EVERY WOMAN
EVERY CHILD

EVERY NEWBORN ACTION PLAN METRICS

DESIGN WORKSHOP FOR FACILITY-BASED TESTING OF COVERAGE METRICS

20TH-22ND APRIL 2016
BEAUMONT ESTATE, OLD WINDSOR, UK

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KEY ABBREVIATIONS

ACS	Antenatal corticosteroid
AMDD	Averting Maternal Death and Disability
BeMOC	Basic emergency obstetric care
CeMOC	Comprehensive emergency obstetric care
CIFF	Children's Investment Fund Foundation
DHS	Demographic Health Survey
EMMP	Ending Preventable Maternal Mortality
ENAP	Every Newborn Action Plan
HBB	Helping Babies Breathe
HFA	Health Facility Assessment
HMIS	Health Management Information Systems
ICD	International Classification of Diseases
IMNCI	Integrated Management of Neonatal and Childhood Illnesses
KMC	Kangaroo Mother Care
MCHIP	Maternal and Child Health Integrated Program
MICS	Multiple Indicator Cluster Survey
OPD	Outpatient Department
PSBI	Possible serious bacterial infection
SARA	Service availability and readiness assessment
SDG	Sustainable Development Goal
SPA	Service Provision Assessment
UNICEF	United Nations Children's Fund
UNFPA	United Nations Population Fund
UNSG	Secretary-General of the United Nations

BACKGROUND

The ENAP measurement improvement roadmap

The Every Newborn Action Plan (ENAP) is underwritten by a 2014 World Health Assembly Resolution, and aims to support countries in reaching **the target of no more than 12 newborn deaths per 1,000 live births, and no more than 12 stillbirths per 1,000 total births by 2030 [1]**. This work is also closely linked to the Ending Preventable Maternal Mortality plan (EPMM), The Global strategy for Women, Children and Adolescents, and supports the Sustainable Development Goals (SDGs) [2, 3]. Data are crucial to track progress towards this ENAP vision for quality of care at birth. However, there is a major gap for data to track programmatic coverage, quality and service readiness. As seen from programmes such as immunisation, malaria and HIV, these data are fundamental for local programme planning and financing, especially to ensure we reach the poorest families, as well as for global governance [4].

The ENAP Metrics working group, co-chaired by World Health Organization (WHO) and the London School of Hygiene & Tropical Medicine (LSHTM), has a mandate to work with countries and all partners involved with ENAP to ensure the milestones in the Action Plan related to metrics are met on time, and tools and learning are shared and available in open access for widespread use in countries. The ENAP measurement improvement roadmap sets out an ambitious five-year plan to improve, institutionalise and use metrics by the year 2020, in order to drive the reduction of neonatal mortality and stillbirths, as well as maternal deaths, towards 2030 targets [4]. This improvement Roadmap has been developed and refined through an inclusive consultation process, including a WHO technical meeting in Geneva in 2014 [5] and is now closely linked with EPMM.

Table 1. ENAP core and additional indicators

Current status	Level	Core ENAP Indicators	Additional indicators	
Definitions clear – but quantity and consistency of data lacking	*Impact*	1. Maternal mortality ratio*		
		2. Stillbirth rate*	Intrapartum stillbirth rate	
		3. Neonatal mortality rate*	Low birth weight rate	
			Preterm birth rate	
			Small for gestational age	
			Neonatal morbidity rates	
			Disability after neonatal conditions	
Contact point definitions clear but data on content of care are lacking	*Coverage:* Care for all mothers and newborns	4. Skilled attendant at birth*	Antenatal Care*	
		5. Early postnatal care for mothers and babies*		
		6. Essential newborn care (tracer is early breastfeeding)	Exclusive breastfeeding up to 6 months*	
Gaps in coverage definitions, and requiring validation and feasibility testing for HMIS use	*Coverage:* Complications and Extra Care	**7. Antenatal corticosteroid use**	Caesarean section rate	Focus of this research & the protocol
		8. Neonatal resuscitation	*Uterotonic use (EPMM)*	
		9. Kangaroo mother care		
		10. Treatment of serious neonatal infections	**Chlorhexidine cord cleansing**	
	Input: Service Delivery Packages for Quality of Care	Emergency Obstetric Care		
		Care of Small and Sick Newborns		
		Every Mother Every Newborn Quality Initiative with measurable norms and standards		
	Input: Counting	Birth Registration	Death registration, cause of death	

Shaded = Not currently routinely tracked at global level
Bold red = Indicator requiring additional testing to inform consistent measurement
*also SDG core or complementary indicator. Indicators to be disaggregated by equity such as urban/rural, income, and education.
Adapted from WHO and UNICEF, Every Newborn Action Plan (2014), Mason et al. Lancet (2014), Moxon et al., BMC Pregnancy & Childbirth (2015) [4]

Facility-based testing research

The first priority of this Roadmap is on facility-based testing of coverage indicators for selected interventions for ENAP and EPMM (Table 1). None of these interventions have routine coverage data available and all are important to track in order to monitor scale up and ensure safety, in line with WHO guidelines (e.g. antenatal corticosteroids, gentamicin) [6]. Therefore, the first step on the measurement improvement roadmap requires facility-based testing of proposed numerators and denominators for capturing coverage of selected interventions for ENAP and EPMM (Table 2).

Table 2. Indicators to be tested in terms of numerator and denominators

Indicator	Numerator #	Place of Care	Denominator options
Uterotonic use for 3rd stage of labour	Number of women who received a uterotonic immediately after birth	Labour ward or theatre	**Per 100 total births, also could compare to currently used denominator (per 100 live births)**
Antenatal corticosteroid (ACS) use	All women giving birth in a facility who are <34 completed weeks and received one dose of ACS for being at risk of preterm birth (note initial focus on counting all while testing ways to split by GA at birth to identify women treated who did not deliver <34 completed weeks)*	Labour ward or antenatal ward	**TO BE COMPARED FOR ALL 4 INDICATORS:** a) Target population requiring the specific intervention (True measure of coverage) b) Live births in the facility c) Total births in the facility (including stillbirths) d) Estimated births (live or total)
Newborn resuscitation	Number of newborns for whom resuscitation actions (stimulation and/or bag and mask) were initiated	Labour ward or Theatre	
Kangaroo mother care (KMC)	Number of newborns initiated on facility-based KMC	Newborn care ward or KMC ward	
Treatment of neonatal possible serious bacterial infection (PSBI)	Number of newborns (< 28 days old) who received at least one dose of antibiotic injection for PSBI in the facility	Inpatient newborn care, and/or outpatient service	

Note: Note that numerators do not include everything that needs to be measured for effective coverage, but if these numerators are measured then additional indicators can be added e.g. which uterotonic, what time etc.
*For ACS focus is to track safety, test methods to include gestational age and relevant safety outcomes. 24-34 weeks as per WHO guidelines [7]

This phase of research aims to assess the validity of routine health facility-level registers and reporting documentation to measure the selected coverage indicators in order to inform use (or not) of these indicators in national and global reporting. This will involve observations in facilities, comparing this with routine health facility level documentation. For some interventions this may also involve use of film data. Funding from the Children's Investment Fund Foundation (CIFF) will support research in facilities in Tanzania and Bangladesh and UNICEF funding will support research in facilities in Nepal, rapidly leading to feasibility assessment of different indicators in a wider group of countries and health care contexts.

Workshop Aim and Objectives

The main focus of this workshop was to enable technical review of the plans for facility-based research and to bring together researchers who are undertaking/have undertaken similar work, as well as relevant experts to ensure programmatic relevance, with results appropriately targeted for wide use in national data platforms at a later stage.

The overall research is based on five objectives (Table 3), and the research protocol was drafted by a working group and shared before the workshop for inputs. Following this design workshop, the protocol will go through wider review and refinement during the formative research stage, and then it will be made available in an open access format with linked tools to facilitate comparison and combination of ongoing research. A diagram featuring the process of the protocol development is in Annex 4, and a peer reviewed paper is anticipated with group authorship including those actively involved in the process at the workshop.

During Day 1 of the workshop general introductions and overviews of the ENAP measurement improvement roadmap, the workshop and the research protocol were presented in the morning. In the afternoon, working groups focused on the five indicators to be tested (uterotonics, resuscitation, KMC, PSBI treatment and ACS). The groups worked on the intervention specific research questions for the proposed numerator and denominator options, and refined or planned the tools needed for the observers and data extraction, and then identified additional important questions that could be considered to include in this research where around 5,000 births are to be observed.

Table 3. Five objectives of the facility based research showing working group tasks

	Primary Research Objective	Research Questions	Workshop Tasks for Intervention Groups
1	To determine the validity in terms of accuracy and precision of recording for the practice (numerator) for selected facility-based care interventions for mothers and newborns.	**Research question 1: NUMERATOR** Are the registers and hospital level documentations of maternal and newborn interventions a valid representation of the number of mothers/ newborns receiving the intervention?	**TASK 1** **Numerator** To review objective 1 research question for this specific intervention and to review/develop checklists for observers, plan data extraction from health record/registry and other tools needed
2	To assess the advantages and disadvantages of alternative denominator options: a) Target population requiring the intervention in the facility b) Live births in the facility c) Total births in the facility (including stillbirths) d) Estimated births (live or total) in the entire population to be reached (including home births)*	**Research question 2: DENOMINATORS** What are the feasible denominator options for each of the interventions using available data sources (population data and hospital registers) or documentation?	**TASK 2** **Denominator** To consider denominator options and advise on issues specific to this indicator especially for the target group based on clinical need and if/how this could be assessed by observers and/or film
3	To examine a few priority questions for each intervention with respect to effective coverage (e.g. content, timing, completion rates, etc.).	**Research question 3: CONTENT/QUALITY OF CARE** What content of care do mothers and newborns receive for each intervention? Which aspects of the content of care are already accurately recorded?	
4	To determine the accuracy of maternal recall of the practice (numerator) and need (denominator) to inform feasibility of capture in household surveys	**Research questions 4: MATERNAL RECALL** Can coverage and content of care received of these interventions be accurately recalled by mothers at discharge?	**TASK 3** **Effective coverage or content/quality of care** To propose additional questions regarding effective coverage and prioritise a few that could be included in this research opportunity. (e.g. film recording to assess how continuous is KMC)
5	To assess reported barriers and facilitators to the completion of documentation (such as registers) by health workers. To provide recommendations for the feasibility testing phase of the study.	**Research question 5: METRICS, BARRIERS AND ENABLERS** How facility recording of newborn interventions can be improved? - What are the barriers and enablers to measurement of these interventions? - What are the barriers and enablers to recording? - Recommendations to the ENAP Metric Roadmap (Q1-Q4) [4]	

* The focus of this work will be to determine the facility-based denominator options

During Day 2 of the workshop working groups focused on Methods and Systems and integration group work. See the lists below for the total of 12 working group sessions on Day 2.

