### Appendix 7 Quality, Availability and Knowledge of Rational Use and Storage Requirements of Oxytocics in Malawi

#### SAMPLE SITE & DRUG PURCHASE RECORD

<table>
<thead>
<tr>
<th>Drug samples collected</th>
<th>Desired quantity</th>
<th>Obtained quantity</th>
<th>QOM reference number</th>
<th>Reason for not obtaining the desired quantity:</th>
<th>Price per tablet/vial in MKW (if applicable)</th>
<th>Stock on hand (in tablet/vials)</th>
<th>Monthly consumption (in tablet/vials, based on last six months)</th>
<th>Stockout time in last 6 months (+total number of days when this medicine was not available)</th>
<th>SOP for oxytocics storage available? (yes/no)</th>
<th>If yes, please take picture / copy</th>
<th>STGs for oxytocics available? (yes/no)</th>
<th>If yes, please take picture / copy</th>
<th>Storage conditions:</th>
<th>If samples taken from bulk / without original package, please take picture of original package / bulk container (showing label, batch number, expiry date, manufacturing date, name / address of manufacturer):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misoprostol 0.2mg tab.</td>
<td>50</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(yes/no)</td>
<td>If yes, please take picture / copy</td>
<td></td>
<td></td>
<td></td>
<td>1) Thermometer kept with oxytocics medicines (yes/no) 2) Temperature recorded daily (yes/no) If yes, please take picture</td>
</tr>
<tr>
<td>Oxytocin 10 IU vial</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(yes/no)</td>
<td>If yes, please take picture / copy</td>
<td></td>
<td></td>
<td></td>
<td>1) yes no                                      2) yes no</td>
</tr>
</tbody>
</table>

**Arrival dates and origin (eg CMST, donation) of last two orders:**

**Expected arrival date and origin of next order:**

**What do you do with expired samples?**

**Comments:**

If samples taken from bulk / without original package, please take picture of original package / bulk container (showing label, batch number, expiry date, manufacturing date, name / address of manufacturer)!

**Collected samples were replaced:**

YES ☐ NO ☐

**Collected samples were paid for:**

YES ☐ (Attach receipt!) NO ☐

**Name of sampling person:**

**Signature:**

**Name of accompanying person:**

**Signature:**

**Name of person responsible for health facility:**

**Signature:**
Appendix 8 Quality, Availability and Knowledge of Rational Use and Storage Requirements of Oxytocics in Malawi

Name of survey site: __________________________________________________________ Date of visit: ______________________________________________

QUESTIONNAIRE FOR KNOWLEDGE OF RATIONAL USE AND STORAGE REQUIREMENTS OF OXYTOCICS:

1. Profession / training level of person responsible of oxytocics /who administers oxytocics: □ Nurse □ Pharmaceutical technician □ Pharmacist □ other: ______________________________________________________________

2. How long has he/she been doing this work? □ less than 1 year □ 1-3 years □ 4-7 years □ 7-12 years □ more than 12 years

3. Has he/she ever attended training on storage, distribution and handling procedures of cold chain medicines? □ yes □ no
   If yes, how many times has he/she attended such a course within the last three years? □ once □ twice □ thrice □ more than thrice □ none within last three years

4. How should oxytocin be stored? □ depending on manufacturer □ at room temperature □ in a fridge

5. How should misoprostol be stored? Multiple answers possible! □ at a dry place □ at room temperature □ in a fridge □ in aluminium blisters

Oxytocin, that is used right now (manufacturer, declared storage conditions):
__________________________________________________________________________________

Other oxytocin products (+ its storage conditions) that have been used in the last 12 months:
__________________________________________________________________________________

Misoprostol, that is used right now (manufacturer, declared storage conditions):
__________________________________________________________________________________

Other Misoprostol products that have been used in the last 12 months:
__________________________________________________________________________________

6. Have you ever experienced ineffective oxytocics? □ Misoprostol: □ yes □ no □ Oxytocin: □ yes □ no
   If yes, what brand? __________________________________________________________
   What actions have been taken? Multiple answers possible!
   □ notify authorities (DHO/PMPB) □ notify supplier (CMST, Wholesaler) □ nothing □ buy different brand

7. Do you usually also have (methyl-)ergometrine on stock? □ yes □ no

8. What time do you switch off the fridge in the facility? □ evening □ over the weekend □ never switched off
9. How often do you have power black-outs (approx.)? □ less than once a month □ 1-3 times a month □ once a week □ 1-3 times a week □ daily

