

# MODULE 6: COMMUNITY ENGAGEMENT



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# 1. INTRODUCTION

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Since the beginning of the HIV epidemic, community engagement has played an important part in clinical research and drug development. This is particularly true for adults living with HIV, in which activists are strongly involved in clinical trials and policy decisions – notably through community advisory boards. In addition, countries in Europe and the United States of America are starting to include patient perspectives in their health-care systems and decision processes, using value frameworks (1).

Although community involvement in biomedical research is not only expected but an essential requirement for funding (2), the involvement of children (or their caregivers) and adolescents lags behind that of adults.

This module describes the issues and complexity associated with engaging the paediatric community in the process of HIV drug research and development. It also provides solutions as to how best to involve the community. It aims to help researchers, drug manufacturers and regulatory authorities strengthen existing partnerships and develop new ones.

Despite limited evidence, the recommendations should facilitate effective engagement of the paediatric HIV community, taking into account consent procedures, legal and policy frameworks as well as the geographical and cultural context of the research.

## 1.1 Definition

This section aims to explain what “community” and “community engagement” mean in clinical research involving children and adolescents and in the context of this toolkit.

### 1.1.1. Community

Community is a broad and fluid concept. Individuals are always members of multiple communities, with views and perspectives that may have competing interests, potentially shifting over time with changing priorities.

#### Box 6.1. Definitions used in paediatrics

**Trial participant** (also called a human subject) – a person who participates in research and is observed by researchers

**Paediatrics** – the management of medical conditions affecting babies, children and young people

**Minor** – a minor is a person below a certain age (usually the age of majority) that legally separates a child from an adult; the age varies between countries and settings but is generally 18 years

**Legal guardian** – a person who acts as the primary caretaker and makes decisions on behalf of a child or minor

**Infant** – a child younger than one year of age

**Child** – a person 19 years or younger unless national law defines a person to be an adult at an earlier age. WHO defines a child as a person 1–9 years of age

**Adolescent** – a person from puberty to legal adulthood. WHO defines an adolescent as a person 10–19 years of age

**Vulnerable groups** – groups of people who are particularly vulnerable to HIV infection in certain situations or contexts. These include: adolescents (particularly adolescent girls), orphans, street children, people in closed settings (such as prisons or detention centres), people with disabilities and migrant and mobile populations.

The United States National Institutes of Health defines community as the population in and for which the research is being conducted (3). For the purpose of this toolkit, community refers to trial participants (children and adolescents living with HIV), their caregivers and advocates as well as others who may be affected by HIV and/or the research being conducted (see the module on trial design). Box 6.1 shows other definitions.

### 1.1.2 Community engagement

Community engagement in research is a complex, dynamic and interactive relationship between researchers, policy-makers and the community (3). The aim is to involve participants and their advocates as partners in research rather than merely trial subjects or eventual users of the drug or intervention.

Effective community engagement should result in the community becoming increasingly critically aware of and involved in research activities, processes and decision-making.

The balance of power between researchers and participants can affect how communities engage, who represents the different communities and what type and level of interaction exists between the different stakeholders and at what stage of the research process. Successful engagement that considers the research priorities alongside the needs of the community improves the quality and outcomes of research (4).

### 1.1.3 Levels of community engagement

Fig. 6.1 illustrates everyone who represents the different communities and their level of engagement in research.

Scientists, researchers and other stakeholders involved in clinical trials have a critical role to play in how they engage and interact with the paediatric community. Even where the selection of community and community representatives is clear, the way they communicate, the language and scientific terms they use, how they perceive community involvement and their level of understanding can influence how the community engages in the research process (4).

**Fig. 6.1.** Levels of community engagement



- **Trial participants** – neonates, infants, children and adolescents directly involved in the trial
- **Host community** – children living with and affected by HIV, adolescents and their caregivers, advocates and community-based and nongovernmental organizations (such as community advisory boards) that represent the paediatric HIV community directly
- **National stakeholders** – anyone who has a role in the political, scientific, social enterprise of developing drugs at the national level, including political decision-makers, regulatory authorities, ethical review committees, health ministry, national nongovernmental organizations, civil society advocates, donors and funders
- **International civil society** – non-profit, organized, citizen-led groups interested in the goals, processes and outcomes of paediatric HIV research and drug development and/or in the rights of communities and research participants (such as WHO and UNAIDS) networks or the media

Source: Slevin et al. (2). Reproduced from the PATH website at [www.path.org](http://www.path.org), 14 June 2018.