GROUP WORK B: Methods Group Work

1. Analysis planning for denominator options for testing
2. Training observers
3. Filming, including ethics, methods, and analysis
4. Pre-discharge interviews to assess maternal recall
5. Qualitative health-worker interviews to assess barriers and facilitators to data recording
6. Knowledge management/dissemination

GROUP WORK C: Systems and integration group work

1. Analysis planning for denominator options for testing
2. Training observers
3. Filming, including ethics, methods, and analysis
4. Pre-discharge interviews to assess maternal recall
5. Qualitative health-worker interviews to assess barriers and facilitators to data recording
6. Knowledge management/dissemination

Workshop objectives

Overall the workshop focused upon the following objectives:

1. **Coverage and quality of care metrics for facility-based testing of maternal/newborn interventions:** To review and refine the draft protocol including adaptations for observation/filming the practice of each intervention. Metrics working groups also contributed towards specific observation checklists and tools for each intervention.
2. **Analytical plan and database:** Advance draft analytical plan and develop an outline of a common database for the facility-based testing sites as well as process for data collection, checks etc.
3. **Service readiness for care of small and sick newborns:** Update on ENAP work to scope parameters to assess service readiness domains, and input to plans to compare data and processes for Health Facility Assessment (HFA) surveys (SPA and EmONC) with Health Management and Information System (HMIS) data in Malawi.
4. **Perinatal audit:** Update on WHO tools and testing, plan linkages with ENAP facility-based research and with work on maternal death surveillance and response.
5. **Operational research plans:** Further advance plans for commencing facility-based data collection in sites in Bangladesh and Tanzania.

Expected workshop outputs

Throughout the two day workshop, the following outputs were expected from the working group discussions:

- **Facility based research protocol** including design/refine the draft approaches for:
  - » Observation and/or film records for intervention practices (numerator “gold standard”) with specific adaptations for labour ward (to observe resuscitation, uterotonics, ACS) and newborn care site (to observe KMC and PSBI treatment).
  - » Assessing recording of the practices in routine or special registers (varies by intervention and site).
  - » Overview of analytical plan to compare numerator “gold standard” with recorded data to enable calculation of sensitivity/specificity etc.

  - » Overview of analytical plan to compare denominators.
  - » Plan for ensuring open access protocols to enable other comparable research (likely published paper with group authorship).
- **Guidelines for field work including ethical considerations and the following operational components:**
  - » Observation checklists and tools.
  - » Observer training materials (adapting from MCHIP manual).
  - » Considerations for use of video records and analyses.
- **Draft of database plan and variables, including plan for smartphone/tablet data collection and for platform facilitating comparable data collection and quality checks across different research sites and settings.**
- **Research plan for initial phase of improving metrics for service readiness for care of small and sick newborns:**
  - » Draft analysis plan for quantitative comparative analysis of health facility assessment tool data with HMIS with respect to service readiness data for care of small and sick newborns.
  - » Plan for qualitative comparison of data collection processes for HFA and HMIS with respect to service readiness for care of small and sick newborns.
- **Plan for testing and implementation of perinatal audit tools linked to ENAP facility-based testing sites.**
- **More detailed operational planning** for Bangladesh and Tanzania sites and teams including ethical review board submissions.

Structure of meeting

April 20th	All Day	All participants in workshop
April 21st	All Day	All participants in workshop, with evening departures if appropriate
April 22nd	9-1pm	ENAP metrics coordination group, Tanzania and Bangladesh country teams review next steps and operational plans

A full workshop agenda, including a detailed timetable with plenary and working group sessions, is included in Annex 1.

INTRODUCTION TO THE COUNTRY TEAMS AND TESTING SITES

Tanzania

Context

Tanzania has made remarkable progress in reducing deaths of children under five in the past 20 years, and the country successfully met Millennium Development Goal (MDG) 4, although reducing neonatal mortality and still birth rates have been slow as well as progress toward MDG 5 target [8]. Newborn health has gained attention only since 2005, whereas before it was almost unmentioned in policy and had negligible funding.

The Government has ambitious plans for scaling up key interventions and has already made substantial progress, such as for neonatal resuscitation. Tanzania is one of the 3 countries to undertake a national scale up of newborn resuscitation in the 'Helping Babies Breathe' initiative. Tanzania could make rapid progress if high-impact interventions for neonates are now scaled up; however, the lack of national data on coverage and quality of these interventions is a recognised impediment to improving programme management and tracking quality and equity of care.

Data for Reproductive, Maternal, Newborn and Child Health (RMNCH) programming has been very dependent on Demographic Health Survey (DHS) and health facility assessments but is now shifting to focus more on HMIS, with District Health Information software (DHIS) 2 as the main platform. RMNCH score cards are carried out by districts and reported up through the systems, with high political visibility and helping to drive demand for improved data quality. It is however noted that there is a specific gap for newborn indicators.

The facility-based testing of coverage metrics is an important next step for sustaining and accelerating progress towards ENAP and EPMM targets in SDGs.

Country team and study sites

Following the request for applications (RFA), it was announced during the workshop that Ifakara Health Institute (IHI) in collaboration with Muhimbili University of Health and Allied Sciences (MUHAS) were awarded the opportunity to conduct the proposed study in Tanzania. The study will be led by a core Ifakara ENAP metrics technical team, under the advice of a National Project Advisory Group, along with a Senior Investigators Technical advisory group, a data management and statistics team and a project management team. Muhimbili National Hospital and Temeke Municipal Hospital have been selected as the two facility study sites with a site supervisor and 12 observers planned for each facility.

Bangladesh

Context

Over the past 20 years, Bangladesh have expanded women's access to maternity services, especially to delivery and comprehensive emergency care in new, private-sector health facilities, and have increased the use of skilled childbirth care and facility-based deliveries, especially among the poor.

These efforts have supported Bangladesh's progress towards the achievement of MDG 4 for child survival and achieved a 40% decline in maternal mortality. However, 57% of under-five mortality is in the neonatal period. Rapid scale up of life saving interventions, improved access to services for the poor and improved systematic focus on quality of care are important conditions to sustain progress [9].

The implementation and monitoring of life saving newborn interventions are necessary conditions to sustain and accelerate the current rate of progress.

Country team and study sites

The International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR, B) will conduct the proposed study in Bangladesh. The study will be led by a core ICDDR, B ENAP metrics technical team, under the advice of a National Project Advisory Group, in close collaboration with Saving Newborn Lives team.

One of the selected study sites is the Maternal and Child Health Training Institute (MCHTI), a tertiary facility in Dhaka with 173 beds. Two additional study sites were selected in Kushtia: the District Hospital (DH), a secondary facility with 250 beds, and Daulatpur Sub-district Hospital (UHC), a primary referral facility with 51 beds.

Nepal

Context

During the MDG reporting period, Nepal has been an early achiever of MDG 4 on reducing under-five mortality by 2/3rd [10]. However, during the same reporting period, the neonatal mortality has reduced by 57% [11]. In 2015, the neonatal mortality rate is 23 per 1,000 live births and stillbirth rate is 18 per 1,000 births and Nepal has pledged to reduce the mortality rate to 10 or less by 2035 [12-14]. Despite the efforts and investment made in the facility and community based newborn program, the improvement in the coverage and quality of newborn interventions has been low [15]. Among the ENAP core coverage indicator, the reach of four antenatal care, skilled birth attendance and postnatal care within 2 days has been low and only just above 50% of the women receive these services [12]. The quality of these services has been inadequate [16]. These core indicators are monitored both in the routine HMIS and periodic national and sub-national survey [17]. Nepal is currently graduating from the paper-based information management system to electronic system from the districts and sub-district level, customizing the DHIS 2 platform.

Country team and study site

Following the 2016 ENAP metrics workshop in April, Nepal, led by UNICEF country office, will become the third country site. The UNICEF country office together with Uppsala University has been conducting several health facility based observational studies as well as Randomised Controlled Trials for newborn interventions. In 2012, the country team led the evaluation of Helping Babies Breathe Quality Improvement Cycle on health worker performance of neonatal resuscitation using video filming [18]. Between 2014 and 2016, the country team has spearheaded three randomised controlled trials on the effects of timing of umbilical cord clamping in different groups of babies on birth and developmental outcomes. The country team has a strong research team for conducting health facility based studies.

The study site will be Paropakar Maternity and Women's Hospital, a government tertiary hospital of Nepal in Kathmandu, which provides obstetric, gynaecological and neonatal service. The annual number of deliveries is 22,000 births with early neonatal mortality rate at 9 per 1,000 live births and a stillbirth rate of 19 per 1,000 total births [19].

Data context for maternal and newborn health events, Session C4

During the workshop, the data context for maternal and newborn health events was discussed in detail. A group of experts provided information about Health Management and Information System (HMIS), a data collection system specifically designed to support planning, management and decision-making that routinely collects and reports health information directly from facilities and districts providing real-time, locally owned data for policy-making. It is agreed that HMIS should be strengthened as they are less expensive than large-scale, representative household surveys and can be organised by national decision-makers. Additionally, the validity of HMIS indicators should be improved, and use of these data for reviewing programme performance should be increased.

Further, it was discussed that the Health Information System Program (HISP) is a global network established and coordinated by the Department of Informatics at the University of Oslo (UiO). This program supports the core development, implementation and training of

District Health Information software (DHIS 2). DHIS 2 is a software tool for collection, validation, analysis, and presentation of data, tailored (but not limited) to integrated health information management activities. It is platform independent, can run on both online and offline modes, is multi-language enabled and offers ability to manage aggregate, routine data through a flexible meta-data model which has been field-tested for more than 15 years. DHIS 2 has been successfully implemented in over 30 countries as the preferred HMIS backbone software and even more with partial use via non-governmental organisations (NGO)s or other non-governmental supported surveillance systems.

DHIS 2 is open source software licensed under the liberal BSD license and is free for everyone to install and use. Each Ministry of Health (MoH) implementation of DHIS 2 is fully owned and governed by the country, i.e. the server, database and data are maintained by the country. Therefore, each country has a different "DHIS 2 instance" built on the platform variations in indicators, disaggregation, reports and analytical outputs. It was highlighted that there are ongoing efforts by global actors like WHO to provide recommended configuration packages that countries can adopt to support sharing of best practices and standardisation of key indicators. There is a growing global DHIS 2 community and the DHIS 2 academy is a regional training program focused on strengthening national and regional capacity to successfully set up, design and maintain DHIS 2 systems. It is typically run through local regional partners that are usually hosted via implementing partners working with standardised materials from UiO. It was noted that both Tanzania and Bangladesh are using DHIS 2 at national scale with respective DHIS 2 local partners supporting the MoH.

The working group discussed that currently there are no standard registers or systems to systematically collect data on coverage of newborn health interventions or impact level indicators such as newborn or stillbirth death rates. Most of these indicators are yet to be integrated in HMIS. Some data on newborns are available from a variety of data sources, and not all the data and information are currently available. Therefore, there is a need to develop better indicators. The DHIS 2 system is currently being scaled up and integrated.

The group determined that the most common sources at national level for maternal/newborn health relevance include the following: Birth registration / birth certificates, e.g. could be registered in DHIS 2; Death surveillance & classification, e.g. International Statistical Classification of Diseases and Related Health Problems, version 10 (ICD-10); Maternal and perinatal death audits; Notifiable disease reporting; and Facility assessment surveys, e.g. SARA. It was noted that many of these sources could potentially be captured in DHIS 2 as they do not necessarily need to have a patient identifier and do not need to be immediately linked with the internet.

