Developing a Reporting Item Checklist for Studies of HIV Drug Resistance Prevalence: A Mixed Methods Study

Cristian Garcia MSc (c)[1], Daeria O Lawson PhD (c)[1], Pascal Djiadeu PhD[1], Nadia Rehman, MSc (c)[1], Lawrence Mbuagbaw MD MPH PhD[1,2]

[1] Department of Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, ON, Canada; [2] Biostatistics Unit, Father Sean O'Sullivan Research Centre, St Joseph's Healthcare, Hamilton, ON, Canada

Introduction

- HIV drug resistance limits the effectiveness of antiretroviral therapy[1,2]
- Adequate **surveillance** of HIV drug resistance prevalence is challenged by heterogenous and **inadequate data reporting**[3,4]
- Previous work has demonstrated the need for **guidance** on **complete reporting** for studies of HIV drug resistance[4]

In this poster, we present the findings from the mixed methods study used to **develop reporting guidelines** for studies of HIV drug resistance prevalence

Objectives

1. Using survey methods, identify **a list of potential reporting items** for studies of HIV drug resistance prevalence
2. Using focus group methods, **explore the perspectives** of HIV drug resistance researchers on what makes a reporting item is essential to HIV drug resistance research
3. Using integrative methods, describe how group discussions with HIV drug resistance researchers help **explain the findings** of the cross-sectional survey

Methods

- A mixed-methods **sequential explanatory** design among content experts with research experience or work in the field of HIV drug resistance

Quantitative phase:

- Cross-sectional electronic survey sent to a purposeful convenience sample of HIV researchers (n=160) to **rate various reporting items** on whether they are essential to report
- **Content validity ratios** calculated and compared to critical values. Ratios above the critical value of **0.253** were kept and below were dropped

Qualitative phase:

- Purposeful sample of survey respondents attended two focus groups to **evaluate the initial list** of reporting items on item wording, grammar, and grouping
- **Thematic analysis** of discussion transcripts informed by grounded theory

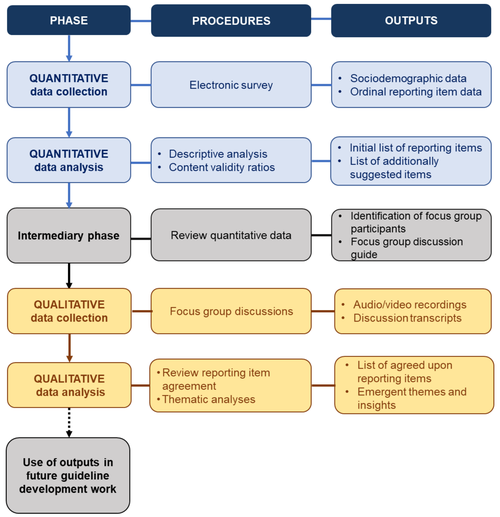

Figure 1: Outline of mixed-methods study

Results

Quantitative phase

- 51 participants responded to the survey (**31.9% response rate**)
- Mean age was 48.1 years (SD=10.51) with 17 females (33.3%)
- At least one participant from **each WHO region was represented**, with responses from over 24 countries
- 15 of the 23 survey items were retained for further evaluated based on their content validity ratios (see Table 1 below)
- **58 additional reporting items** were suggested by survey participants

Table 1: Initial reporting item checklist from the survey, with content validity ratios (CVR)

Reporting item	CVR	Status
Study-level items		
Study setting	0.569	Kept
Study location	0.451	Kept
Study design	0.490	Kept
Sample size justification	0.176	Dropped
Participant items		
Age	0.320	Kept
Sex	0.320	Kept
Sexual orientation	0.000	Dropped
Transmission risk group	0.400	Kept
Profession	-0.440	Dropped
Place of residence	-0.360	Dropped
Ethnicity	-0.280	Dropped
Level of education	-0.640	Dropped
Income	-0.760	Dropped
Exposure to ART	0.920	Kept
HIV resistance items		
Type of resistance test	0.760	Kept
Mutation list used	0.840	Kept
Number of genotypes	0.600	Kept
Resistance, by drug class	0.920	Kept
Clinical relevance	0.840	Kept
Other items		
Source of funding	-0.160	Dropped

Qualitative phase:

- In total across the two focus groups (n=9 in total) four participants were female
- Participants agreed on a list of **38 essential reporting items**
- **Six emergent themes** were identified (four representative themes and quotes are presented below):

Theme: Ethical concerns

"Individual genotype reports do not have that [data] and should not have that for ethical reasons"

Theme: Context

"In some studies, you would like to report [item] and in others you just don't need it"

Theme: Interpretability

"I think it's important that they report their methods for the interpretation of drug resistance"

Theme: Comparability

"*Without that information, you don't know whether you can generalize beyond the study at all"*

Discussion

- Most participants suggested adding drug-resistance testing items to the checklist. Such items involve details on **laboratory methods, data sources, and the year, version and type of mutation list used**.
- Our participants made several comments on the **current lack of guidance** for reporting HIV drug resistance prevalence data, reaffirming the need for reporting guidelines
- Participants expressed concern regarding the **ethics of requiring reporting of sensitive personal information** for research conducted in settings where HIV is criminalized.
- Participants also voiced the importance of appreciating the diverse types of HIV drug resistance research being conducted across **various cultural settings**.

Strengths:

- Integration of quantitative and qualitative methodologies to generate **insights**
- Validation checks made in both phases to improve **data quality**

Limitations:

- Lower survey **response rate** than expected
- Not all **WHO regions** were represented in the qualitative sample

Conclusions

We have developed both a **list of reporting items** for prevalence studies of HIV drug resistance with qualitative understanding on what makes these items important to this research

The resultant checklist and qualitative insights will directly inform the **accompanying explanation and elaboration document**.

References

1. Gupta RK, Jordan MR, Sultan BJ, Hill A, Davis DH, Gregson J, et al. Global trends in antiretroviral resistance in treatment-naive individuals with HIV after rollout of antiretroviral treatment in resource-limited settings: a global collaborative study and meta-regression analysis. Lancet. 2012;380(9849):1250-8.
2. Cambiano V, Bertagnolio S, Jordan MR, Lundgren JD, Phillips A. Transmission of drug resistant HIV and its potential impact on mortality and treatment outcomes in resource-limited settings. J Infect Dis. 2013;207 Suppl 2:S57-62.
3. Macdonald V, Mbuagbaw L, Jordan MR, Mathers B, Jay S, Baggaley R, et al. Prevalence of pretreatment HIV drug resistance in key populations: a systematic review and meta-analysis. J Int AIDS Soc. 2020;23(12):e25656.
4. Mbuagbaw L, Ongolo-Zogo C, Mendoza OC, Zani B, Morfaw F, Nyambi A, et al. Guidelines are needed for studies of pre-treatment HIV drug resistance: a methodological study. BMC Med Res Methodol. 2021;21(1):76

Cristian Garcia (he/him)
Email: garcim12@mcmaster.ca

BRIGHTER WORLD