## 1.2 The need to engage the community in research and drug development

Once communities have been identified, knowing why they should be involved in the research process is important. This section examines the rationale, principles and ethical considerations for engaging the community in the research process and drug development.

### 1.2.1. Rationale behind community engagement in the research process

Engaging the paediatric community in the clinical research process may require different approaches because of regulatory, cultural, political, traditional, religious or socioeconomic factors prevailing in the communities and countries of interest.

Community engagement can provide valuable input in identifying ways to improve clinical study outcomes, for instance, through helping to facilitate recruitment and participant retention (5). Community members are frequently highly motivated and invested in support of the planned and ongoing research. One of the benefits of community engagement can be increased support and investment in the research, and this can improve study success by helping to identify and address potential issues.

A collaborative approach and effective communication between researchers and the community are paramount to ensure that those representing the paediatric community truly understand the purpose and procedures of research. Such an approach can also help enhance mutual trust and create a sense of collective ownership.

### 1.2.2. Principles of community engagement in research

To support researchers in involving communities in the research process, the United States National Institutes of Health developed a set of principles (Table 6.1) (3).

### 1.2.3. Ethical considerations

Guidelines on ethics in clinical research are well established with the Nuremberg Code and the Declaration of Helsinki as the core foundation. The purpose of ethical conduct in research is both to protect trial participants and to preserve the integrity of the science (6). Nevertheless, ethical considerations in community-engaged research raise additional questions when community representatives and trial participants may take part in relationships among or between communities, the researchers and research institutions as well as other stakeholders, with principles and codes that are not as well defined (5,6). This is especially true in research involving children and adolescents, a population dependent on their adult caregivers.

The Nuffield Council on Bioethics (7) recently published a report focusing on the ethical aspects of involving children and young people in research, providing recommendations about the roles and responsibilities of children, their parents or guardians, researchers and others.

The United Kingdom Medical Research Council (8) and the European Commission (9) have also produced extensive guidance on the ethics of conducting medical research among children, though these documents tend to refer to children and adolescents as trial participants and less about considering their role as collaborators in the research process.

Researchers must pay particular attention to their role and responsibilities related to child protection and safety when dealing with vulnerable groups. Caregivers have an important duty as gatekeepers whose informed consent must always be sought when involving minors as participants or collaborators in research. In addition, children younger than the age of consent should be able to provide their assent within a safe and non-coercive environment when working under supervision with adult researchers.

**Table 6.1.** Principles of community engagement in research

<b>Set clear goals</b>	Community engagement must meet the needs of the populations and/or communities affected by the research, strengthening the community's role and capacity to actively address research priorities and helping to ensure the development and implementation of relevant, feasible and ethical research.
<b>Learn about the community</b>	It is important to become knowledgeable about the social and cultural context of the community in terms of its economic conditions, political leadership, demographic trends, history (overall and regarding research) as well as its perceptions of and experience with engagement activities.
<b>Develop cultural competence</b>	Knowledge and understanding of the community's predominant attitudes, perceptions and practices will help ensure more effective and respectful communication and interactions, leading to culturally responsive engagement activities.
<b>Foster transparency</b>	The community should be encouraged to express itself independently during the community engagement process.
<b>Build partnerships and trust</b>	Partnering with community stakeholders is necessary to create change, build mutual trust and improve health. Toward that end, it is important to seek commitments from community-based organizations and to identify formal and informal leaders in the community.
<b>Provide and promote capacity-building</b>	Sustainable community engagement can only be achieved by identifying and mobilizing the community and by developing the capacities and resources within the community.
<b>Maintain a long-term commitment</b>	Community collaboration requires an ongoing, long-term commitment by the research organization, its partners and the community.

Source: adapted from *Recommendations for community engagement in HIV/AIDS research: a guide for communities and researchers, version 2.0* (3).



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## 2. CHALLENGES

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The research community can often perceive community engagement in research as demanding and time-consuming. This section highlights some challenges researchers might consider when engaging the paediatric HIV community in the research process and drug development.

### 2.1 The paediatric community

#### ***Working with children and adolescents***

Children and adolescents are not “miniature adults” but a heterogeneous group with unique and complex characteristics, marked by different physical and cognitive developmental stages that not only affect the pharmacokinetics and pharmacodynamics of medicines (see the module on pharmacokinetics) on the body but also the way adults interact and collaborate with them.