Depending on the setting, all facilities may have DHIS 2 integrated within, or it may only be integrated in high volume hospitals. The facility paper registers and tally sheets are the source of the DHIS 2 data, and it was recommended that these tools first need to be changed and integrated. Through the study, the participants agreed that the timelines for these revision processes in Tanzania, Bangladesh and Nepal will be reviewed and specific guidance will be given to countries that are ready to revise their facility paper tools. Further, it was suggested that there is also a need to observe workflow around data collection and approval at health facility level to better understand how to improve data quality.

Case study: Tanzania

The National strategic plan managed by the HMIS team is positioned within the Ministry of Health and Social Welfare (MoHSW), which includes intervention specific/ package specific specialists and partners. The regional health management team comprising of an HMIS focal person are responsible for managing DHIS 2 at regional level. At the District level, there are additional health team members responsible for managing data from the facility level.

All district councils, district and regional hospitals are linked with the online national server through the use of internet connectivity. At the facility level, HMIS registers and tally sheets are used by practitioners to capture daily information and produce summaries at the end of the month. The monthly summary forms collected at the facility are submitted at the district level and entered into the DHIS 2. The information gathered is mostly of aggregate format with little use of patient data, e.g. HMIS death notification form and electronic integrated diseases surveillance system (eIDSR). The system is configured with data quality checks for data cleaning and analytical tools such as dashboard, charts and map for data analyses and dissemination. Ideally supervision and feedback mechanisms to the facility level have been set on a quarterly basis, however, this is often not fully functioning. To promote open access, the MoHSW has implemented a web-portal to provide open access to all cleaned data to its stakeholders. The portal can be found at https://hmisportal.moh.go.tz/hmisportal/#/home and the aim is to update the portal regularly, at least quarterly.

To accommodate missing indicators which are not collected at the registers level, a review of tools needs to be done. A similar review process of HMIS tools has been done in 2013 and 2014 which was followed by the updating of forms in the DHIS 2.

Ethics and institutional review board submission

Ethics and institutional review board (IRB) submissions are indicated for this multi-partner multi-country ENAP metrics facility-based study. It is especially important regarding the consent of women and hospital staff and to address ethical issues involving the use of observers and filming. Additionally, data ownership, management and disclosure of error must be clearly outlined in the protocol. The ethical issues are explained in more specific detail in the following sections.

The three country sites will submit their ethics and IRB submissions as indicated in country to their ministries and regulating bodies, and LSHTM will submit their ethics and IRB submission for the international research study. The IRBs are planned for submission end of quarter 2 of 2016 pending approval in quarter 3 of 2016 to facilitate the timeline of the formative research phase activities.

INTERVENTION GROUP WORK

During Day 1 of the workshop, the working groups focused on the five indicators to be tested: uterotonics, KMC, resuscitation, PSBI treatment and ACS. The groups worked on the intervention specific research questions for the proposed numerator and denominator options, refined or planned the tools needed for the observer checklists and data extraction, and then identified some important additional questions that could be considered to include in this research where around 5,000 births are to be observed.

Uterotonics, Session A1

Postpartum haemorrhage (PPH) still remains the most common cause of maternal death in low-income countries, despite the majority of these deaths being preventable through the use of prophylactic uterotonics during the third stage of labour. Active management of the third stage of labour is best practice for the prevention of PPH, with uterotonics being the most critical element. All women giving birth should be offered uterotonics during the third stage of labour for the prevention of PPH. Oxytocin remains the uterotonic of choice based on studies of safety and effectiveness, and when oxytocin is not available ergometrine or misoprostol should be given.

Proposed numerator

The primary research question was determined by the working group to be 'What is the validity of uterotonic indicators measured through a record review of the delivery room registers compared to observations?' and, even more specifically, 'What is the sensitivity and specificity of the recording in health facilities?'. The place of observation is in the delivery room so the labour and delivery room registers will be checked. The working group recommended that the observer is at least paramedic level and must have some recognised training, is female and external to the health facility. The group also recommended that all levels of facilities should be included in the sample.

Proposed denominator

Through the working group discussion, the true denominator, i.e. the target population for this intervention, was determined to be 'All women with normal vaginal births (including live births and still births) seen at the health facility.' However, it is acknowledged that the current indicator only captures facility based coverage and that the only information for the numerator is for facility births. The working group identified that ideally population coverage would be able to be gathered and suggested a research agenda to determine how to capture the true population coverage. Therefore, the true denominator was suggested to be 'all women in need of uterotonics'. The group highlighted the need to distinguish whether or not the country is providing data at the community level, and in countries that do not have a policy for community based distribution of uterotonics, facility based coverage could be used to estimate population coverage.

Content and quality of care

The working group considered additional questions regarding effective coverage such as content and quality. They highlighted the need to know the timing of administration, if there was appropriate active management of the third stage of labour after the uterotonic injection was given, and if additional doses were given as a proxy for continuous bleeding. It was noted that the opportunity of having observers present was valuable in capturing data on whether high levels of obstetric care are being given after the uterotonic.

Further, during the formative assessment phase, the working group emphasised there is a need to look at the registers and health facility records to ensure key data elements are currently captured, and, if not, to ensure the orientation of health workers to improve data capture. It was also discussed that it will be important to compare urban and rural uterotonic data.

Checklist and/or tool development

The working group discussed the development of a checklist for observers, and the following key components were recommended for inclusion in an uterotonics checklist:

Was uterotonic administration provided in line with evidence and WHO guidelines:

- Type, dose and route of drug used?
- Timing of uterotonic administration?
- Respectful care and attainment of informed consent?
- Measurement of additional doses of uterotonics as a proxy for PPH management/case.
- Uterotonic provided as part of active management of the third stage?
- Cold chain, and supply of drug and equipment maintained?

Following the workshop, the uterotonic observer tool was developed further based upon the working group discussions and related tools provided. The draft Immediate Uterotonic Administration Tool was collated with the Antenatal Corticosteroid Verification, Essential Newborn Care and Newborn Resuscitation Tools to develop the Labour ward observer checklist (See Annex 7). It is anticipated that this observer checklist, in addition to the KMC and PSBI observer checklists, will be refined during the formative and piloting phases.

Conclusion and next steps

Though the denominator is recommended as all women having normal vaginal births within a health facility, there is a need for additional research to look at true population coverage including the community level as highlighted above. It is also recommended to look at health facility records from the previous three months to assess evidence of the Hawthorne effect and for observations to continue up to time of transfer from delivery ward to get information on other doses of uterotonic and obstetric procedures.

Operationally, further discussion is needed to determine how to capture when a record is completed and also to consider looking at monthly summaries versus delivery records versus observation to assess the accuracy of data flow.

Finally, the ethical issues surrounding the use of observers for assessment of uterotonic administration need to be considered. If a life threatening condition is observed, it is recommended the observer intervenes. In instances where sub-standard care is delivered, the observer could raise the issue with the field supervisor who could feedback to the facility in-charge but would not intervene.

Kangaroo mother care, Session A2

Kangaroo mother care (KMC) is “a method of caring for low birthweight newborns (mostly preterm) in direct and continuous skin-to-skin contact, in the kangaroo position, with their mother (or guardian), with support for early and exclusive breastmilk feeding. The current evidence to achieve mortality reductions supports KMC for clinically-stable newborns, weighing less than 2,000g, initiated in a facility. WHO guidelines support that the infant is cared for in the kangaroo position for the equivalent number weeks it would have taken for the infant to reach full term (or as long as the baby will tolerate the position) accompanied with appropriate follow up after discharge.” [4]

Proposed numerator

During the working group, the proposed numerator ‘the number of newborns initiated on facility based kangaroo mother care’ was discussed in regards to facility based initiation. It was determined that the WHO definition of KMC will be used; however, the group noted it is challenging to measure when KMC is initiated given multiple components of WHO definition and that the definition of ‘stability’ is variable. It was emphasised that the numerator doesn’t have weight specification because eligibility criteria vary between countries.

The group members determined that the KMC facility based initiation rate could be observed in the post-natal ward, neonatal intensive care/special care unit and KMC unit/defined KMC space. It was noted that observations of skin to skin at birth will also be necessary to consider in the labour and delivery room to ensure that KMC initiation is differentiated from basic skin to skin at birth for all babies. It was discussed that KMC is recorded in the KMC register and that filming on KMC/newborn units may be useful for comparison with the registers, especially at times when the observers might not be present. The group members discussed that a detailed checklist for observers will need to be developed covering the key KMC components, such as breast milk feeding, if the mother has undergone counselling, if the baby is in kangaroo position with hat, if the baby is in correct

KMC position continuously (and when not in KMC position on the mother, to observe where the baby is placed), and if the mother/family is counselled on ambulatory follow-up (at times including appointment for check-up after discharge).

Proposed denominator

As already established, the true denominator, i.e. the target population for this intervention, was determined not to be simple. The working group members noted it is critical to measure all facility births, gestational age (where possible, including method of assessment), birth weight (to identify <2,500g and, <2,000g) but none are a "true denominator". It was recommended that gestational age assessment and accurate birthweight will need to be included in addition to the observation.

Content and quality of care

The working group also discussed research questions regarding content and which observations could be useful sentinel measures of quality of care for babies on KMC. They noted it is important to include observations on KMC adherence, such as daily weighing, regular breast milk feeding, number of hours in KMC position, temperature monitoring and regular clinical assessment, both on the KMC unit and possibly on Special Care Baby Unit (SCBU)/Neonatal Intensive Care Unit (NICU). It also will be important to conduct qualitative interviews with providers on what influences initiation, on both babies initiated and not initiated on KMC. Further, exit interviews with mothers on KMC follow up (i.e. to check if the women have a discharge and follow up plan) should be completed and could be validated with documentation.

Checklist and/or tool development

The working group discussed the development of the KMC observer checklist for KMC initiation and noted that it should cover the following key components:

Was KMC provided in line with evidence and WHO guidelines:

- KMC adherence achieved (daily weighing, regular breastmilk feeding, number of hours in KMC position, temperature monitoring etc.)?
- Is the clinical space and equipment required for KMC available?
- Are babies discharged from the health facility's KMC ward with an appropriate follow up plan?

The group members recommended to review examples of relevant research including the KMC implementation guide/supervision checklist and the daily assessment forms, such as the KMC wrap study, and shared relevant tools to measure KMC initiation rate.

Following the workshop, the draft KMC observer checklist was developed further based upon the working group discussions and tools provided (See Annex 7). It is anticipated that this observer checklist, in addition to the Labour ward observer checklist and the PSBI Assessment and Treatment site observer checklist, will be refined during formative and piloting phases. Formative research will be critical to better understand the cultural adaptations of KMC in the research setting to ensure that the checklist accurately captures the process of initiation, as this differs between settings.

Conclusion and next steps

The working group concluded that it would be of great value for KMC initiation to be both observed and filmed, taking into account specific filming locations might be context specific and the ethical issues regarding consent of the women and use, storage and analysis of films. It is anticipated that the draft KMC/newborn observer ward checklist and the specific use of filming will be explored further during formative research phase. It is particularly important to interview mothers to establish whether or not they would be comfortable with the use of cameras on the KMC/newborn unit.

Resuscitation, Session A3

"Basic neonatal resuscitation describes assessment and actions for every newborn at the time of birth, to assist in establishing breathing and circulation; it should be practised on all non-macerated newborns not breathing spontaneously following immediate drying in accordance with current WHO guidelines. Effective and safe resuscitation of these babies is highly time-sensitive and should be initiated within the first minute after birth. The actions include additional stimulation and positive pressure ventilation with bag and mask if clinically indicated following stimulation. The intervention definition does not include advanced resuscitation measures such as intubation and/or medications." [4]

Proposed numerator

During the workshop, the proposed numerator of 'number of newborns for whom resuscitation actions (stimulation and/or bag and mask) were initiated' was discussed. The numerator was determined to be babies who do not breath/cry at birth who receive

stimulation or/and bag and mask ventilation.

