Background: WHO PPH Bundle Development

• 2016 Lancet Maternal Health Series: Why, despite technology, interventions, increased facility births, published guidelines, were too many women still dying from pregnancy and birth?

• TLTL/TMTS:
  • Lack of dignity and respect in childbirth
  • Lack of early recognition and early action for complications, delays
  • Lack of adherence to evidence-based care promulgated in guidelines

Maternal Health 2
http://dx.doi.org/10.1016/S0140-6736(16)31472-6
2018, WHO & BMGF

Asks:

• Question: Would a PPH Bundle comprised of evidence-based technologies and strategies improve guideline adherence and improve outcomes?

• Question: What interventions would be included in a PPH Bundle?

• BMGF/WHO/UCSF/MGH/ICES: a Delphi consultation on PPH interventions for PPH Bundles
What is a Clinical Care Bundle?

• Institute for Healthcare Improvement (IHI) Definition:
  • Small set of evidence-based interventions for a defined patient population and care setting that, when implemented together, results in significantly better outcomes than when implemented individually

• “Bundling” care improves quality of care and efficiency of care delivery

• Emphasis on clinical activities, but also
  • Teamwork
  • Communication
  • Cooperation

2018 WHO Technical Consultation on PPH Bundles

• Primary Response PPH Bundle
  • IV Fluids
  • Massage Uterus
  • Uterotonic Medication
  • TXA (if < 3 h post delivery)

• If the above, with two doses of Uterotonic and TXA did not arrest bleeding, move on (Escalate) to a REFRACTORY BUNDLE
2019 BMGF RFP for PPH Bundle Implementation Project

- Response was the collaboration that became the E-motive Project
- Designed to address challenges to implementation and adherence to evidence based PPH guidelines by using a bundle approach
Challenges & Solutions of Implementing PPH guidelines

**Challenge #1**

- Delays detecting PPH
- Life-saving treatment is not promptly initiated

**Solution**

*Early detection and treatment of PPH*
Challenges of implementing the PPH guideline and solutions (contd.)

Challenge #2

• Delayed or inconsistent use of interventions for PPH management
  - Late, delayed, or non-use of tranexamic acid (TXA)
  - Inconsistent application of uterine massage and IV fluids

Solution

The Bundle

Figure 1: The E-MOTIVE intervention

Figure 3: The E-MOTIVE intervention
Challenges of implementing the PPH guideline and solutions (contd.)

**Challenge # 3**

- Many health providers do not follow PPH guidelines

**Solution**

Implementation strategy targeting Capabilities, Opportunities and Motivations for Behaviour change (COM-B)

**Demonstrated barriers to bundle implementation**
- Lack of knowledge and skills
- Lack of qualified staff
- Lack of self-efficacy
- Inappropriate expectations
- Lack of engagement or buy-in of staff or management
- Lack of leadership or champions
- Fear of reprisals
- Lack of awareness

**Proposed implementation strategies to address barriers to bundle implementation**
- Simulation-based team learning at each site
- Deliberate skills practice and repeated refresher training, facilitated by designated peers (peer-assisted learning)
- Introduction of calibrated drapes with trigger line to increase motivation for bundle use
- Actionable data feedback to providers

**Physical – Work overload and workflow inefficiencies**
- Difficult access to resources

**Social – Lack of teamwork and communication**
- Lack of awareness

**Physical – Facilitated workflow through the introduction of MOTIVE emergency kits with all bundle components enabling easy and timely access to commodities**
- Peer assisted learning and champions

**Figure 2** E-MOTIVE implementation strategy and rationale
COM-B: Framework for Implementation

Demonstrated barriers to bundle implementation
- Lack of knowledge and skills
- Lack of qualified staff
- Lack of self-efficacy
- Inappropriate expectations
- Lack of engagement or buy-in of staff or management
- Lack of leadership or champions
- Fear of reprisals
- Lack of awareness

Proposed implementation strategies to address barriers to bundle implementation
- Simulation-based team learning at each site
- Deliberate skills practice and repeated refresher training, facilitated by designated peers (peer-assisted learning)
- Introduction of local E-MOTIVE champions who encourage, support, and model bundle use
- Introduction of calibrated drapes with trigger line to increase motivation for bundle use
- Actionable data feedback to providers

**Physical** – Work overload and workflow inefficiencies
- Difficult access to resources

**Social** – Lack of teamwork and communication

**Physical** – Facilitated workflow through the introduction of MOTIVE emergency kits with all bundle components enabling easy and timely access to commodities

**Social** – Peer assisted learning and champions

**COM-B**: Framework for Implementation

**Capability**

**Motivation**

**Opportunity**

**Figure 4**: E-MOTIVE implementation strategy and rationale.
E-MOTIVE programme

Project outline

COVID 19

Months

0 6 17 19 30 36

Adaptive cycle 1  Adaptive cycle 2

Baseline

RI

Intervention

Analysis, reporting and dissemination

MAIN TRIAL

Sites:
- Kenya
- Tanzania
- Nigeria
- So. Africa
- Sri Lanka
Research Questions:

- How is PPH currently detected and managed?
- What are the individual, socio-cultural and environmental influences on PPH detection and management?
- What are the potential barrier and enablers to implementing the E-MOTIVE care bundle?

