778. https://doi.org/10.1177/0011392115590093

Lange, M. M., Rogers, W., & Dodds, S. (2013). Vulnerability in research ethics : A way forward. *Bioethics, 27*(6), 333–340. https://doi.org/10.1111/bioe.12032

Levine, C., Faden, R., Grady, C., Hammerschmidt, D., Eckenwiler, L., & Sugarman, J. (2004). The limitations of "vulnerability" as a protection for human research participants. *The American Journal of Bioethics, 4*(3), 44–49. https://doi.org/10.1080/15265160490497083

Lorimer, K., Knight, R., Shoveller, J., Lorimer, K., & Knight, R. (2020). Improving the health and social wellbeing of young people : Exploring the potential of and for collective agency exploring the potential of and for collective agency. *Critical Public Health*, 1–8. https://doi.org/10.1080/09581596.2020.1786501, 00(00).

Lotz, M. (2016). Vulnerability and resilience : A critical nexus. *Theoretical Medicine and Bioethics, 37*(1), 45–59. https://doi.org/10.1007/s11017-016-9355-y

Luna, F. (2009). Elucidating the concept of vulnerability: Layers not labels. *International Journal of Feminist Approaches to Bioethics, 2*(1), 121–139.

Luna, F. (2019). Identifying and evaluating layers of vulnerability – a way forward. *Developing World Bioethics, 19*, 86–95. https://doi.org/10.1111/dewb.12206

Luna, F., & Vanderpoel, S. (2013). Not the usual suspects: Addressing layers of vulnerability. *Bioethics, 27*(6), 325–332. https://doi.org/10.1111/bioe.12035

Lyerly, A. D., Little, M. O., & Faden, R. (2009). The second wave: Toward responsible inclusion of pregnant women in research. *Int J Fem Approaches Bioeth, 1*(2), 1–12. https://doi.org/10.1353/ijf.0.0047 (The).

Macklin, R. (2010). The art of medicine Enrolling pregnant women in biomedical research. *The Lancet, 375*(9715), 632–633. https://doi.org/10.1016/S0140-6736(10)60257-7

Ngwenya, N., Luthuli, M., Gunda, R., Gumede, N. A., Adeagbo, O., Nkosi, B., et al. (2020). Participant understanding of informed consent in a multidisease community-based health screening and biobank platform in rural South Africa. *International Health, 12*, 560–566. https://doi.org/10.1093/inthealth/ihaa072

Nkosi, B., Seeley, J., Chimbindi, N., Zuma, T., Kelley, M., & Shahmanesh, M. (2020). Managing ancillary care in resource-constrained settings: Dilemmas faced by frontline HIV prevention researchers in a rural area in South Africa. *International Health, 12*, 543–550. https://doi.org/10.1093/inthealth/ihaa045

Nowell, L. S., Norris, J. M., White, D. E., & Moules, N. J. (2017). Thematic analysis : Striving to meet the trustworthiness criteria. *International Journal of Qualitative Methods, 16*, 1–13. https://doi.org/10.1177/1609406917733847

Rendtorff, J. D. (2002). Basic ethical principles in European bioethics and biolaw: Autonomy, dignity, integrity and vulnerability–towards a foundation of bioethics and biolaw. *Medicine, Healthcare & Philosophy, 5*(3), 235–244. https://doi.org/10.1023/A:1021132602330

Rodriguez, J. D. (2017). The relevance of the ethics of vulnerability. *The Ethics Forum, 12*(2–3), 154–179.

Rogers, W., Mackenzie, C., & Dodds, S. (2012). Why bioethics needs a concept of vulnerability. *International Journal of Feminist Approaches to Bioethics, 5*(2), 11–38. https://doi.org/10.2979/intjfemappbio.5.2.11

Sengupta, S., Lo, B., Strauss, R. P., Eron, J., & Gifford, A. L. (2011). How researchers define vulnerable populations in HIV/AIDS clinical trials. *AIDS and Behavior, 14*(6), 1313–1319. https://doi.org/10.1007/s10461-010-9785-x.How

Shahmanesh, M., Okesola, N., Chimbindi, N., Zuma, T., Mdluli, S., Mthiyane, N., et al. (2021). Thetha nami: Participatory development of a peer-navigator intervention to deliver biosocial HIV prevention for adolescents and youth in rural South Africa. *BMC Public Health, 21*(1), 1–13. https://doi.org/10.1186/s12889-021-11399-z

Strode, A., Richter, M., Wallace, M., Toohey, J., & Technau, K. (2014). Failing the vulnerable : Three new consent norms that will undermine health research with children. *South African Journal of Bioethics and Law, 15*(2), 46–49. https://doi.org/10.7196/SAJHIVMED.1014

Tong, A., Sainsbury, P., & Craig, J. (2007). Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews and focus. *Groups, 19*(6), 349–357.

Zagorac, I. (2017). What vulnerability? Whose vulnerability? Conflict of understanding in the debate on vulnerability. *Law and Politics, 15*(2), 157–169. https://doi.org/10.22190/FULP1701157Z