The group members discussed that the place of observation is the labour and delivery unit/operating theatre and that the intervention is recorded in the routine register, in addition to supplementary register (i.e. HBB where data points are missing). The group discussed that it will be important to know the country protocols for resuscitation and the level of resuscitation. It also was discussed that sometimes only suction is noted in registers.

Proposed denominator

Through the working group discussion, the true denominator, i.e. the target population for the indicator of proportion of babies who receive resuscitation, was noted as being difficult to capture and will need further thought. The true denominator was suggested to be 'Number of newborns who were not breathing spontaneously/crying at birth for whom resuscitation actions (stimulation and/or bag and mask) are needed'. It was emphasised that the denominator should never be just live births for this indicator as it should specifically be babies who do not breath/cry at birth. The group members agreed that the key outcome data is important to collect, including live, still born (fresh, macerated) or death in the delivery room.

Content and quality of care

The working group also discussed research questions regarding content and quality of care. Questions about the quality of bag and mask ventilation were determined to be important both for the timeliness of care, such as the timing of specific actions with stimulation and/or positive pressure ventilation, and if the ventilation was performed according to HBB standards, e.g. position of head, size of mask used, if proper seal achieved (newborn's chest rising) and rate of ventilation. Regarding the rate of ventilation, it was recommended to review existing resuscitation checklists compiled and identify key items.

An additional question was discussed about essential newborn care practices, such as use of chlorhexidine, immediate drying, delayed cord clamping, skin to skin and breastfeeding within one hour.

It was discussed that filming for this intervention would have utility for quality and content of care and group members agreed to share related quality of care checklists following the session.

Checklist and/or tool development

Through the working group discussions, a checklist for observers was discussed and it was agreed that the HBB evaluation checklist could be considered as the observer checklist. It was discussed that the following key areas should be included in the checklist items for validation of resuscitation indicator:

Was newborn resuscitation provided in line with evidence and WHO guidelines:

- Timing of initiation of resuscitation actions?
- If resuscitation actions were of sufficient quality to be effective; position of head, size of bag and mask used, if seal achieved (chest rising), rate of ventilation etc.
- For all babies, rather than those requiring resuscitation specifically:
  - » Were essential newborn care practises delivered?
  - » Was chlorhexidine cord cleansing provided?

Following the workshop, this draft Newborn Resuscitation Tool was developed further based upon the working group discussions and related tools provided, and was collated with Immediate Uterotonic Administration, Essential Newborn Care and Antenatal Corticosteroid Verification Tools to develop the Labour ward observer checklist (See Annex 7). It is anticipated that this observer checklist, in addition to the other two observer checklists, will be refined during the formative and piloting phases.

Conclusion and next steps

The working group determined that both observing and filming would be important for this intervention, noting the key areas listed above for inclusion in the observer checklist. The group members also discussed potential questions for inclusion in the maternal recall survey specifically related to resuscitation, such as 'Did your baby cry immediately after birth?', 'Was your baby immediately dried?' and 'Was your baby put skin to skin?'. Finally, the working group recommended to review and refine the agreed quality of care observer checklists to adapt for this study.

Treatment of possible severe bacterial infection, Session A4

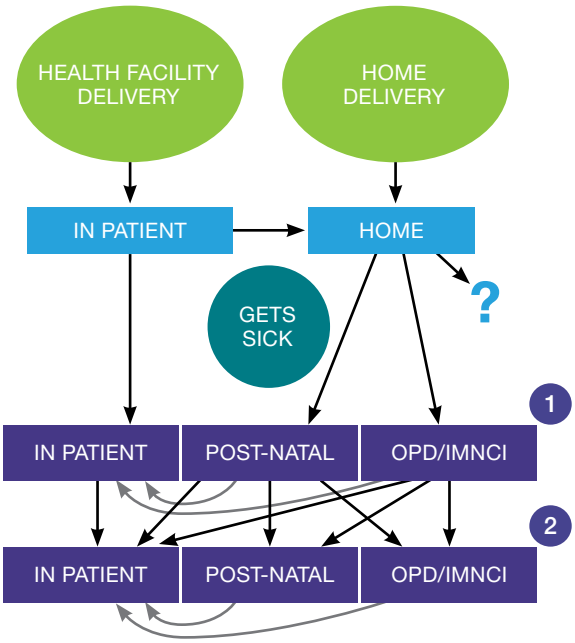
"The provision of antibiotics to newborns admitted for inpatient care with possible serious bacterial infection (PSBI), in accordance with current WHO treatment guidelines and diagnostic algorithms. Case

management can also be considered by levels of care: administration of oral antibiotics only, injectable antibiotics only, or full case management of neonatal infection (potentially second line antibiotic therapy, IV fluids, oxygen therapy, other supportive measures). Recent trials of Simplified Antibiotic Therapy show that, where referral is not possible, treatment with the simpler regimes by lower level workers is feasible." [4]

Proposed numerator

The working group discussed that possible severe bacterial infection treatment has a different care chain with multiple points of entry and related care, even when focused in public health facilities (see Figure 1). With this in mind, the place of observation for the proposed numerator 'number of newborns (< 28 days old) who received at least one dose of antibiotic injection for PSBI in the facility' was discussed considering inpatient versus outpatient facilities. It was recommended to avoid higher level inpatient health facilities (i.e. hospital paediatric in-patient and NICUs) since the first dose is variably given, often there is wide use of antibiotics and poor record keeping. Facilities with an Outpatient Department (OPD) or Integrated Management of Neonatal and Childhood Illnesses (IMNCI) would be using syndromic care (i.e. assessing for PSBI which is the target group and the "true denominator") and should capture first dose initiation (which is the numerator to be measured). The group considered public sector health facilities as a prudent starting point, but noted that private sector is still an issue given source of antibiotics and supplies for public sector PSBI treatment may come from outside public health facilities.

Figure 1. PSBI Treatment Care Chain



The group members determined that a clinical observer is needed for assessing subtle signs and that it would be better to have trained clinicians assessing lower level health facilities. It was discussed that care givers should also be assessed regarding their exit instructions.

Routine registers, such as IMNCI/OPD registers, will capture the recording for antibiotics given. Nevertheless, there are problems of conflation and reverse causality with PSBI assessment and antibiotics given for PSBI. It is important to be aware that registers may not discriminate among newborns aged 0-2m for weight, temperature, respiratory rate, heart rate and danger signs.

Proposed denominator

Through the working group discussion, the true denominator (i.e. the target population for this intervention) was determined to be 'all neonates less than 28 days presenting with clinical signs of PSBI'. It was noted that a population-based denominator is elusive, given catchment isn't clear and often there are proxies for PSBI and clinical blurring in assessed health facilities, such as PSBI, meningitis and pneumonia. The group members highlighted that the observer needs to be an advanced trained clinician to assess subtle signs; however, PSBI is still a difficult condition to observe. It was noted that the denominator can be validated at first level health facilities (i.e. probably not hospitals), which would validate presenting PSBI at first level health facility rather than true incidence. Data (left) truncation would further impact incidence; exacerbated by a high proportion of home births with difficult access as well as more severe or rapidly lethal disease.

Content and quality of care

The working group also discussed additional research questions regarding content and quality of care. The group members recommend to improve recording, especially to address higher level inpatient sites highlighting the need to understand clinical user interface, process of recording and standardisation. The group emphasised measurement of pre-referral care, such as correct antibiotics with correct dose and route, the timing of antibiotics administration and referral, and the appropriateness of co-treatments including steroids etc. The measurement of treatment completion was also emphasised, including program monitoring and safety, standardisation and follow-up. Despite the potential with new information systems like DHIS 2, it was noted it is not likely to be included in HMIS in the near future so need to consider link to household survey but also would need to understand recall bias. The group didn't identify a specific question

regarding filming in PSBI, and noted that it may be useful in assessing quality of care (e.g. algorithm use or safety in gentamicin dosing). The country teams will consider possible roles for film evidence during the feasibility phase.

Checklist and/or tool development

Through the working group discussions, a checklist for observers was discussed and the following key areas were highlighted:

Was treatment of PSBI provided in line with evidence and WHO guidelines:

- Type, dose, and route of drug used?
- Timing of administration?
- Appropriateness of co-treatment (steroids etc.)?
- Was the full course of treatment completed?
- Was referral to higher level care made appropriately?

It was noted that there is a need to be able to document the health worker who:

- First identified a case as PSBI (vs. Fast Breathing etc.),
- Second administered first dose; and
- Third administered antibiotics given for PSBI recorded.

The working group also discussed other IMNCI work to identify severe pneumonia/sepsis, such as the Ugandan tools ASSIST etc.

Following the workshop, the draft PSBI Assessment and Treatment site observer checklist was further developed based upon the working group discussions and tools provided (See Annex 7). It is anticipated that this observer checklist, in addition to the Labour ward observer checklist and the KMC observer checklist, will be refined during formative and piloting phases.

Conclusion and next steps

The working group concluded that PSBI may be better considered as a sub-study with different observation sites and staffing. The group highlighted their concern that this indicator does not include a measure of quality of care and would not be able to measure effective coverage.

Antenatal corticosteroids with focus on safe use, Session A5

"Currently, antenatal corticosteroid therapy (ACS) (24 mg of intramuscular dexamethasone or betamethasone in divided doses over 24 hours) is recommended by WHO for all mothers at risk of imminent preterm birth (delivery before 34 completed weeks of gestation) when the mother is in a facility where accurate gestational age can be obtained, where there is no clinical evidence of maternal infection, and there are adequate levels of maternity care and special newborn care available (WHO guidelines [7]). These guidelines reflect changes after the Antenatal Corticosteroids Trial (ACT) which evaluated prescription of ACS at lower levels of the health system, with approximately half of births occurring at home, and found a risk of adverse outcomes especially amongst births after 34 completed weeks of gestation. This trial underlines the importance of measuring gestational age, and better tracking of coverage and outcomes." [4]

Proposed numerator

Through the group discussion, the numerator for this intervention was determined to be all women seen at <34 weeks that were given antenatal corticosteroids (ACS), in line with WHO guidelines[1]. The place of observation is the labour and delivery triage, labour and delivery ward and antenatal ward, and this information would likely be recorded in clinical records, medical round book and the prescription or drug chart. It was determined that the information would less likely be in the register and probably not justified.