Although personal motivation and commitment is key, it is important to recognize that children and adolescents require age-appropriate information and support from adults as well as time, flexibility, patience and additional resources from the research community to improve their collaboration in the research process.

#### ***Identifying representatives of the paediatric community***

Another challenge with engaging the paediatric community in research is identifying those who best represent children, from neonates to adolescents, alongside their caregivers.

With power inequity (especially for young girls) compared with adults, children and adolescents are usually underestimated in their capacity to experience life and make meaningful decisions for themselves. Their lack of experience and knowledge of research alongside the ethical issues

of working with children and adolescents, as well as vulnerable groups, can affect researchers’ willingness to engage with this community.

The research community should take on board the voices of children and young people that have already been captured, such as those published in the Nuffield Council on Bioethics report (7). Asked what qualities they thought were important for clinical researchers, young people themselves included “courageous” alongside the more expected descriptors such as “trustworthy” and “openness”.

### 2.2 Stigma, disclosure, confidentiality and fear

HIV continues to be stigmatizing beyond children’s ability to understand the root of such behaviour. Confidentiality and the parents’ fear of disclosing their own status to their extended community, and to their children, can be challenging. Sometimes the children participating in clinical trials have not yet been told their HIV status by their caregivers. The risk that children living with HIV could be hurt, misjudged or poorly treated because of their health condition causes great anxiety for parents.

Research can also raise parental concern when it investigates HIV drugs using data extrapolated from adult clinical studies and for which safety and efficacy needs to be proven among children. The feeling of personal risk related to treatment side-effects and associated interventions as well as stringent trial design may deter trial participation (10). Children and young people participating in research on drug development may worry about their ability to manage their new treatment or the possible disruption hospital appointments and treatment side-effects might have on their daily routine and lifestyle.

Further, misconceptions, rumours and suspicions can potentially arise about specific research projects and hinder research progress and drug development (5,11). Particular attention should be brought to those who might

not directly be included in the community of interest (such as extended family members and religious leaders) but who have considerable power and influence over and above local beliefs and cultural practices.

**Table 6.2.** Requirements to support children’s participation in the reporting process

<b>Transparent and informative</b>	Children must receive full, accessible, diversity-sensitive and age-appropriate information about their right to express their views freely and to have their views given due weight and about how this participation will take place, its scope, purpose and potential impact
<b>Voluntary</b>	Children should not be coerced into expressing views against their wishes and must be informed that they can cease involvement at any stage
<b>Respectful</b>	Children’s views have to be treated with respect, and children should be provided with opportunities to initiate ideas and activities
<b>Relevant</b>	Children should draw on their knowledge, skills and abilities to express their views on relevant issues. Space needs to be created to enable children to highlight and address issues they have identified as relevant and important
<b>Child-friendly environment</b>	Environments and working methods should be adapted to children’s capacity (time and resources)
<b>Inclusive</b>	Participation needs to provide for equality of opportunity for everyone, including marginalized children, without discrimination on any grounds, including age, and be culturally sensitive to children from all communities. Special measures should be taken to include very young children and other children from marginalized communities
<b>Capacity-building</b>	Adults need preparation, skills and support to facilitate children’s participation effectively. Children also require capacity-building to strengthen their skills relevant to the process
<b>Safe and sensitive to risk</b>	Adults have a responsibility towards the children with whom they work and must take every precaution to minimize the risk of violence, exploitation or any other negative consequences of their participation.
<b>Accountable</b>	Child-led organizations, children’s groups and nongovernmental organizations should ensure that children have a clear understanding of their role and how their views will be interpreted and used.

Source: adapted from *Working methods for the participation of children in the reporting process of the Committee on the Rights of the Child* (13).

## 3. SOLUTIONS

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Although challenges may arise while engaging with the paediatric community, as with any other stakeholders, effective communication and trusting relationships are key to successful collaboration. The following section proposes several ways to improve how scientists and researchers engage with the community in the research process.

### 3.1 Involving children and adolescents in research

According to the United Nations Convention on the Rights of the Child (12), children should be taken seriously and given every opportunity to express their views and concerns on matters that affect their lives. Every effort should be made to provide children and adolescents a safe environment to encourage and enable them to participate in identifying research priorities and decision-making. Researchers need to ensure that “an invitation to participate in research constitutes a ‘fair offer’ to children, young people and their parents” (7).

