

Questionnaire on UNAIDS guidelines

Hello. The following questionnaire will ask you about ethical standards extracted from UNAIDS-WHO (2007) *Ethical considerations in biomedical HIV prevention trials* and UNAIDS-AVAC (2007) *Good participatory practice guidelines for biomedical HIV prevention trials*. The first 10 standards are about prevention and the rest are about care.

Before you begin, please indicate the stakeholder group to which you belong by marking with an X

Site staff member	<input type="checkbox"/>
CAB member	<input type="checkbox"/>
REC member	<input type="checkbox"/>
Regulatory member	<input type="checkbox"/>
Sponsor	<input type="checkbox"/>
Other (please specify)	<input type="checkbox"/>

You may worry that we are testing how much you know about ethical standards. This is not the case. Rather, we hope to identify those areas where ethical standards may have to be clarified, disseminated better, or even changed.

For each ethical standard you will be asked to rate five things:

- How familiar you are with the ethical standard
- How easy you think it is to understand the ethical standard
- How easy you think it is or will be to implement the ethical standard
- How much the ethical standard protects participants
- How strongly you agree with the ethical standard

The relevant ethical standards are written in the left-hand column.

Next to each ethical standard are five rating boxes. Please carefully read the ethical standard and then choose a number between 1 and 5 for each of the five ratings before moving on to the next ethical standard.

For example:

Trial participants should be treated with respect.	<input checked="" type="checkbox"/>	5	I am very familiar with this ethical standard	<input type="checkbox"/>	5	This ethical standard is very easy to understand	<input type="checkbox"/>	5	This ethical standard is very easy to implement	<input type="checkbox"/>	5	This ethical standard greatly protects trial participants	<input type="checkbox"/>	5	I strongly agree with this ethical standard
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	<input type="checkbox"/>	3		<input type="checkbox"/>	3		<input checked="" type="checkbox"/>	3		<input type="checkbox"/>	3		<input type="checkbox"/>	3	
	<input type="checkbox"/>	2	I am not at all familiar with this ethical standard	<input type="checkbox"/>	2	This ethical standard is very hard to understand	<input type="checkbox"/>	2	This ethical standard is very hard to implement	<input type="checkbox"/>	2	This ethical standard minimally protects trial participants	<input type="checkbox"/>	2	I strongly disagree with this ethical standard
	<input type="checkbox"/>	1		<input checked="" type="checkbox"/>	1		<input type="checkbox"/>	1		<input type="checkbox"/>	1		<input type="checkbox"/>	1	