Proposed denominator

Through the working group discussion, the true denominator, i.e. the target population for this intervention, was determined to be all women <34 weeks. The working group discussed that the place of assessment will be when the women are triaged on admission to the labour ward and found it useful to draft the following two by two table:

	< 34 weeks	**>34weeks**
+ACS		
-ACS		

1 WHO guidelines recommend 24-34 weeks of gestation for administering ACS [7]

Other denominators that were discussed for consideration are also included below:

- Facility live births <34 weeks
- Facility total births <34 weeks
- Estimated population denominator <34 weeks
- All women triaged to labour ward <34 weeks
- All eligible women = All women < 34 weeks who should have received ACS (accurate GA, imminent preterm birth, no infection, context of care i.e. availability of childbirth care and care for preterm infant)

It was considered that the denominator should only include women <34 weeks with fetal heart rate present on admission or at time of decision to provide ACS. It also was noted that the methods of assessment of gestational age for all women assessed to be <34 weeks needed to be documented, e.g. either by ultrasound, CNP, frontal height etc. Further, the working group determined that postnatal newborn examination is needed for all newborns where the mother was assessed to be <34 weeks. Assessment tools such as the Ballard and Dubowitz were discussed and, while the specific tool will need to be decided, it was indicated the modified Ballard would likely be preferred but that it was noted both have limitations.

Content and quality of care

The working group also discussed additional research questions regarding content and quality of care, based on WHO recommendations for safe administration of ACS. The group members highlighted that it is important to know if there was an assessment for 'imminent preterm birth' and how it was defined, e.g. uterine contractions with cervical change and effacement, or maternal complications at high risk for PTB. They also noted it is also important to know if there was an assessment for maternal infection and how it was defined, e.g. fever, offensive liquor, uterine tenderness, maternal/fetal tachycardia or leucocytosis. Further, they discussed the importance of knowing which drug (Betamethasone vs. Dexamethasone) was used, along with how many doses/courses were administered and what the timing of administration was. It was noted that Prednisone should be included on list; though not the appropriate drug, it is used by some and needs to be documented. The working group members highlighted that the context of care will already be known, i.e. availability of care around the time of birth and care for preterm infant.

Checklist and/or tool development

A checklist was developed by a core working group for observers based upon the following key areas discussed:

Was ACS provided in line with evidence and WHO guidelines:

- Assessment of gestational age made?
- Type, dose and route of drug used?
- Assessment of maternal conditions which increase the risk of pre-term labour made?
- Assessment for any evidence of maternal infection made?
- Assessment of clinical status and diagnosis of threatened / pre-term labour made?
- Assessment of fetal condition made?

It was determined that the checklist will be more of an observer verification tool rather than by direct observation given this would be difficult to do. Various ACS tools, guidelines and assessments were provided by group members, in addition to a tool for gestational age assessment, to reference for the drafting of the ACS observer tool.

Following the workshop, this draft Antenatal Corticosteroid Verification Tool was further developed based upon the working group discussions and was collated with Immediate Uterotonic Administration, Essential Newborn Care and Newborn Resuscitation Tools to develop the Labour ward observer checklist (See Annex 7). It is anticipated that this observer checklist, in addition to the other two observer checklists, will be refined during the formative and piloting phases.

Conclusion and next steps

The working group concluded that many ACS events are not likely to be directly observed, in comparison to resuscitation for example, and that it is likely that clinical records will not be complete. Further it was noted that maternal recall may not be accurate regarding ACS administration due to poor communication from clinicians and that data recording may vary by facility.

DATA COLLECTION PROCESS AND TOOLS

On Day 2 of the workshop, experts were divided in parallel sessions to discuss elements of the data collection procedures such as the use of observers, the use of film evidence, the design of the maternal exit interview and the use of qualitative data to support the design of the study and to help answer some of the research questions.

Use of observers, Session B2

In session B2 of the workshop, a group of experts discussed the use of observers, including the locations and qualification profile of the observers and supervisors of the study. During the study, the observers will use clinical checklists to assess to what extent the standard protocol was followed. The information gathered through these observation checklists will subsequently be compared with hospital registers. This will allow assessment of the quality of the recording of hospital data on newborn health interventions.

The groups recommended that observers will be placed in labour delivery room (for the use of uterotonics and resuscitation), in postnatal or special care area (for KMC), special care unit, OPD, or postnatal ward (for PSBI). The group also discussed the observation of the administration of antenatal corticosteroid and agreed that the most appropriate location for observation would be the ANC unit. However, it was not recommended to place an observer in ANC because ACS is a rare event (only 0.5% of all deliveries need ACS).

The group agreed to have at least two observers on duty at the same time to observe different cases given that deliveries will be happening concurrently in high caseload facilities. It also was recommended that a supervisor should come periodically, especially at the beginning, and observe the same case as the observer and compare notes as a data quality check. Further, it was agreed that the labour ward should have a 24-hour coverage, whereas for PSBI this should be done when the outpatient department is open. The total number of observers should be decided depending on the case load of the hospital. The exact work schedule of the observers will be finalised after the formative stage of the research in late 2016 and during the pilot stage in early 2017.

At the workshop the advantages and disadvantages of clinical versus non-clinical observers were discussed in relation to logistics, training, cost and ethics. These advantages and disadvantages of non-clinical and clinical observers are summarised in Annex 3. It was agreed that it will be necessary to employ clinical observers in order to properly understand whether recordings of the five selected interventions were done appropriately in hospital registers. In each country, the country team will assess the appropriate cadre necessary for the observation of each clinical intervention.

For this study, it also was recommended that the observers should be currently practising clinicians who have received training in the last three years on the interventions/procedures they will be observing. In cases where observers have not received training in the past three years (either in-service or pre-service) then a clinical update will be conducted as part of the data collector training workshop.

The working group discussed that the use of clinical observers might raise ethical considerations in

particular circumstances where clinical observers identify that the clinical protocol was not appropriately followed and where the life of mothers and newborns are under threat. Procedures will be put in place in order to best overcome these issues. These will include an assessment of the legal environment and training of clinical observers to deal with alternative scenarios for each life treating situation. The observer checklists also will include clear actions and steps to be followed by the observers.

The group recommended that the supervisors of the study should be experienced peers, ideally selected amongst trainee observers and those who have shown clear understanding of the scope of the study and the observation checklists. Supervisors should observe procedures with the observers and should assess the quality of the answers. In the first six months the supervision should be more frequent and each supervisor should record their observation in a supervisor report.

Consent forms will collect patients' approval to be part of this observation study. In some circumstances women might reach the hospital at a late stage of the delivery, may be experiencing a complication that requires immediate treatment or may be unconscious if they have eclampsia, and therefore it might be difficult to collect consent to record the service delivery from some patients. In these and similar circumstances the next of kin could be an alternative. During the formative stage of this research, each country will assess appropriate consent form procedures according to their country context and the cultural environment to tailor the consent forms and related procedures so as to be culturally sensitive (e.g. in line with gender norms, traditional practices around birth etc.).

Training of observers, Session B2

The importance of training of observers before any data collection was discussed in detail during the workshop, and it was decided that training observers on the study aims, objectives, and design, as well as their role and responsibilities, was essential. It also was recommended that the training introduce observers to the checklists and tools they will be using, any electronic or mobile devices that may be used for data entry, and the procedures and forms surrounding informed consent. Further, the training will involve clear guidance on an ethical protocol, detailing a clear course of actions where malpractice or inappropriate practice occurs. For example, the group discussed that the observers should call for a supervisor or other provider at the facility if life-threatening care is observed. It was noted that there will be ample time during this training for observers to raise any concerns or questions they may have, and that the training will be based on MCHIP's observer guide: http://reprolineplus.org/resources/clinical-observer-training-learning-resource-package

It was suggested that the training consist of two parts: first, a clinical update on the skills and procedures to be observed which may be more or less important depending on the background of the observer and recent experience they have had of the interventions; second, a training in the collection of data via both observation and record review. It also was discussed that a training of sub-groups of observers by service delivery area may be needed, meaning there would be a mixture of concurrent training, common sessions, subgroup-training and training of supervisors.

Content of data collection training workshop agenda could include the following:

1. Clinical update (can be prior training or integrated in data collection training)
2. Expectations of observer (role, conduct and behaviour such as body language etc.)
3. Ethical considerations (role, conduct and behaviour, informed consent, poor quality of care)
4. Content of the tools
5. Standardisation of observation skills (must include training inter-rater reliability exercise)
6. Record review (to be determined if this will be intermittent/part of observation checklist or separate)
7. Mobile device and programme (focusing on how to use device and programme)
8. Role of supervisor

The following themes were decided to be central to all sections of the training: orientation on clinical aspects, observer/observed relationship, behavioural/communication aspects, professional conduct and observer's role. The group recommended that observers also be trained on how to accurately review records and extract the required data.

The following training methods were described for the standardisation and assessment of observer skills (these are in accordance with the methods used in the MCHIP observer's guide):

1. The clinical trainer performs a perfect simulated demonstration of the skills/procedure with an anatomic model (the observers follow on the observation checklist), e.g., normal birth, resuscitation, uterotonic.
2. The clinical trainer performs a "flawed" performance of the skills/procedure (the observers

score the procedure on observation).
3. The group reviews and discusses the scores and any differences there may be between observers.
4. Repeat step 2 (or use training video).

It was decided that the observer training would also include the inter-rater reliability/validity testing of all observers prior to pretesting. The pre-testing will involve using observation checklists and mobile devices at the health facility with observers working in pairs and debriefing on their experience afterwards. A session would also be dedicated to fieldwork logistics.

Case Study: MCHIP Experience

The Maternal and Child Health Integrated Program (MCHIP) included observations of labour and delivery care and management of maternal and newborn complications in six African countries and a HBB Evaluation in Malawi. The data collectors were midwives, nurses, and doctors and were only familiar with basic mobile phones. Typically, a training took place over 7-10 days with 10-20 participants, however in Zimbabwe it is noted there were 50+ participants. The training structure included hands on training, such as role playing, observing simulations, inter-rater reliability, testing, mobile devices and 1-2 days of practice at health facilities. See more information here: http://www.mchip.net/QoCSurveys

Use of film for data capture, Session B3

For the primary purpose of this research, observation is the 'gold standard', however, through the workshop discussions it was determined that filming will have utility to answer a specific question regarding objective three for one of the five interventions, resuscitation procedures, and possibly for KMC and PSBI. Discussions at the workshop stressed the importance of making sure the use of film is beneficial and adds value to the observations, as well as taking in to account cultural sensitivities and contextual realities. Ethics discussions included the need for both women and health workers to give consent to the filming and that consent may need to be given twice, once before filming and again before discharge to confirm the woman and family are happy with the data being used. The group also discussed that filming was potentially useful for events that unfolded over a relatively short period of time in one location, and that it may involve a series of steps.

Case Study: Learning from the use of film in a study in Nepal [20]

In Nepal, a hospital-based study was conducted to evaluate the change in health workers' performance both in simulated and clinical settings as well as perinatal outcome after implementation of Helping Babies Breathe Quality Improvement Cycle (HBB QIC) [18]. Video filming of the neonatal resuscitation was done to evaluate the change in the health workers' performance after the introduction of HBB QIC [21]. The study was conducted in a tertiary, publicly funded hospital of Nepal. More than 5,000 births were observed through video recording over a 15-month period. During this research specific measures were put in place to ensure women were given the necessary information to give informed consent and to ensure their right to privacy. If the woman later withdrew consent to participate in the study, their data were excluded from the study and all analyses and the video film of the baby was deleted from the central database. The study shows the feasibility and utility of using video recording for assessment of clinical practise. Current practices were compared and of the 5,000 births only 50 women or caregivers requested to delete the video of the recording.

Utility of filming the five interventions

Based upon discussions at the workshop, Table 4 highlights the potential research questions which video recording may have utility in addressing for each intervention.