Recent years have witnessed a shift in how scientists and researchers view the paediatric community. Children and adolescents are starting to be recognized as being extremely resourceful and committed to dealing with their own health issues. It is also being recognized that their input is essential to understanding how to get it right, as evidenced by data showing that the HIV response is failing children and adolescents.

The United Nations established a set of requirements to support children’s participation in the reporting process (Table 6.2) (13). These requirements can also be applied to the participation of children and adolescents in the scientific HIV research process.

### 3.2 Community advisory boards

A community advisory board engages in a two-way relationship between researchers and the targeted community (3,14). Community advisory board members commonly include volunteers from activist and patient groups as well as nongovernmental and sometimes government organizations that best represent the community affected by the research. The involvement of community advisory boards in the research process can:

- improve communication and cooperation between community representatives and researchers;
- develop the treatment and research literacy of community representatives;
- give community participants the opportunity to provide input on and help to resolve challenges for the trial; and
- advocate for implementing the trial results in national plans and guidelines.

A community advisory board aims to ensure community engagement, ensure that the research is conducted in the best interests of the community, develop mutual trust between the researchers and the community and dispel any myths and rumours that might arise because of lack of information and understanding fuelled by local beliefs (3,14). Such considerations tend to foster transparency and the implementation of culturally sensitive strategies that are best suited to the setting, local practices and the targeted population.

Community advisory board activities can also help stimulate the participation of the community at various stages of the research process, including providing input on trial design, informed consent forms and other community materials and participating in study implementation, expanded access programmes and pharmacovigilance.



In addition, community advisory boards can support partnerships between researchers and the community and the dissemination of research results. This model has also proven to be effective in recruiting and retaining study participants, since it promotes collaboration that leads to practical advice and constructive feedback (3,14).

Although community advisory boards have played an important role in HIV research and drug development, questions are starting to emerge about the limitations of their approach, which may not be entirely independent and representative of the overall HIV community (2). Community advisory boards increasingly include young people as established board members. However, younger children remain underrepresented, which constitutes an important gap in research.

### **3.2.1 Children and adolescent advisory groups or networks**

In recent years, children and adolescent advisory groups or networks have started to arise because of increasing demand and are being solicited to provide valuable input to the research process. It is therefore essential to provide those representing the community with age-appropriate information and the opportunity to develop this.

With support, their active community participation and collaboration in clinical trial discussions can enrich the process. Enabling children and adolescents to share their views on protocol design and ethical issues and welcoming their input in developing age-appropriate treatment literacy materials and consent forms can help trial participants to be better informed when enrolling in drug trials (15).

Several paediatric community networks have recently emerged at the national and international levels, giving children and adolescents a safe space to voice their views and concerns on matters that are relevant to them. A non-exhaustive list can be found in the section on resources of this module.

### **3.2.2 Community empowerment**

WHO refers to community empowerment as “the process of enabling communities to increase control over their lives. It assumes that people are their own assets, and the role of the external agent is to catalyse, facilitate or “accompany” the community in acquiring power” (16).

Scientists and researchers have a responsibility to help to empower those directly affected by the research being conducted. This can mean: shared ownership on defining priorities, supporting the process of community–researcher partnership and addressing the social, cultural, economic and political aspects of research.

Children and adolescents can be supported to take a leadership role in engaging in every step of the research process: for instance, by ensuring adequate information-sharing, ensuring transparency and allowing sufficient time for critical-thinking. Valuing the voices of children and adolescents in research and understanding their lives from their own perspective is an important contribution to paediatric studies.

### **3.2.3 Capacity-building**

Capacity-building is an important part of responsible engagement of the paediatric community. Children and adolescents may be from different socioeconomic and cultural backgrounds and at different stages of development, with different skills and knowledge. With an emphasis on their existing talents, researchers should invest time, resources and logistical support in training children and adolescents representing their community who are committed to becoming collaborators in the research. Their ability to develop confidence and treatment knowledge will be of immense value to community engagement and research involving children.

Capacity-building should be tailored and appropriate to the age and developmental stage and stage of life of the community being engaged. This will be very different for young children than for adolescents.

Adolescents are transitioning into adulthood, and capacity-building should also provide them with transversal skills that will help them in their personal and professional development.