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8. Stakeholders should discuss disseminating results about how the standard of prevention was implemented in the trial.	<table border="1"> <tr><td>5</td><td>I am very familiar with this ethical standard</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>I am not at all familiar with this ethical standard</td></tr> <tr><td>1</td><td></td></tr> </table>	5	I am very familiar with this ethical standard	4		3		2	I am not at all familiar with this ethical standard	1		<table border="1"> <tr><td>5</td><td>This ethical standard is very easy to understand</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard is very hard to understand</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard is very easy to understand	4		3		2	This ethical standard is very hard to understand	1		<table border="1"> <tr><td>5</td><td>This ethical standard is very easy to implement</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard is very hard to implement</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard is very easy to implement	4		3		2	This ethical standard is very hard to implement	1		<table border="1"> <tr><td>5</td><td>This ethical standard greatly protects trial participants</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard minimally protects trial participants</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard greatly protects trial participants	4		3		2	This ethical standard minimally protects trial participants	1		<table border="1"> <tr><td>5</td><td>I strongly agree with this ethical standard</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>I strongly disagree with this ethical standard</td></tr> <tr><td>1</td><td></td></tr> </table>	5	I strongly agree with this ethical standard	4		3		2	I strongly disagree with this ethical standard	1	
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9. Researchers and trial sponsors should collaborate with government to strengthen capacity to deliver HIV prevention services.	<table border="1"> <tr><td>5</td><td>I am very familiar with this ethical standard</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>I am not at all familiar with this ethical standard</td></tr> <tr><td>1</td><td></td></tr> </table>	5	I am very familiar with this ethical standard	4		3		2	I am not at all familiar with this ethical standard	1		<table border="1"> <tr><td>5</td><td>This ethical standard is very easy to understand</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard is very hard to understand</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard is very easy to understand	4		3		2	This ethical standard is very hard to understand	1		<table border="1"> <tr><td>5</td><td>This ethical standard is very easy to implement</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard is very hard to implement</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard is very easy to implement	4		3		2	This ethical standard is very hard to implement	1		<table border="1"> <tr><td>5</td><td>This ethical standard greatly protects trial participants</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard minimally protects trial participants</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard greatly protects trial participants	4		3		2	This ethical standard minimally protects trial participants	1		<table border="1"> <tr><td>5</td><td>I strongly agree with this ethical standard</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>I strongly disagree with this ethical standard</td></tr> <tr><td>1</td><td></td></tr> </table>	5	I strongly agree with this ethical standard	4		3		2	I strongly disagree with this ethical standard	1	
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11. Trial participants should get access to optimal care and treatment for HIV infection, including ART.	<table border="1"> <tr><td>5</td><td>I am very familiar with this ethical standard</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>I am not at all familiar with this ethical standard</td></tr> <tr><td>1</td><td></td></tr> </table>	5	I am very familiar with this ethical standard	4		3		2	I am not at all familiar with this ethical standard	1		<table border="1"> <tr><td>5</td><td>This ethical standard is very easy to understand</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard is very hard to understand</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard is very easy to understand	4		3		2	This ethical standard is very hard to understand	1		<table border="1"> <tr><td>5</td><td>This ethical standard is very easy to implement</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard is very hard to implement</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard is very easy to implement	4		3		2	This ethical standard is very hard to implement	1		<table border="1"> <tr><td>5</td><td>This ethical standard greatly protects trial participants</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard minimally protects trial participants</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard greatly protects trial participants	4		3		2	This ethical standard minimally protects trial participants	1		<table border="1"> <tr><td>5</td><td>I strongly agree with this ethical standard</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>I strongly disagree with this ethical standard</td></tr> <tr><td>1</td><td></td></tr> </table>	5	I strongly agree with this ethical standard	4		3		2	I strongly disagree with this ethical standard	1	
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15. Stakeholders should discuss disseminating results about how access to care was implemented in the trial.	<table border="1"> <tr><td>5</td><td>I am very familiar with this ethical standard</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>I am not at all familiar with this ethical standard</td></tr> <tr><td>1</td><td></td></tr> </table>	5	I am very familiar with this ethical standard	4		3		2	I am not at all familiar with this ethical standard	1		<table border="1"> <tr><td>5</td><td>This ethical standard is very easy to understand</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard is very hard to understand</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard is very easy to understand	4		3		2	This ethical standard is very hard to understand	1		<table border="1"> <tr><td>5</td><td>This ethical standard is very easy to implement</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard is very hard to implement</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard is very easy to implement	4		3		2	This ethical standard is very hard to implement	1		<table border="1"> <tr><td>5</td><td>This ethical standard greatly protects trial participants</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard minimally protects trial participants</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard greatly protects trial participants	4		3		2	This ethical standard minimally protects trial participants	1		<table border="1"> <tr><td>5</td><td>I strongly agree with this ethical standard</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>I strongly disagree with this ethical standard</td></tr> <tr><td>1</td><td></td></tr> </table>	5	I strongly agree with this ethical standard	4		3		2	I strongly disagree with this ethical standard	1	
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16. Researchers and trials sponsors should collaborate with government to strengthen capacity to deliver care services.	<table border="1"> <tr><td>5</td><td>I am very familiar with this ethical standard</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>I am not at all familiar with this ethical standard</td></tr> <tr><td>1</td><td></td></tr> </table>	5	I am very familiar with this ethical standard	4		3		2	I am not at all familiar with this ethical standard	1		<table border="1"> <tr><td>5</td><td>This ethical standard is very easy to understand</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard is very hard to understand</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard is very easy to understand	4		3		2	This ethical standard is very hard to understand	1		<table border="1"> <tr><td>5</td><td>This ethical standard is very easy to implement</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard is very hard to implement</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard is very easy to implement	4		3		2	This ethical standard is very hard to implement	1		<table border="1"> <tr><td>5</td><td>This ethical standard greatly protects trial participants</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard minimally protects trial participants</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard greatly protects trial participants	4		3		2	This ethical standard minimally protects trial participants	1		<table border="1"> <tr><td>5</td><td>I strongly agree with this ethical standard</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>I strongly disagree with this ethical standard</td></tr> <tr><td>1</td><td></td></tr> </table>	5	I strongly agree with this ethical standard	4		3		2	I strongly disagree with this ethical standard	1	