Table 4. Use of film evidence in this research

INDICATOR	POTENTIAL QUALITY OF CARE QUESTION	VALUE ADDED OF FILM VS CHECKLIST OBSERVATION	FEASIBILITY?	SUGGESTED USE OF FILM
UTEROTONIC USE FOR 3RD STAGE OF LABOUR	Has oxytocin been administered within the recommended one minute? Is the correct drug, dose used? Is the drug expired?	Could add value on precise measure of timing.	Likely to be challenging to get good film and potential invasion of woman's privacy.	Not planned in this research work.
ANTENATAL CORTICO-STEROID (ACS) USE	Safety of use for targeted GA and excluding women with possible infection.	No clear added value.	N/A	Not planned in this research work.
NEWBORN RESUSCITATION	Have the correct assessment and initial steps been undertaken before us of bag and mask?	Yes, for quality and content of care. Not likely to help on true denominator measurement ("need for resus") as filming will start after identified need to move to resus table.	Yes – this has been done with large numbers in Nepal and the film focus will be on the resus table not on the woman.	Yes, with refinement during formative research phase in late 2016.
KANGAROO MOTHER CARE (KMC)	How many hours are babies held in the KMC position? Is feeding human milk support (e.g. cup or nasogastric feeding) being carried out as appropriate? etc.	Yes – especially overnight when observers may not be present, and also for checking timing of parent diary records.	Yes, would be ethical with usual safeguards re clinical film evidence and should be feasible with a few cameras in the KMC room.	To explore during formative research phase in late 2016.
TREATMENT OF NEONATAL POSSIBLE SERIOUS BACTERIAL INFECTION (PSBI)	Are the recommended dose/safety standards followed? The denominator assumes that the algorithm applied correctly?	Filming has been used for IMNCI QoC but usually more to assess correct assessment using algorithm.	Would be feasible and ethical in IMNCI/ PSBI out-patient assessment. But Observers should be able to achieve this and likely to be better than film for checking safety e.g. of gent dosing.	If clear question for film work is identified where film would be added value to observers then this can be explored during formative research phase in late 2016.

As highlighted above, video recording was recommended for resuscitation procedures and to be explored in the formative phase for KMC and PSBI.

Use of video recording for the observation of Resuscitation procedures

The use of video recording would be useful to record the sequencing of the resuscitation procedure once the baby was placed on the resuscitation table. In the formative phase the team will assess the practicality of this approach based on extensive learning from Nepal of filming 5,000 babies to assess resuscitation procedures as detailed in the case study above [20].

Use of video recording for the observation of Kangaroo Mother Care intervention

The use of video recording of the KMC room could allow assessment of the continuity of KMC, e.g. the number of hours that the baby is held in KMC position, the regularity of the feeding and observations (e.g. temperature). A subset of women will be asked to fill in a KMC diary (number of hours, frequency of feeding etc.). However, in order to do this assessment, it was not recommended to have 24 hour individual video recording on each women as the addition of a camera over the bed space may be too invasive. Instead, a few cameras placed to film the entire unit were thought to be more appropriate. This could then

be used to validate the parent diaries and observer records and provide additional insights into the quality and adherence to KMC practices. The use of video in the KMC room will be further explored during formative research phase in late 2016.

Use of video recording for the PSBI

The use of video recording for the treatment of severe bacterial infection could provide additional insight in to quality of care or to what extent the guideline on protocol are fully observed. The formative stage of this research will assess if there are specific questions that could be addressed by employing the use of film evidence.

Ethical issues regarding use film

From workshop discussions it was concluded that the use of film in this study will only be done when seen to add benefit and purpose to the observations being made. When the additional benefits to observations can be clearly argued, film will be used as a data collection method with the following considerations and protocols in place to make sure its use is entirely ethical. Film related ethical issues highlighted during the workshop included the need to have procedures in place to address ethical issues relating to the women and families, the health workers, the anonymisation of film data, and the management of film data. These ethical issues raised during the workshop went on to be addressed in the protocol (see Annex 6). Regarding the anonymisation of the film data, it was discussed that upon analysis data will be extracted from the films and recorded in a database system, linked to the film by a unique, anonymised identification code.

Pre-discharge maternal recall survey procedures and tools, Session B4

A maternal recall survey at discharge will be administered to collect data on selected interventions from mothers who received at least one of the selected interventions to assess the quality of recall at discharge and to inform potential inclusion of these recall questions in survey tools. The process for designing the maternal recall survey module was based upon the workshop discussions and a review of the tools (see Annex 7).

Through the workshop discussions, it was determined that all mothers who were observed during labour and delivery for the five interventions and who consent to a follow-up interview will be asked to confirm their consent again before the interview begins. For treatment of neonatal possible severe bacterial infection, mothers or caretakers of newborns observed will also be interviewed before they leave the facility. For newborns whose mothers died during delivery, the next immediate caretaker will be invited for the interview.

The group decided that the interview will be carried out before the mother is discharged from the facility.

It was also agreed that different data collectors from those who conducted the clinical observations will carry out the interviews in order to avoid contamination. Interviewers will be trained to be culturally sensitive and approach respondents with tact, especially those who have experienced adverse events such as stillbirths, newborn deaths or obstetric complications, including C-section.

Qualitative health-worker interview procedures and tools, Session B5

During the workshop discussions, it was agreed that qualitative methods such as key informant interviews or focus group discussions could be employed to help with the how, what, and when of the study.

It was agreed that a formative phase of the study will be helpful to tailor the observer checklists and maternal recall survey to the local context. During this stage, it was recommended to administer focus groups discussions with health workers to identify the what, where, when, how who of routine data collection procedures within each setting. It was recommended to get input from providers carrying out interventions, as well as those staff doing the recording (if they are not the same person).

In addition, in order to further understand reasons for disparity between the observed intervention and recording in routine hospital data, semi-structured in-depth interviews with health workers will be carried out after the completion of the observation study with the aim of assessing the barriers and facilitators to correct completion of routine reporting documentation (such as registers) by health workers.

Health worker informed consent will be given via consent forms. Health workers will be informed of the study aims and what their participation involves.

Observer survey procedures and tools

During the workshop, several groups discussed the importance of surveying the observers regarding data flow and observed barriers and facilitators to complete the data checklists and register reviews. During the formative phase, this procedure will be explored further and technical tools will be developed as indicated.

STATISTICAL DESIGN AND ANALYSIS

Statistical design, Session C1

During the workshop, statistical design and analysis planning for the numerators and denominators were discussed in session 1 on Day 2. The session aimed to provide specific recommendations regarding the use of methodological approaches to assess the validity of the indicators and to test alternative denominator options.

Assessing validity and accuracy of hospital recording for selected newborn health indicators.

In order to assess the validity and accuracy of hospital level recording of the five interventions, the observer checklist data will be compared with the data from the routine hospital records or special registers. During the formative stage of this research, the observer checklists for each intervention will be refined and considered the gold standard.

In order to assess the validity and accuracy of the hospital recording of these interventions, the working group decided that 'sensitivity' and positive predictive value (PPV) parameters will be calculated (see Table 5). In addition, the true denominator is only available for uterotonics and so the specificity for this intervention alone will also be calculated.

Sensitivity means those receiving the intervention who were recorded as receiving the intervention. The sensitivity expresses the level of true positives that were recorded. It is the ratio between the true positive (received the intervention and were recorded as receiving the intervention) and the total number of patients recorded as having received the intervention (some of which did not actually receive the intervention).

Specificity means those who did not receive the intervention (uterotonics) who were recorded as having not received the intervention. The specificity expresses the chances of misreporting the coverage of the intervention and it is the ratio of those who were recorded as not receiving the intervention over those who didn't receive the intervention (some of whom received the intervention and were wrongly recorded).

Positive predictive value (PPV) is the ratio between the true positive and the total observations recorded as receiving the intervention [TP / (TP + FP)[2].

2 Other indicators to consider are: Negative predictive value (NPV) = TN / (TN + FN); False discovery rate (FDR) = FP / (TP+FP); Positive likelihood ratio (LR+) = sensitivity / (1 – specificity); Negative likelihood ratio (LR–) = (1 – sensitivity) / specificity.

Table 5. Sensitivity and specificity for observed intervention vs recorded

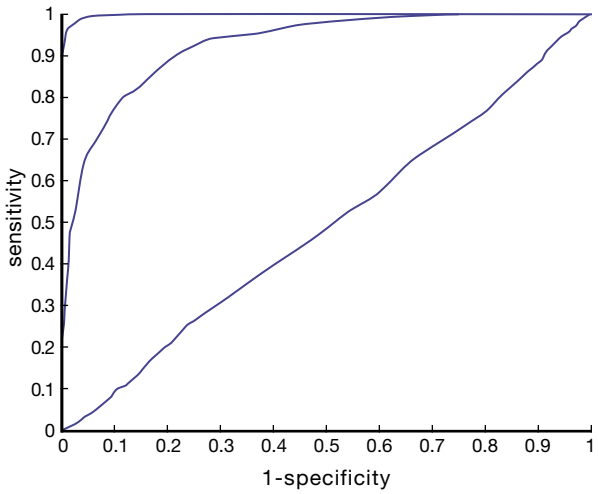
	OBSERVED INTERVENTION (GOLD STANDARD)		
	+ ve	- ve	
RECORD OF INTERVENTION + ve	True positive (TP)	False positive (FP)	Total recorded receiving intervention= TP + FP
- ve	False negative (FN)	True negative (TN)	Total recorded as not receiving intervention= FN + TN
	Total receiving the intervention TP + FN	Total not receiving the intervention FP +TN	Total observed cases TP+FN+FP+TN
	Sensitivity = TP/(TP+FN)	Specificity = TN /(FP +TN)	

Note: True positive: an activity occurred (+) and there is record in a registry (+), False positive: an activity did not occur (-) but there is a record in a registry (+), True negative: an activity did not occur (-) and there is no record in a registry (-), False negative: an activity occurred (+) but there is no record in a registry (-), Sensitivity = TP / (TP + FN), Specificity = TN / (TN + FP), Accuracy = (TP+TN) / (P+N).

Analysis planning for numerators and denominators, Session B1

In order to analyse these values, it was discussed that other studies have created the ROC (Receiver Operating Characteristic) plot, which shows the sensitivity against 1 minus the specificity (1-specificity). ROC curves compare sensitivity versus specificity across a range of values for the ability to predict a dichotomous outcome. ROC curves are a plot of false positives against true positives for all cut-off values. These plots allow us to calculate the area under the curve (AUC), which is the area under the ROC curve. AUC is a measure of degree of discrimination, ranges from 0.5 to 1.

Figure 2. Generic example of ROC and AUC



Although other studies have used the AUC to assess the level of accuracy (see Blank, A. 2016), during the workshop discussions it was agreed not to use the AUC as a metric for assessing validity as it is mostly suited to analysing continuous variables [18] [22]. In addition, to calculate the AUC the level of true negatives would need to be calculated or estimated. In this particular study, it will be difficult to capture the true negative values i.e those recorded as having not received the intervention and who did not receive the intervention.

A detailed analysis plan and an extended discussion of these issues can be found in the draft research protocol (Annex 6).

