Inclusion of Adolescents into Research: Assessment of Cognitive Capacity of Adolescents and Parents to Provide Informed Consent in Rakai, Uganda

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Research Question: What level of cognitive capacity do adolescents have to provide informed consent for sexual reproductive health research compared to adults?

BACKGROUND

- Adolescents tend to be excluded from biomedical research despite their significant risk of HIV infection.[1] This is due in part their status as a vulnerable population and to confusion around who should give consent for their participation in research.[1,2]
- To provide fundamental evidence to address this bioethical challenge, it is crucial to assess the cognitive capacity of adolescents and parents/guardians to provide informed consent, assent, and permission.[3]

DESCRIPTION OF ORGANIZATION

Columbia University has been collaborating with Rakai Health Science Program in Uganda. Structural and Social Transitions among Adolescents and young adults in Rakai (SSTAR) is one of our projects to examine social determinants of transitions from adolescence to adulthood, and this bioethics research is a supplemental study of SSTAR.

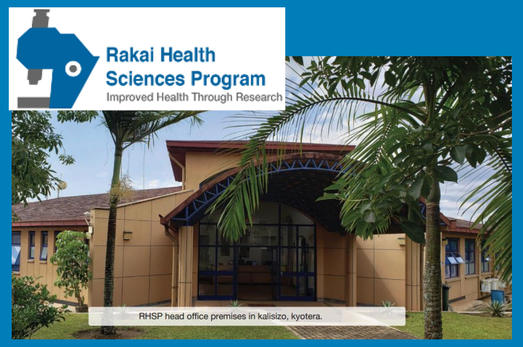

photo credit: Rakai Health Science Program

METHODS

1) **Scoring of Interviews + Guideline Development**:

- Conducted interviews based on the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR)[3]

Components of the MacCAT-CR	
1. **Understanding** of research components	10 questions
2. **Appreciation** of research effects	3 questions
3. **Expression** of voluntary participation	1 question
4. **Reasoning** about their choice to participate	4 questions

- Scored transcripts and discussed to refine the scoring guideline
- Two scorers reached an **intraclass correlation coefficient (ICC) for inter-rater reliability of 0.888** (95% Confidence Interval: 0.663-0.959).

2) **Qualitative Analysis**:

- Conducted preliminary qualitative analysis of the 78 interviews

RESULTS

Example of an adolescent's decision-making process from 3. Expression of voluntary participation	
Excerpt	Interpretation
Interviewer: Did you want to participate in the RCCS?	
Participant: **Yes**.	Expressing a clear choice
I: Why did you want to participate?	
P: **I wanted to participate because the research included HIV testing** since I have never been tested, I wanted to test.	Expressing a clear reason
I: Whose decision was it for you to participate in the RCCS?	
P: It was **not my decision, it was a decision for my parent**.	Involving parents to make a decision
I: If your parent wanted you to participate but you did not, would you have to participate?	
P: Yes because **I cannot despise my mother** meaning that I would still participate	Showing possibility of pressure from parent

RESULTS, continued

Well described topics: direct specific benefits	
Category	Topics
1. Understanding of research components	Listing **individual** benefits (e.g. - HIV testing and referral for treatment - Pregnancy test)
2. Appreciation of research effects	Articulate reasoning of **personal** benefit

Difficult topics: abstract ideas and what happens if they don't participate	
Category	Topics
1. Understanding of research components	Listing **community** benefits (e.g. - general medical care - free condoms)
4. Reasoning about their choice	**Comparative** reasoning - Identifying why participating in research is a better decision for them than not participating in research

MAIN FINDINGS

Participants understood direct individual benefits well but abstract ideas about risks and benefits and what happens if they don't participate seemed difficult to describe. Thus far, **we found no noticeable differences on these features between adolescents and adults.**

DISCUSSION

- The preliminary results suggest that even the youngest adolescents have the capacity to provide informed consent as well as adults.
- To enhance ethical inclusion of adolescents into research, it is crucial to further investigate the cognitive capacity to provide consent of adolescents and parents/guardians considering the complexities of decision-making process among adolescents and adults we identified.

REFERENCES

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