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17. In the informed consent process, trial participants should be told what care and treatment services they will receive.	<table border="1"> <tr><td>5</td><td>I am very familiar with this ethical standard</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>I am not at all familiar with this ethical standard</td></tr> <tr><td>1</td><td></td></tr> </table>	5	I am very familiar with this ethical standard	4		3		2	I am not at all familiar with this ethical standard	1		<table border="1"> <tr><td>5</td><td>This ethical standard is very easy to understand</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard is very hard to understand</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard is very easy to understand	4		3		2	This ethical standard is very hard to understand	1		<table border="1"> <tr><td>5</td><td>This ethical standard is very easy to implement</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard is very hard to implement</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard is very easy to implement	4		3		2	This ethical standard is very hard to implement	1		<table border="1"> <tr><td>5</td><td>This ethical standard greatly protects trial participants</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard minimally protects trial participants</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard greatly protects trial participants	4		3		2	This ethical standard minimally protects trial participants	1		<table border="1"> <tr><td>5</td><td>I strongly agree with this ethical standard</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>I strongly disagree with this ethical standard</td></tr> <tr><td>1</td><td></td></tr> </table>	5	I strongly agree with this ethical standard	4		3		2	I strongly disagree with this ethical standard	1	
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18. Trials should only take place in communities where participants will have ongoing access to psychosocial services and legal support.	<table border="1"> <tr><td>5</td><td>I am very familiar with this ethical standard</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>I am not at all familiar with this ethical standard</td></tr> <tr><td>1</td><td></td></tr> </table>	5	I am very familiar with this ethical standard	4		3		2	I am not at all familiar with this ethical standard	1		<table border="1"> <tr><td>5</td><td>This ethical standard is very easy to understand</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard is very hard to understand</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard is very easy to understand	4		3		2	This ethical standard is very hard to understand	1		<table border="1"> <tr><td>5</td><td>This ethical standard is very easy to implement</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard is very hard to implement</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard is very easy to implement	4		3		2	This ethical standard is very hard to implement	1		<table border="1"> <tr><td>5</td><td>This ethical standard greatly protects trial participants</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard minimally protects trial participants</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard greatly protects trial participants	4		3		2	This ethical standard minimally protects trial participants	1		<table border="1"> <tr><td>5</td><td>I strongly agree with this ethical standard</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>I strongly disagree with this ethical standard</td></tr> <tr><td>1</td><td></td></tr> </table>	5	I strongly agree with this ethical standard	4		3		2	I strongly disagree with this ethical standard	1	
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19. Trials should help to develop HIV care services within the host country.	<table border="1"> <tr><td>5</td><td>I am very familiar with this ethical standard</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>I am not at all familiar with this ethical standard</td></tr> <tr><td>1</td><td></td></tr> </table>	5	I am very familiar with this ethical standard	4		3		2	I am not at all familiar with this ethical standard	1		<table border="1"> <tr><td>5</td><td>This ethical standard is very easy to understand</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard is very hard to understand</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard is very easy to understand	4		3		2	This ethical standard is very hard to understand	1		<table border="1"> <tr><td>5</td><td>This ethical standard is very easy to implement</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard is very hard to implement</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard is very easy to implement	4		3		2	This ethical standard is very hard to implement	1		<table border="1"> <tr><td>5</td><td>This ethical standard greatly protects trial participants</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard minimally protects trial participants</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard greatly protects trial participants	4		3		2	This ethical standard minimally protects trial participants	1		<table border="1"> <tr><td>5</td><td>I strongly agree with this ethical standard</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>I strongly disagree with this ethical standard</td></tr> <tr><td>1</td><td></td></tr> </table>	5	I strongly agree with this ethical standard	4		3		2	I strongly disagree with this ethical standard	1	
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20. Care approaches, and their successes and failures, should be carefully documented.	<table border="1"> <tr><td>5</td><td>I am very familiar with this ethical standard</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>I am not at all familiar with this ethical standard</td></tr> <tr><td>1</td><td></td></tr> </table>	5	I am very familiar with this ethical standard	4		3		2	I am not at all familiar with this ethical standard	1		<table border="1"> <tr><td>5</td><td>This ethical standard is very easy to understand</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard is very hard to understand</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard is very easy to understand	4		3		2	This ethical standard is very hard to understand	1		<table border="1"> <tr><td>5</td><td>This ethical standard is very easy to implement</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard is very hard to implement</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard is very easy to implement	4		3		2	This ethical standard is very hard to implement	1		<table border="1"> <tr><td>5</td><td>This ethical standard greatly protects trial participants</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>This ethical standard minimally protects trial participants</td></tr> <tr><td>1</td><td></td></tr> </table>	5	This ethical standard greatly protects trial participants	4		3		2	This ethical standard minimally protects trial participants	1		<table border="1"> <tr><td>5</td><td>I strongly agree with this ethical standard</td></tr> <tr><td>4</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>2</td><td>I strongly disagree with this ethical standard</td></tr> <tr><td>1</td><td></td></tr> </table>	5	I strongly agree with this ethical standard	4		3		2	I strongly disagree with this ethical standard	1	
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21. Do you have any comments or thoughts about the ethical standards listed in this questionnaire?