The following list is intended to provide examples of training topics that can support the involvement of children and adolescents as research participants and can develop important research and social skills:

- communication;
- presentation and public speaking;
- listening abilities;
- information and technology training;
- introduction to HIV, treatment and prevention;
- ethics and human rights in clinical research;
- advocacy and peer representation;
- introduction to research and clinical trials;
- confidentiality; and
- understanding committees and related expectations.

### 3.2.4 Confidentiality

Ethical considerations and principles related to confidentiality, anonymity and data protection are the same whether researchers are working with adults or with children and adolescents. Age-appropriate information on confidentiality and data protection must be provided to those involved in research either as trial participants or community representatives. This should be agreed at the start of the collaboration and reiterated when necessary.

### 3.2.5 Community engagement models and frameworks

Community engagement in research and drug development means that innovator manufacturers – and researchers – should acquire better understanding of the health needs and challenges patients experience in their daily lives, beyond seeking the opinion of advocacy and market

research groups after the drug has been developed (17). With limited evidence on the benefits of engaging the community (adults) in health care and the research process, which is often inconsistent, recommendations on best practice are lacking.

Nevertheless, such patient groups as #PatientsIncluded and PatientsLikeMe are increasingly being invited to share their views and opinions during decision-making. In addition, regulatory authorities are proactively taking on patient-centred activities in drug development to gather patients' perspectives on various aspects of health. For instance, the United States Food and Drug Administration started the Patient-Focused Drug Development Initiative that helps evaluate the advantages and disadvantages of new therapies (17).

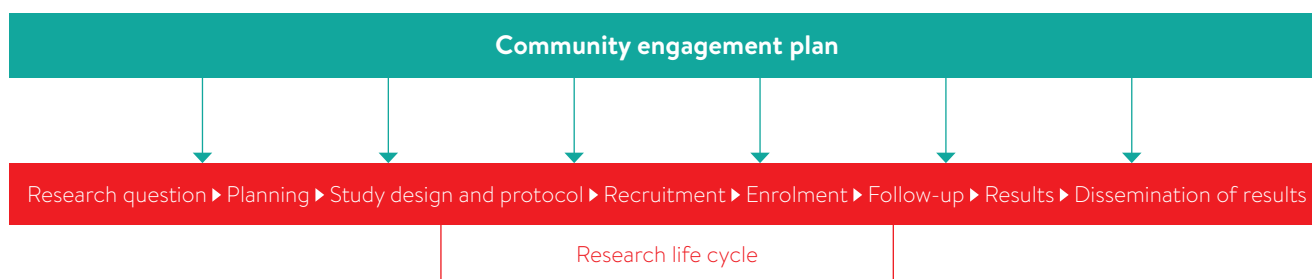
Pharmaceutical companies are encouraged to engage with the community, including the paediatric community, in a true partnership during the research and drug development process, if they want to better understand the needs and concerns of their customers. Community engagement models and frameworks should be developed with the community, alongside recommendations based on evidence, to strengthen present and future collaboration and community engagement.

### 3.2.6 Community engagement plan

Based on the stakeholder engagement plan developed by UNAIDS and the AIDS Vaccine Advocacy Coalition (18), a community engagement plan (Fig. 6.2) provides a structured approach for researchers to engage with the paediatric HIV community in every aspect of the research process, including planning, designing, implementing, reviewing and disseminating the results of the research being conducted.

Researchers must identify relevant community stakeholders and representatives in a broad, multifaceted, inclusive way and develop partnerships that support effective and locally acceptable research. This process should consider the trial population to be studied

**Fig. 6.2.** Community engagement plan



and known stakeholders and understand the differences and power relations of potential and known stakeholders.

Involving the community in developing the plan will ensure that research priorities and community needs are included, help determine the frequency and methods of engagement and inform the process of reviewing and adopting community engagement plans.

### 3.3 A child- and adolescent-friendly approach to research

Children and adolescents must feel welcomed and valued if researchers want them to actively engage in clinical trials. Whether as trial participants or collaborators working with researchers, children and adolescents are not only sensitive to their environment but also to the approach adults use to communicate with them. Ensuring a child- and adolescent-friendly and safe environment in which they feel comfortable expressing their views and ideas is one of the many requirements researchers must consider when working with the paediatric community.

Children and adolescents should also be presented with information adapted to their age and in a friendly manner. A family-centred approach and age-appropriate communication methods are preferred to encourage their involvement while providing a positive and meaningful experience. Seeking children's and adolescents' contribution to clinical research in an innovative and creative way, for instance by

using illustrations and cartoons in the design of information sheets and consent forms, is likely to boost interest and encourage participation.

