



MTN-034 in Context: Understanding the Legal and Ethical considerations: Zimbabwe



Presenter

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Matters of Consent in Zimbabwe

- 1) Constitution - Legal age of majority in Zimbabwe is 18 years
- 2) Constitution & Marriage Act - No person to be married before age 18 both men and women
- 3.) Current national guidelines on HIV testing, STI testing, STI treatment and contraception – consent at 16 – individuals aged 16 can access contraception without their parent`s consent
- 4) Girls under 16 years can not in any way consent to sexual intercourse
- 5) NAC HIV policy on adolescents includes emancipated minors married or adolescent mothers
- 6) Abortion is illegal except for rape, medical reasons (threat to life of mother) and incest

Back to reality

- Constitution allows marriage at 18 (and yet sex at 16).
- Child-bearing age in Zimbabwe is 15-49 years

Interesting findings about Zimbabwe

- Remez L, Woog V and Mhloyi, M, Sexual and reproductive health needs of adolescents in Zimbabwe, *In Brief*, New York: Guttmacher Institute, 2014, No. 3.
 - As of 2011, 38% of young Zimbabwean women have had sex by age 18, as have 23% of young men.
 - Nearly one-quarter of all 15–19-year-old Zimbabwean women (23%) are currently in a union.
 - 13% of 15–17-year-olds have been in a union as of 2011, and these very early marriages are more common in rural than in urban areas (16% vs. 8%).
 - One-quarter of 15–19-year-old women have started childbearing; one-third of all births to adolescents are unplanned (wanted later or not at all).
 - Single, sexually active adolescents have by far the greatest unmet need—62% as of 2011, compared with 19% among their married counterparts.

Cultural Sensitivity

- Topic of sexual intercourse is taboo.
- Parents and adolescents not comfortable to discuss topic
- Parents do not want to acknowledge that their children are engaging in sexual activity
- Society is against premarital sex, with virginity testing in some tribes
- Adolescents do not want their parents to know about their activities.
- Sensitive nature complicates the consent/assent process and affects both privacy and confidentiality.
- To grant permission for one's child to participate in a HIV prevention trial is as good as granting them a **“sex license”**.

Confidentiality

- National guidelines adolescents should be afforded confidentiality on HIV testing, STI testing, STI treatment and contraception issues
- Adolescents can seek these key services without parental consent
- Adolescents expect assurances of confidentiality and will only access services if assured of confidentiality.
- **Mandatory reporting:** Cases of sexual abuse must be reported to relevant authorities

MRCZ experience with previous trials (Case 1: SHINE STUDY)

- Waiver for parental consent has been granted in previous studies that enroll emancipated minors eg **SHINE study** enrolled adolescent mothers.
- Age of target study participants was initially 18 years and above.
- Amendment submitted requesting to enroll young mothers below 18 years old.
- Waiver of parental consent was granted –
- **JUSTIFICATION:** minimal risk study and the women stood to benefit from latrine and interventions

Case 2: PREP STUDY

- Uptake and adherence to daily oral PrEP as a primary prevention strategy for young African women : A Vanguard Study
- Parental consent was waived for 16 - 17year olds
- **JUSTIFICATION:**
- Risk level was considered minimal,
- This is the age at highest risk, they are most likely to benefit from the findings
- Requiring parental consent likely to introduce a barrier to the minor`s participation

Case 3:KAP Study on HIV

- Study evaluating knowledge on HIV testing and counseling: Condom use and VMC amongst population aged 15-49 years
- **JUSTIFICATION:**
- Risk level was considered minimal,
- This is the age at highest risk, they are most likely to benefit from the findings
- Requiring parental consent likely to introduce a barrier to the minor`s participation

Case 4 :KAP Study on HIV

- Knowledge, Attitudes and Behaviour relation to sexual and reproductive health including HIV prevention of youth 15-24 years
- **JUSTIFICATION:**
- Risk level was considered minimal,
- This is the age at highest risk, they are most likely to benefit from the findings
- Requiring parental consent likely to introduce a barrier to the minor`s participation

How to make the IC Procedures more appealing to young women and teens

- Use of young experienced research staff
- CABS with adolescent reps necessary also need to involve Specialists in adolescent issues (Youth CAB)
- Avoid use of old, mature research staff as these might have rigid cultural mindsets and intimidate the sexually active adolescent girls
- Generation gap, older counselors could be judgmental.
- The young research staff understand the adolescent language and challenges around reproductive issues
- Innovative activities that are involve adolescents during sensitisation activities.
- Improve quality of information disclosed
- Test understanding before enrolment and during trial
- HIV prevention trials need to be **blended** together with other health promotion activities.

Addressing the cultural concerns

- In attempts to ensure that the 16-17 year olds are captured, the following are suggested:
- Propose to recruit from places where adolescents access reproductive health services.
- Sensitisation at places frequented by adolescents eg Colleges and then providing number for SMS “JOIN” to “999”
- Will these introduce bias.....???????
- What are the options?

MRCZ Position on waiver of parental consent

- MRCZ is flexible when it comes to making decisions.
- Any request requires adequate justification.
- Justification should be supported by evidence.
- Request should be such that it does not cause friction.
- **REC members are parents too!**
- For studies requiring parental consent, when participant turns 18, need for consent.

CONCLUDING REMARKS:

By involving adolescents...

- Adolescents stand to benefit personally through the various benefits that come with the trials.
- They benefit other adolescents now and in future – as products are licensed for adolescents.
- We shorten the product development pathway.
- Globally – we can achieve the goal of an AIDS- free generation in a much faster way.

Thank You

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