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22. To what extent do you think that HIV vaccine trial sites in South Africa are able to meet these standards?

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23. Please indicate whether you think it is essential or not that South African HIV vaccine trial participants get access to the following preventative measures:

A. Male condoms	<input checked="" type="checkbox"/> Essential	<input type="checkbox"/> Nice-to-have but not essential
B. Female condoms	<input checked="" type="checkbox"/> Essential	<input type="checkbox"/> Nice-to-have but not essential
C. Risk reduction counselling	<input checked="" type="checkbox"/> Essential	<input type="checkbox"/> Nice-to-have but not essential
D. Sterile injecting equipment	<input checked="" type="checkbox"/> Essential	<input type="checkbox"/> Nice-to-have but not essential
E. Treatment of STIs	<input checked="" type="checkbox"/> Essential	<input type="checkbox"/> Nice-to-have but not essential
F. Post-exposure prophylaxis (PEP)	<input checked="" type="checkbox"/> Essential	<input type="checkbox"/> Nice-to-have but not essential
G. Male circumcision	<input checked="" type="checkbox"/> Essential	<input type="checkbox"/> Nice-to-have but not essential

If funds were limited, which THREE of the above prevention services would you prioritize (A, B, C, D, etc.)?

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Other preventative measures that you consider ESSENTIAL to provide to participants

Other preventative measures that you consider NICE-TO-HAVE BUT NOT ESSENTIAL

Preventative measures (including those listed above) that you think should NOT be provided

24. Please indicate whether you think it is essential or not that South African HIV vaccine trial participants get access to the following care services:

A. Positive prevention counselling	<input type="checkbox"/> Essential	<input type="checkbox"/> Nice-to-have but not essential
B. Social support	<input type="checkbox"/> Essential	<input type="checkbox"/> Nice-to-have but not essential
C. TB prevention and treatment	<input type="checkbox"/> Essential	<input type="checkbox"/> Nice-to-have but not essential
D. Opportunistic infection prevention and treatment	<input type="checkbox"/> Essential	<input type="checkbox"/> Nice-to-have but not essential
E. STI treatment	<input type="checkbox"/> Essential	<input type="checkbox"/> Nice-to-have but not essential
F. Nutrition	<input type="checkbox"/> Essential	<input type="checkbox"/> Nice-to-have but not essential
G. Testing of CD4 counts/ viral loads	<input type="checkbox"/> Essential	<input type="checkbox"/> Nice-to-have but not essential
H. Antiretroviral therapy (ART)	<input type="checkbox"/> Essential	<input type="checkbox"/> Nice-to-have but not essential
I. Palliative care	<input type="checkbox"/> Essential	<input type="checkbox"/> Nice-to-have but not essential
J. Home-based care	<input type="checkbox"/> Essential	<input type="checkbox"/> Nice-to-have but not essential
K. Reproductive health care for pregnancy and childbirth	<input type="checkbox"/> Essential	<input type="checkbox"/> Nice-to-have but not essential
L. Prevention of mother to child transmission (pMTCT)	<input type="checkbox"/> Essential	<input type="checkbox"/> Nice-to-have but not essential

If funds were limited, which FIVE of the above care services would you prioritize (A, B, C, D, etc.)?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Other care measures that you consider
ESSENTIAL to provide to participants _____

Other care measures that you consider
NICE-TO-HAVE BUT NOT ESSENTIAL _____

Care measures (including those listed
above) that you think
should NOT be provided _____

Thank you for your participation!