10. How do you maintain appropriate storage condition in the event of power failure? □ gas □ solar □ no measures

11. Do you have an automated functional generator system in case of power failure? □ yes □ no

For maternity wards / health centers / health posts only:

Number of deliveries in last 6 months: __________________________ Number of reported cases of PPH in last 6 months: __________________________

1. Have the numbers of deliveries in the last 6 months significantly increased or decreased? □ yes (increased: □ decreased: □ ) □ no
   If yes, reasons? Multiple answers possible!
   □ availability of infrastructure (e.g. power / water)
   □ availability of medical staff
   □ availability of medicines / medical devices
   □ lack of family planning
   □ other: __________________________

2. When do you give oxytocin to prevent / treat PPH? □ a) always after delivery of child □ b) always before delivery of child □ c) only when woman is bleeding

3. When do you give misoprostol to prevent / treat PPH? multiple answers possible!
   □ no misoprostol on stock □ if oxytocin is not available □ if oxytocin is not working □ if home delivery is planned/most likely
   □ other: __________________________
PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM (COPY FOR INVESTIGATOR)

Title of the research project: A survey on quality, availability and knowledge of rational use and storage requirements of oxytocics in Malawi.

Principal investigator:
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You are being invited to take part in the survey as titled above. Please take some time to read the information presented here, which will explain the details of this survey. Please ask the study staff any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is entirely voluntary and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the College of Medicine Research and Ethics Committee and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, Malawi Guidelines for Good Clinical Practice.

What is this research study all about?

➢ This study will be conducted in various districts in Malawi

➢ The aim of the study is to investigate quality, availability and knowledge of rational use and storage requirements of oxytocics at different points of care and different points of the supply chain in Malawi

Why have you been invited to participate?

➢ You have been asked to participate in this study because you are involved in distribution and/or administration of oxytocics and your knowledge and experience in this area will help in collecting vital information for this study.

What will your responsibilities be?

➢ Your responsibility is to provide samples of oxytocics and all information that you know on the questions asked, as honestly and as openly as you can.
To investigate storage conditions of oxytocics, we will place single-use temperature loggers where you store oxytocin and misoprostol, which will be re-collected after three months. Please ensure, that these loggers are not moved during these three months.

Will you benefit from taking part in this research?

The benefits of participating in this study is that the data will help policy makers on possible ways of improving quality and availability of oxytocics in the country as such you will not directly benefit.

Are there any risks involved in your taking part in this research?

There are no risks in taking part in this research and all participants' names and places will be kept confidential, nor will they be published.

If you do not agree to take part, what alternatives do you have?

You are free to decline to take part in this study. Nothing will happen to you if you decide to decline. You can also decide to decline parts of the study (e.g. placing temperature loggers)

Who will have access to the records of the data?

The data will be kept confidential. Only the investigator in this study will have access to the data. When the data is published, we will not use names or any other information that may lead to readers identifying you.

Results will be presented to you via a letter to your DHO, before being made available to any other party or to the public or being published in reputable journals.

Will you be paid to take part in this study and are there any costs involved?

No you will not be paid to take part in the study. There will be no costs involved for you, if you do take part. The samples you provide will be replaced or paid for.

Is there anything else that you should know or do?

You can contact PI at tel: 0999289874 if you have any further queries or encounter any problems.

You can contact the Secretariat of College of Medicine Research and Ethics Committee at 0111871 911 if you have any concerns or complaints that have not been adequately addressed by the study staff.

You will receive a copy of this information and consent form for your own records.
Declaration by participant

By signing below, I ........................................... agree to take part in a research study entitled A Survey on quality, availability and knowledge of rational use and storage requirements of oxytocics in Malawi.

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is voluntary and I have not been pressurized to take part.
- I may choose to leave the study at any time and will not be penalized or prejudiced in any way.

Signed at (place) ........................................... on (date) ......................... 2018.

..............................................................

Signature of participant

Declaration by investigator

I (name) ....................................................... declare that:

- I explained the information in this document to ............................................
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above and that his/her participation is voluntary
- I did not use an interpreter.

Signed at (place) ........................................... on (date) ......................... 2018.

..............................................................

Signature of investigator

Further queries should be addressed to:

The Chairperson
College of Medicine Research and Ethics Committee (COMREC)
Private Bag 360, Chichiri, Blantyre 3
Tel: + 265 (0) 1871 911