QUALITY CONTROL DOCUMENT (QCD)

Pre-trial facility visit checklist

THIS DOCUMENT IS ONLY VALID ON THE DAY OF PRINTING

QCD Number: EMOTIVE-QCD-01
Version Number: 1.0
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1. VERSION HISTORY LOG

| Version Number | Effective Date  | Details of Changes          |
|----------------|-----------------|-----------------------------|
| 1.0            | 11-May-2020     | QCD template created        |
Country:
Site name:
Date of visit:

Names of E-MOTIVE team members conducting the visit

| Name | Role |
|------|------|
|      |      |
|      |      |
|      |      |
|      |      |
|      |      |
|      |      |
## 1. Pre-visit activities

| Item                                                                 | Tick if completed | Notes |
|----------------------------------------------------------------------|-------------------|-------|
| Notify the facility management about the E-MOTIVE trial visit and permissions are obtained as required | ☐                 |       |
| Notify the lead clinician of the day and time of the E-MOTIVE visit | ☐                 |       |
| Notify the lead clinician to instruct the labour ward team to prepare the following items: | ☐                 |       |
| ▪ One consultant (ideally the local champion for E-MOTIVE) is available at the time of the visit |                   |       |
| ▪ Nurse/midwife in charge is available at the time of the visit      |                   |       |
| ▪ 1-2 nurses/midwives are available at the time of the visit (if applicable) |                   |       |
| ▪ 1-2 trainees are available at the time of the visit (if applicable) |                   |       |
| ▪ Facility statistics (total births, vaginal births, laparotomies, Uterine Balloon Tamponades, uterotonic drug and Tranexamic acid usage) obtained using the practical arrangements survey and is available at the time of the visit |                   |       |
| ▪ A sample of an empty medical record                                |                   |       |
| ▪ Local protocols for PPH management if available                    |                   |       |
## Site visit activities

| Item                                                                 | Tick if completed | Notes |
|----------------------------------------------------------------------|-------------------|-------|
| Welcome and introductions                                            | □                 |       |
| Thank the team for making the time to have this discussion with the E-MOTIVE team |                   |       |
| Introduce the background to the trial                               |                   |       |
| *(add names and roles of staff in the notes section)*               |                   |       |
| Confirm the numbers provided on the practical arrangements survey   | □                 |       |
| *(complete table below)*                                            |                   |       |
| See a medical record/birth record and any registries that relate to PPH outcomes (e.g. PPH, blood transfusion registries) | □                 |       |
| See any registries of equipment or PPH medicine usage               | □                 |       |
## Item

| Total number of births (both vaginal and caesareans) that have taken place in the facility in the last 12 months? |
| Total number of caesareans that have taken place in the facility in the last 12 months? |
| Total number of vaginal births that have taken place in the facility in the last 12 months? |
| Total number of women who have been referred from other facilities to this facility in the last 12 months? |
| Total number of women who have been treated for PPH at this facility in the last 12 months after vaginal birth only? |
| Total number of women who have been treated for PPH at this facility in the last 12 months after caesarean section only? |
| Total number of women who have had a blood transfusion for PPH at this facility in the last 12 months after vaginal birth? |
| Total number of women who have died from PPH in the last 12 months after vaginal birth only? |
| Total number of women who have had a uterine balloon tamponade for PPH in the last 12 months after vaginal birth only? |
| Total number of women who have had laparotomy for PPH (hysterectomy, compression sutures or arterial ligation) in the last 12 months after vaginal birth only? |
| Total number of women who have had a hysterectomy for PPH in the last 12 months after vaginal birth only? |

## Routine care for the third stage of labour and facility resources

| Question | Notes |
| --- | --- |
| Who performs the delivery? *(Who is present routinely?)* | |
| How many women does that person look after at the same time? | |
| Is active management of labour practised and which components are used? *(Do they use CCT? Do they routinely administer oxytocin for prevention and what dose and route?)* | |
| Question                                                                 | Answer |
|-------------------------------------------------------------------------|--------|
| If the uterus is soft, what do they do?                                 |        |
| If there is bleeding, what do they do?                                  |        |
| How do they assess the amount of bleeding?                              |        |
| At what blood loss volume do they usually start treatment?              |        |
| *(Probe 300ml, 500ml or 700ml)*                                        |        |
| Do they obtain observations? How and where do they record them? How often? |        |
| If they are worried about the amount of bleeding, what do they do?      |        |
| Please explain the whole process of what happens normally              |        |
| *Ask the nurses/midwives and move up to the doctors – do not interrupt the narrative* |        |
| Clarify doses and routes for drugs and define which one is used 1st line, 2nd line etc. |
|----------------------------------------------------------------------------------------------------------------------------------|
| What barriers are there for their management of PPH?  
For example stock outs, unavailability of obstetrics machines, staffing shortages, written guidelines. |
| Does the facility have a dedicated theatre for obstetrics? Do they have good availability? |
| Does the facility have a blood bank? How long does it take to get blood? How many women do they transfuse in a month for PPH after vaginal birth? |
| Provide an assessment on whether there is adequate scope for implementation of the E-MOTIVE trial at this facility |
## Inspection of the labour ward and delivery suite

| Question                                                                 | Notes |
|--------------------------------------------------------------------------|-------|
| Inspect the delivery bed and how it is set up for normal or instrumental birth. |       |
| Take pictures of the delivery bed and blood collection methods            |       |
| Ask for a demonstration of how they could collect blood and when they would trigger treatment |       |
| Ask to see the medicines and equipment                                   |       |
| Take pictures of all PPH medicines, equipment and kits                   |       |
| Take pictures of the labour ward                                         |       |
| Take pictures of the team with the local champion and nurse/midwife in charge clearly visible |       |
| Take pictures of the facility facade                                     |       |
| Thank the team for sharing all the information with us. Advise that we will have a discussion with the central trial team and then we will take things forward following that. |       |

## SIGN OFF BY PERSON PERFORMING VISIT

| Pre-trial facility visit performed by (name): |       |
|---------------------------------------------|-------|
| Signature:                                  |       |
| Date:                                       |       |