Assessing alternative denominator options

Table 6 illustrates the alternative denominator options discussed at the workshop that can be used to construct coverage indicators for the five interventions. It was recognised that two of these indicators (livebirths in facility and total births in facility) can be collected through hospital level data, and was agreed that the study will focus on facility-based denominators. However, it was also highlighted that these two denominators will not give a proper estimate of the coverage of the indicator at population level. During the analysis stage, it was recommended that the total number of births or total number of live births in the community using census data or other administrative data should attempt to be estimated.

Using the observer checklist data, it was also recommended to try to estimate the true denominator at the facility level, or target population denominators, e.g. the population in need of the intervention.

Table 6. Denominator options for newborn interventions

INDICATOR	DENOMINATOR	FEASIBLE TO COLLECT IN RESEARCH FACILITIES	PROPORTION OF BIRTHS WITH MISSING DATA IN FACILITIES COLLECTING THIS DATA	NOTE
GENERAL DENOMINATOR OPTIONS:				
ALL	Live births in facility	Yes – routine already		Available in facility report, e.g. DHIS 2
ALL	Total births in a facility [a b]	Yes – routine already	N/A	Available in facility report, Includes both live and stillbirth
ALL	Estimated total or live births for the given population using the facility	Estimate often provided in many district reports	N/A	Estimate of population-level including home births e.g. based on census or survey and fertility rates
TARGET POPULATION DENOMINATOR OPTIONS:				
KMC	Live births <2,000g	Currently collected routine registers in all test facilities		Need to assess accuracy of birth weight measurement and recording
ACS	All women <34 weeks gestation at risk of imminent birth (fulfilling WHO guidelines)*	Challenging (esp. GA assessment)		Need to assess accuracy of GA measurement and recording
PSBI TREATMENT	All neonates <28 days presenting with clinical signs of PSBI	Possible- but not currently collected in routine registers in all sites		
NEONATAL RESUSCITATION WITH BAG AND MASK	Neonates not breathing spontaneously at birth and requiring bag and mask resuscitation	Very challenging since is a clinical judgement/ subjective		
ESTIMATED TARGET POPULATION DENOMINATOR OPTIONS (PROXY OF EXPECTED LEVEL BASED ON ASSUMED NEED):				
PSBI TREATMENT	7% of live births	Feasible to measure live births		Assumption based on Seale et al. [26]

a For denominator for uterotonics, take account of multiple births so denominator is per women giving birth
b For PSBI at outpatient level the denominator may be all cases
* 24-34 weeks as per WHO guidelines [7]

Table 7 shows the five coverage indicators that will allow the coverage of the intervention at the facility level to be captured. It was highlighted that the facility level coverage of the indicator can easily be estimated for the coverage of uterotonics as the denominator is all births.

Table 7. Proposed coverage indicators of newborn intervention at facility level

INTERVENTION	NUMERATOR	PROPOSED DENOMINATOR
UTEROTONIC USE FOR 3RD STAGE OF LABOUR	Number of women who received a uterotonic immediately after birth	All births
ANTENATAL CORTICO-STEROID (ACS) USE	All women giving birth in a facility who are <34 completed weeks and received one dose of ACS for being at risk of preterm birth (note initial focus on counting all while testing ways to split by GA at birth to identify women treated who did not deliver <34 completed weeks)*	All women <34 weeks gestation at risk of imminent birth (fulfilling WHO guidelines)
NEWBORN RESUSCITATION	Number of newborns for whom resuscitation actions (stimulation and/or bag and mask) were initiated	All babies who do not breath / cry spontaneously at birth
INITIATION OF KANGAROO MOTHER CARE (KMC)	Number of newborns initiated on facility-based KMC	All livebirths that weigh less than 2,000g
TREATMENT OF NEONATAL POSSIBLE SERIOUS BACTERIAL INFECTION (PSBI)	Number of newborns (< 28 days old) who received at least one dose of antibiotic injection for PSBI in the facility	All neonates <28 days presenting with clinical signs of PSBI

* 24-34 weeks as per WHO guidelines [7]

Coverage of these interventions at a facility level would ideally be 100%. It was discussed that benchmarking for the expected coverage of each of these interventions at a population level (using total births in the population as a denominator) will be an important component once the data are available, however, it was recognised this is not the main focus of this initial study.

Sample size calculations for objective 1

Table 8 shows the anticipated prevalence of the practice of each intervention based on expected need and estimated coverage. The sample size is powered for the assessment of the accuracy of recorded practice versus the 'gold standard' of observed practise. In this primary analysis it was agreed that the study population will be all those observed.

Table 8. Expected prevalence of the practice of selected newborn interventions

INDICATOR	ASSUMED NEED	LIKELY COVERAGE OF INTERVENTION	EXPECTED PREVALENCE OF THE PRACTICE OF INTERVENTION*	COMMENTS
UTEROTONIC USE FOR 3RD STAGE OF LABOUR	All women who give birth	High for facility births	High (target all births, high coverage)	Observed in Stanton et al study in Mozambique for 292 cases AUC 0.52 Now could answer additional questions e.g. type of uterotonic, timing etc.
ANTENATAL CORTICOSTEROID (ACS) USE	Preterm prevalence in Tanzania (11.4%) and Bangladesh (14.0%) Approx 25% of preterm births are <34 weeks GA. (Blencowe et al) [23]	Low (eg IQR 30-68% in Vogel et al) [24]	Approx. 0.4 – 0.5% of all births	Challenging to measure
NEWBORN RESUSCITATION	About 3% of births require resuscitation with bag and mask (Lee et al) [25]	HBB wide scale up in both Tanzania and Bangladesh - Moderate – 50% of facility births who need resus?	Expect about 1% to 2% of all births	
KANGAROO MOTHER CARE (KMC)	About 20% in Bangladesh and 10% in Tanzania are <2,000g	Tanzania low to moderate – 20%? Bangladesh – very low <10%? (Vessel et al) [26]	Tanzania- Approx. 2% of live births Bangladesh- Approx. 2% of live births	
TREATMENT OF NEONATAL POSSIBLE SERIOUS BACTERIAL INFECTION (PSBI)	About 7% of live births during neonatal period (Seale et) [27] Over 70% of deaths attributed to neonatal infections are in first week (Oza et al) [28]	Tanzania – moderate as wide scale up of IMNCI – maybe 40%? Bangladesh – low/ moderate – maybe 40% of those in facilities	Tanzania – Approx. 3% of live births Bangladesh – Approx. 3% of live births	

It was recognised that the indicator of uterotonic use immediately after birth applies to all births and so is not a challenge to power for. The estimated prevalence of neonatal resuscitation, KMC initiation and PSBI treatment are expected to be around 2% to 3% each; these are therefore the basis of the sample size calculation. Estimated prevalence of ACS need is lower and coverage may be also low (approximately 0.5% or less of all births), and the very large sample size required would not be feasible in this study. It was decided that data on ACS administration will therefore be captured for those observed during the study period and the research questions will focus on the safety tracking aspects.

The group agreed that the analysis will focus on estimating the sensitivity and PPV of the recording of interventions. The sample size calculations are primarily to answer the first research question on the validity and accuracy of the measurement of these interventions. Assuming a sensitivity of 50%, a sample size of 100 women/babies receiving the intervention and 100 women/babies not receiving the intervention would be required to provide estimates of sensitivity with a precision of ±10% (at the 95% confidence level). If the proportion of all births receiving the intervention is 2% then 5,000 births would need to be observed in order to include around 100 who received the intervention. In addition, in facilities with a high volume of births, a sampling strategy would be used to select births for observation (for example every first and second birth in the morning and evening or every third birth).

A detailed analysis plan and extended discussion of these issues can be found in the draft research protocol (Annex 6).

DATABASE DESIGN AND QUALITY CHECKS

Group work session C1 on Day 2 of the workshop discussed the following issues related to the data collection process, database design and data quality check mechanisms.

Data collection, Session C1

Through workshop discussions, it was agreed that data on the assessment of the clinical practices recorded during the observations will be collected through the series of observation checklists completed on either an electronic tablet or paper based, depending on context, and to be decided on during the formative research phase. The participants strongly recommended that the use of electronic tablets would be preferable as it would increase opportunities for synchronising patients' data in real time via a secured, encrypted connection to a server using WiFi/3G network. This would be particularly useful when a patient has multiple observations collected by several independent observers, e.g. when a patient is moved from one ward to another or is followed-up. It was discussed that it is crucial to capture patients', baby's and providers' (hospital) ID, as well as an ID of registers, to be able to link an observation with medical records. Further, it is important to be aware that some registers are being filled in later on during the day or even week.

Database design and quality checks, Session C1

Variables and definitions

The observer checklists and other data collection tools were drafted during and after the workshop and reviewed by a group of clinicians and team members from Tanzania, Bangladesh, and Nepal. While the content of these checklists is complete, the wording will be finalised during the formative stage so as to make sure they are appropriate to the country setting and correctly understood by the observer and women.

Data quality checks

It was agreed that the validation of records will be assessed by a subset of records having dual observation, ca. 2% of all observations should have double observations with feedback. These observations should take place continuously during the whole process of data collection, with experts visiting various sites.

Linking records and anonymisation

The working group determined that the exact methods used for linking the individual records from different registers to observers' checklist data collection will be refined during the formative stage of data collection as it will be important that the methods are context appropriate and based on individual data easily available. One option discussed at the workshop was to use individual identifiers in the database to allow the data entry team to link records that have been collected from different places e.g. Labour ward and maternal discharge. After linking the records, the identifiers can be removed and the record anonymised. Alternatively, an algorithm taking in to account the name and date of birth in months could be used to a similar end, again removing this identifying information once records have been matched.

Data security

As described above, once data has been linked individual identifiers will be removed the data will be anonymised. The group discussed that at a regular time each week all the anonymised data from that week will be uploaded to a central web-based platform coordinated by LSHTM and following all appropriate confidentiality requirements. From here the data will be stored on the LSHTM Secure Server which is automatically backed-up to an off-site location each night. The data stored on this secure server will be encrypted so it can only be accessed by those with the correct encryption key; the encryption key will only be available to members of the immediate research team who are working on the analysis of the data.

Data Storage

As described above, once data has been linked individual identifiers will be removed the data will be anonymised and stored in a secure server. The group discussed that the data will be stored on this centralised database system which will be encrypted, password protected, and only accessible by authorised members of the research team.

OTHER HEALTH SYSTEMS WORK

Service readiness for care of small and sick newborns, Session C2

Group work session C2 on Day 2 focused upon service readiness measurement for care of small and sick newborns. ENAP metrics inpatient care of small and sick newborns plans to design a module for services readiness for care of small and sick newborns and dedicated an inpatient care of small and sick newborns parallel work stream to development of this work.

Background

Core components of inpatient care of small and sick newborns involve the provision of warmth, feeding support, safe oxygen therapy and effective phototherapy, including kangaroo mother care. Such care needs to be delivered by health workers with specialist training and skills in a facility with a dedicated ward space equipped to prevent and treat infections. In the next few years, ENAP metrics plans to design a module for service readiness for inpatient care of small and sick newborns that could potentially be adapted for context and inserted into a facility-based or HMIS (e.g. DHIS 2) system. In the meantime, there are a number of steps towards this work that are focused mainly on the following two areas:

a) Defining the content and levels of care: Defining and validating “signal functions” for care of small and sick newborns to parallel those used for emergency obstetric care (EmOC). EmOC signal functions are a core list of key interventions that have been used to assess the functionality of health facilities to treat obstetric emergencies at a routine, basic or comprehensive level.

b) Potential ways to collect the data: Currently there are detailed health facility assessments, such as the Averting Maternal Death and Disability (AMDD) Emergency Obstetric Care (EmOC) survey, but there are potential other ways to collect this data. For example, facility-level data systems and/or HMIS that will require further investigation and tool development.