### 3.4 Compensation

Compensating children and adolescents for participating in clinical research and those representing the paediatric community remains controversial. Although the financial coverage of direct trial-related expenses including transport, meal allowance, accommodation and access to health care is commonly accepted in biomedical research in some countries, the payment of children's and adolescents' participation as a token of appreciation for their time and inconvenience is far from straightforward (19–21).

Compensation for minors to participate in clinical research may influence the decision-making of the child and/or caregiver, leading to increased acceptance of risk. This could also influence the decisions made by adolescents who are adults legally (19).

Nevertheless, the absence of reimbursement for direct trial-related expenses, as well as time and inconvenience, may interfere with the opportunity for study participation and enrolment, hindering significant advances in paediatric research (19).

Researchers must recognize the complexity behind compensating trial participation, considering not only the ethical but also the contextual and individual decisions related to trial participation during the entire research process.

## 4. CASE STUDIES

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### **Meaningful participation in dissemination**

Clinical trials involving children significantly emphasize informed consent. This occurs at the opening stages of the trial. A critical element in ensuring young people's meaningful participation in the research process is dissemination towards the end of the trial, which tends to receive far less attention.

We held a dissemination event for participants (10–21 years old) and their caregivers in a clinical trial in Uganda to explain the findings. The investigators explained the trial findings and their implications, answering all the questions posed by the young people and their caregivers. We then held focus groups with the young people a few weeks later to explore their experiences in the trial.

Those involved highly valued this rare event: by being informed appropriately, they better understood what they had been part of and why. Many described understanding for the first time why blood tests had been taken so frequently. This shows the importance of treating informed consent as a process, rather than a single event, and providing regular opportunities to revisit young people's understanding of the trial to ensure and develop their understanding.

Having learned of the potential significance of the trial findings, the participants described pride in their participation because they considered it to have contributed to the more effective treatment and that their fidelity to their assigned trial arm had been worthwhile.

Many had participated in previous trials, but because they were not told about the trial findings appropriately, some had assumed the trial had been a failure. Understanding the results of this trial made them feel it was a success, and this gave them hope for their future health.

Now hearing that the results were successful gave me a lot of hope that, in future, someone can have a break

for more than one day or it could even be a month without taking drugs. (20-year-old man)

You may have something that you do, but when you do not know what you are doing, the progress of something that you are doing. We get to know that this happens and to know the progress of the study we are participating in rather than just coming to have your blood tested then you go back. You go without getting to know anything. (21-year-old man)

Yes, it is good to inform us because we are able to answer some questions: "you are in the study but how is it helping?" If you ask me how it has helped me I can respond that the results were positive. It was important and it also helped us. (20-year-old man)

Why I clapped my hands is because I saw a great achievement because I saw a great achievement in fighting HIV through this research done upon or reducing or ending HIV. (16-year-old woman)

This dissemination was useful. In what way? Okay, let us assume it is like a journey. If you are on a journey and you see where you are heading. When you start seeing there you get the courage to continue walking. But when you are travelling and you do not know where you are heading and you do not see where you have reached, you get discouraged. So, this thing gave us strength. It gave us courage in that when I heard the results, it gave me more courage to adhere to the drugs and I saw that already we have reached somewhere. We are on track. And it gave me more strength and I got to know that, if this was possible, then other things are coming. But if they had not told us about it, we would be there, taking drugs, on the study, not knowing how far it has reached, where it is, you just see, they tell us that we are in the study and we do not know. So it was vital. (18-year-old man)

### **A young person's experience as a trial participant**

A 16-year-old was questioned on his experience as a participant in a clinical trial. Asked about the enrolment process and information received, he experienced some difficulties: "the information was clear, but I did not understand some of the words, as they were a bit complicated and for grown-ups and I was given a month to think about getting enrolled". He shared that research staff members were available to answer any questions,



although he described the process as being “a bit over the top”. He felt very comfortable giving consent: “I did not feel under pressure. I felt like I could say no if I didn’t want to do it” though “there were too many words and it was hard to read”.