**RESEARCH QUESTIONS**

![Diagram](Image)

- Assess barriers and/or facilitators related to implementing the intervention
- Inform development of implementation strategies/co-interventions to overcome barriers/enablers

Formative Research: Methods

• 10-15 IDIs per country with Health Care Providers on current practice, barriers/opportunities to implementation of PPH guidelines

• 800 surveys online

• Existing Evidence: systematic review of Cochrane guidelines

• QES: Qualitative Evidence Synthesis
E-motive Bundle Project

Pre-intervention

Primary qualitative research: in-depth interviews (n=up to 75 total)
Up to 10-15 IDIs per country with midwives, ob-gyn, junior doctors, administrators & managers

Quantitative survey

Existing evidence
(Cochrane reviews, WHO Guidelines)

Qualitative evidence synthesis
(interim findings)

Logic model
guided by the COM-B model of behavior change
to synthesize diverse evidence related to design, implementation and impact of E-MOTIVE components and bundle

Co-design workshops

Adaptive cycles (2)

Intervention

Cost effectiveness

Process evaluation

Parallel cluster randomized trial with baseline control phase

Post-intervention

Revised logic model

Updated WHO guidelines & EtDs

Qualitative evidence synthesis
(full review)
Co-design Workshops

Co-design of the E-MOTIVE bundle implementation strategy will involve stages:

1) Triangulation of findings across data sources by the research team

2) Report back findings to country teams

3) Stakeholder consultation workshops to refine and adapt the implementation strategy to each country’s local context
IMPLEMENTATION STRATEGY: Tested in Adaptive Cycles

- Trialing the strategy (non-study facilities)
- Obtaining feedback and outcomes
- Course Correction and adaptation
- Repeat cycle (non-study facilities)
- Finalize strategy
Training: Bleeding After Birth
Training Package
Adapted for EMOTIVE Bundle

Helping Mothers Survive
Bleeding after Birth Complete
Provider Guide
The E-MOTIVE Intervention Parallel Cluster Randomized Trial

- **Pre-intervention**
  - Primary qualitative research: in-depth interviews (n=up to 75 total)
    - Up to 10-15 IDIs per country with midwives, ob-gyn, junior doctors, administrators & managers
  - Quantitative survey
  - Existing evidence (Cochrane reviews, WHO Guidelines)
  - Qualitative evidence synthesis (interim findings)

- **Intervention**
  - Logic model guided by the COM-B model of behavior change to synthesize diverse evidence related to design, implementation and impact of E-MOTIVE components and bundle
  - Co-design workshops
  - Adaptive cycles (2)

- **Post-intervention**
  - Cost effectiveness
  - Process evaluation
    - Parallel cluster randomized trial with baseline control phase
  - Revised logic model
  - Updated WHO guidelines & EtDs

**Qualitative evidence synthesis** (full review)
Bundle Trial: Randomized Cluster Trial (PICO)

• Multi-country, parallel cluster randomised trial with a baseline control phase, along with mixed-methods and health economic evaluations

• Population
  
  • **Cluster**: Health facility (1,000-4,000 births a year, 2% incidence PPH, can provide comprehensive obstetric care with ability to perform surgery).

  • **Research participants**: All healthcare providers attending vaginal births in the clusters.

• Interventions 1) Strategy for early detection of PPH, which allows triggering of the ‘first response’ treatment bundle. 2) the Motive Bundle 3) Implementation strategy

• Comparator
  
  • Usual care with dissemination of the current guidelines
Outcomes

• **Primary**: Composite: severe PPH (blood loss $\geq 1000$ ml) or postpartum laparotomy for bleeding or postpartum maternal death from bleeding

• **Secondary**: Implementation adherence, resource use, plus clinical outcomes, such as blood transfusion, uterine tamponade, Intensive Care Unit admissions or higher level facility transfers, and newborn deaths,
Sample Size

- 80 clusters randomized to control and intervention
- Average of 2,300 vaginal births per cluster per year
- 337,920 births over 2 years
- 2% PPH incidence
- 6800 PPH cases

This sample size gives over 90% power (at 5% significance) to detect a 25% relative reduction in the composite primary outcome from 2% to 1.5%.
Progress

- Country visits to assess health facility feasibility conducted in 6 countries
  - (Kenya, Tanzania, Nigeria, South Africa, Sri Lanka and India)

- 80 health facilities selected for trial: Secondary level Facilities delivering 1-4,000 per year and with an incidence rate of PPH 2%
  - Sri Lanka, 10, Tanzania, 14, Kenya 16, Nigeria 20, South Africa, 20

- First version of main trial protocol, formative protocol and Concept Foundation protocol finalised

- Full ethical approval granted by the sponsor (University of Birmingham), University of Melbourne, and Nigeria
Progress and Next Steps

- Study Coordinators and Data Managers hired or being hired

- Formative Mixed Methods Research
  - July 2020 Virtual study orientation and training of data collectors in Nigeria
  - August IDIs and Survey in Nigeria
  - September IDIs and Survey Kenya, perhaps So. Africa (may be later)
  - October Sri Lanka

COVID-19 has and may further impact dates
Conclusion

- Innovative mixed methods implementation project
- Formative, mixed methods with a behavior change framework COM-B
- Intervention Randomized Cluster Trial of Motive Bundle and Implementation Strategy
  - Ambitious sample size, based on anticipated number of births
  - 80 clusters with ~2300 births/annum
  - 6800 PPH cases
- If successful result in package of PPH Bundle and Intervention Strategy
- Dissemination via WHO Guidelines and Evidence to Decision framework
Thank YOU!!
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