Confidentiality about his HIV status was not an issue, since he clearly said “No, never, I trust them 100%”, referring to the clinical and research staff. Overall, his experience as a trial participant was good:

“there was an appointment every month for three months, and then the appointments were three times monthly. It was fine because I understood why this was and that they had to check I was okay. For me, everything is really good, it’s going really well”. Although the department was not adolescent-friendly, “No I never got that feeling, it was a very adult environment”, he was motivated and keen to be involved: “I felt good about myself because, if it goes well, I’ll be helping people.”

## 5. SUMMARY

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- Community engagement plays an important role in the development of antiretroviral drugs to treat adults living with HIV, but such engagement has lagged behind for children living with HIV.
- Innovator manufacturers, researchers and other stakeholders involved in clinical trials play a critical role in how they engage with the paediatric community.
- There are legal and ethical frameworks within which the involvement of children and adolescents in clinical research must be conducted.
- Engaging the paediatric community presents many challenges and requires different approaches in different age groups and settings.
- Community advisory boards and children and adolescent advisory groups or networks can provide valuable input to the research process.
- A community engagement plan provides a structured approach for researchers to engage with the paediatric HIV community.
- Children and adolescents can contribute to protocol design and ethical issues and the development of age-appropriate treatment literacy materials and informed consent documents.
- Child- and adolescent-friendly environments are critical to their successful engagement.

## 6. KEY CONSIDERATIONS

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- **Engage community members early in designing the study.** This might mean working with existing national or regional community advisory boards or youth boards or setting up an appropriate advisory board for the study. For infants and other young children, involving parents and caregivers is critical; for older children and adolescents, this should mean engaging those from the relevant age groups.
- **Provide treatment and prevention literacy training.** To contribute in a meaningful way, trial participants and their advocates need to understand the science of HIV and the research interventions.
- **Produce informed consent forms in collaboration with the community.** Giving truly informed consent on behalf of a child or yourself requires that protocols be explained in plain language.

- **Produce age-appropriate, study-related materials in collaboration with the community.** Ensure that information is shared in a way that is acceptable to those who need it. This could mean using illustrations, photographs or videos.
- **Ensure a child- and adolescent-friendly clinic environment with continuity of care.** It is important that families have a research nurse or other relevant health worker that they can rely

on and trust to discuss any concerns or questions that they have over the duration of the trial.

- **Communicate results in a timely and accessible manner.** Participants and/or their caregivers need to receive results, explained in an accessible way, before they are widely disseminated.
- **Consider appropriate, non-coercive forms of compensation.** This could take the form of vouchers for clothes, telephone airtime etc.

## 7. USEFUL RESOURCES

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### Community advisory boards

- European Community Advisory Boards: <http://www.eatg.org/ecab>
- African Community Advisory Boards: <http://www.afrocab.info>
- United Kingdom Community Advisory Boards: <http://www.ukcab.net>

### Children and adolescent advisory groups and networks

- Children's HIV Association Youth Committee: <https://chiva.org.uk/our-work/youth-committee>
- Adolescent HIV Treatment Coalition: <http://www.iasociety.org/HIV-Programmes/Programmes/Adolescent-HIV-Treatment-Coalition>
- International Children Advisory Network: [www.icanresearch.org](http://www.icanresearch.org)
- Youth Trial Board: [www.youthtrialsboard.org](http://www.youthtrialsboard.org)
- Children and Young People Network: <https://www.ncb.org.uk/children-and-young-people-hiv-network>
- HIV/AIDS Network Coordination: <https://www.hanc.info/Pages/default.aspx>
- Adolescent Medicine Trials Network for HIV/AIDS Interventions: <https://atnweb.org/atnweb>
- Global Network of Young People Living with HIV: <http://www.yplusleadership.org>

### Other community engagement networks

- Patients like me: <https://www.patientslikeme.com>
- Patients included: <https://patientsincluded.org>

### Community engagement projects

- National Institute for Health Research: INVOLVE: <http://www.invo.org.uk/about-involve>
- Patient-focused drug development initiative of the United States Food and Drug Administration: <https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm>
- Patient-Centered Outcomes Research Institute: <https://www.pcori.org/engagement/influencing-culture-research>

### National Health Council

- <http://www.nationalhealthcouncil.org>
- <http://www.nationalhealthcouncil.org/sites/default/files/NHC-GA-Patient-Engagement.pdf>

## 8. ACKNOWLEDGEMENTS

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*Special thanks to Sarah Bernays, Abi Carter and Djamel Hamadache for sharing case studies and young people's experiences as trial participants.*

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