A short group working session at this ENAP facility-based testing of coverage metrics workshop was dedicated to work area a) defining the content and levels of care for small and sick newborns.

A separate concept note and set of activities are focused on work area b), including testing potential to collect indicators on facility-based care of small and sick newborns through HMIS. This work area was not addressed directly in this session of the workshop.

Historically, only one signal function out of the EmOC signal functions specifically relates to newborn care – neonatal resuscitation. This signal function alone clearly does not fully represent all interventions needed for emergency newborn care. In 2012, Gabrysch and colleagues identified a set of signal functions for emergency newborn care, many of which have been added to existing survey tools [29].

Figure 3. Current list of proposed signal functions arranged by level of care[4]

4 Figure adapted from Moxon et al (2014) Inpatient care of small and sick newborns. BMC Pregnancy and Childbirth. List of signal functions adapted from Gabrysch et al (2012). New signal functions to measure the ability of facilities to provide routine and emergency newborn care.

Identifying alternative or additional signal functions that could be added to the existing list

The first part of the group work task involved an active discussion on a minimum package of interventions needed to look after small and sick newborns safely in low income settings.

To focus the discussion on the individual signal functions, general agreement within the working group was to separate the health system by the following levels of care:

- **Routine care for all newborns** (which should be available at all BEmOC facilities and upwards).
- **Inpatient care of small and sick newborns** (will be available at select BEmOC and CEmOC facilities). This is similar to what is referred to as "special care" in many settings.
- **Advanced inpatient care of small and sick newborns** (Generally restricted to higher level/ referral facilities. In many settings this will only be available in a small number of tertiary hospitals or centres). This is similar to what is referred to as intensive care (NICU) in many settings.

It was agreed that the process of defining these signal functions would be useful for national programme planning and such definitions are very much needed at the national level. It was acknowledged that the exact names of these levels and appropriate acronyms would need to be developed and may be an important part of wider consultation going forward.

Routine care for all newborns should be available at all facilities where births occur and requires:

- Thermal protection/warmth
- Essential care for all newborns (as per WHO guidelines)
- Support for immediate and exclusive breastfeeding
- Resuscitation for newborns not breathing at birth
- (PMTCT for HIV positive mothers)

If a small and sick newborn is born in a facility with no inpatient care, clear criteria for referral to an inpatient care facility would then need to be defined and geographical distribution considered, based on context. Preferably, in cases of threatened preterm labour, women would be transferred prior to birth. Example referral systems from different contexts (e.g. Malawi) and programmes (e.g. ECSB) were given.

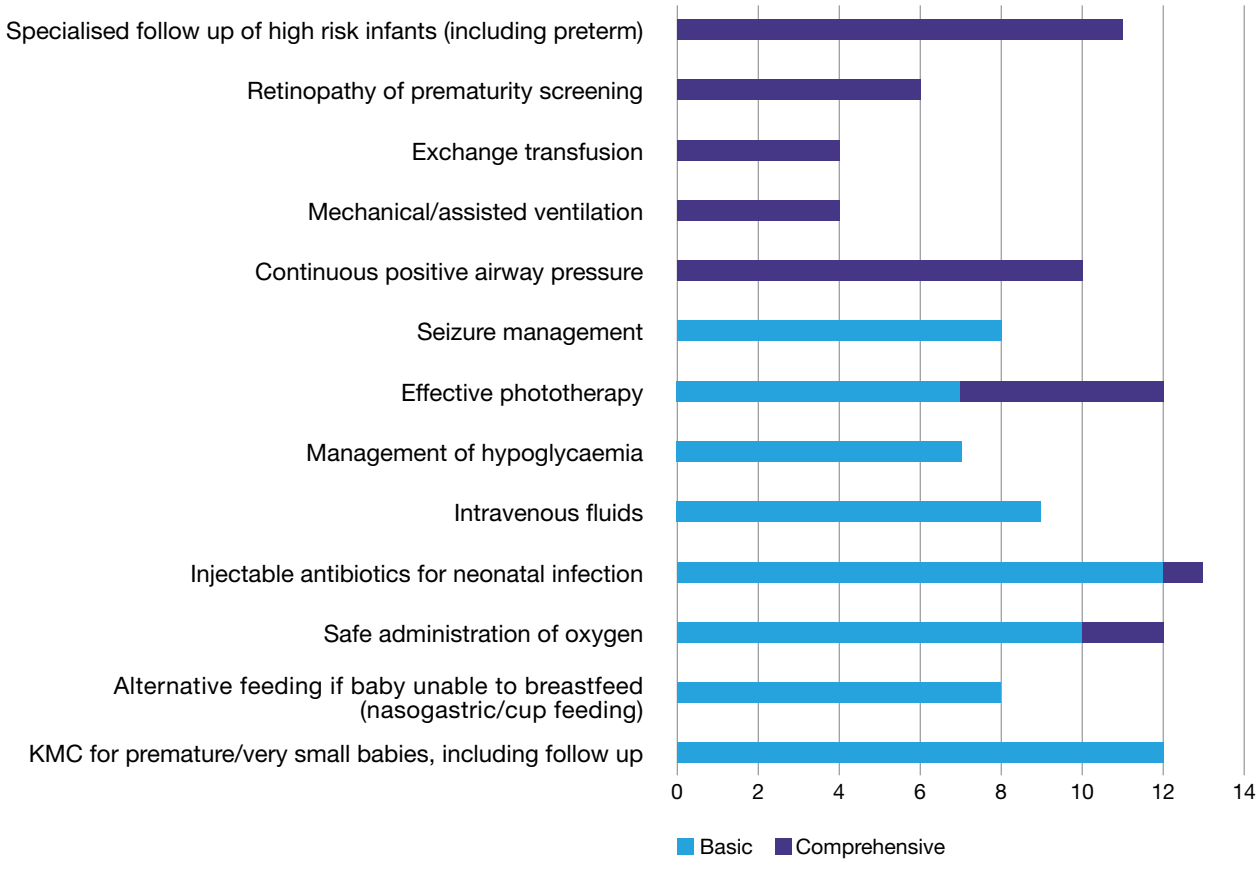
The group discussed an extensive list of signal functions for inpatient care of small and sick newborns. These are noted in Annex 10, with the text in red indicating additions to the original list and the text in italics indicating maternal interventions that are relevant for care of small and sick newborns.

Voting on which newborn signal functions should be provided at each level: routine, basic and comprehensive (using a wall chart)

Following a two-hour discussion, each group participant was given the option to vote for up to (but no more than) eight inpatient care signal functions split between comprehensive and basic, as participants deemed appropriate. The routine signal functions were pre-agreed within the group so that the eight votes were focused on signal functions for inpatient care. There were a total of 73 votes for signal functions at the basic level and 43 votes for signal functions at comprehensive level. The results by signal function are displayed in Figure 4 below and in Annex 10 along with the wall chart picture.

The following signal functions had zero votes and were removed from the final list: Total parenteral nutrition (TPN), surfactant therapy, broncho-pulmonary dysplasia (BDP) screening, head ultrasound, haemodialysis and cooling. The only signal function for which there was not clear preference on the appropriate level was effective phototherapy. This will be important to take forward for further consultation as there may be specific reasons for this (e.g. regional variation in perception of need at the basic level).

Figure 4. Final list of signal functions for inpatient care of small and sick newborns showing number of votes for each signal function by levels of care[5]



5 Antibiotics to mother for prolonged PROM and antenatal corticosteroids for mothers in threatened preterm labour were not the focus on this discussion but it was agreed these were essential interventions for mothers that are relevant for inpatient care of small and sick newborns.

Conclusion and points for further discussion

There were a number of crosscutting themes that formed important parts of the discussion and need to be considered in building the domains/components of the signal functions:

- Staffing and neonatal nursing
- Infection prevention
- Communications, referral systems and transport
- Maintenance and support systems (e.g. engineering and laboratory)

There were also important points made on surgical capacity, particularly on the need to consider basic surgery for common preterm conditions (e.g. necrotising enterocolitis) and abdominal wall defects. However, it was decided that this exceeded the scope of this discussion and that at this stage, the signal functions should be focused on medical rather than surgical inpatient care given the distinct and extensive system readiness needs for neonatal surgical procedures.

There was general agreement, based on expert view, that signal functions needed to be aspirational and look towards where newborn programmes and health systems should be aiming to be in the next five years so that the needs of small and sick babies born in all settings are built into national health system planning.

This working group activity served as an in-depth focus group discussion, using a broad range of diverse newborn expertise that can be used to inform a wider consultation process on signal functions and levels of care for small and sick newborns. In order to measure the signal functions and design the associated tools, the list of signal functions needs to be further developed to consider which components/service readiness domains make up each signal function (e.g. infrastructure, equipment, staffing, policy). Given that inpatient care does not directly parallel EmOC, there was general agreement that the acronym EmONC should not be used.

Due to time restrictions, the potential process for wider expert consultation was not covered, but it was agreed that this was a key next step following the meeting. Wider consultation will form an important part of the ENAP metrics measurement improvement roadmap linked to WHO, UNICEF, AMDD and other key partners (e.g. Every Preemie) in this process. The discussion and process for the future measurement of service readiness for small and sick newborn will also be closely linked to the ongoing discussion on maternal signal functions (EmOC) and their measurement.

Perinatal audit (linked to maternal death surveillance and response), Session C3

Group work session C6 on Day 2 focused upon perinatal audit linked to Maternal Death Surveillance and Response (MDSR) which was identified by the ENAP metrics process as an important parallel work stream.

Background

Access to reliable data about the numbers and causes of death is essential for planning and implementing health services. Systematic analysis of mortality trends and events leading to preventable deaths can help identify breakdowns in care and inspire local solutions to address deficiencies. In response, the World Health Organization developed and pilot tested a new guide and set of tools entitled “Making Every Baby Count: Audit and Review of Stillbirths and Neonatal Deaths.”

Overview of WHO guide

The guide for audit and review of stillbirths and neonatal deaths includes definition and classification of cause of deaths using the WHO application of ICD-10 to perinatal deaths: ICD perinatal mortality (ICD-PM) as well as several approaches for identifying and assigning modifiable factors to each death under review. The guide describes step by step the mortality review process in facilities and proposes ways in which deaths that occur in communities could also be captured and reviewed. As compared to maternal deaths, stillbirths and neonatal deaths carry a higher burden and the guide also suggests an approach to choose cases, if all cases are not feasible to review. An essential component for mortality review is having an enabling legal and ethical environment that allows reviews to take place and contribute to quality improvement processes without fear of blame or punitive actions. Finally, the guide suggests a way forward to scaling up from individual facilities and communities to district, regional and national level and how to create linkage to surveillance systems and civil registration and vital statistics (CRVS) systems. Another feature is the suggested minimum perinatal data set which is a set of six indicators suggested to be collected through the routine information system. Leadership and supervision within a supportive environment are essential to ensure the completion of the audit cycle. Leaders have the ability to create a culture of accountability at all levels involving celebration and affirmation alongside supportive correction.

Links to MDSR

The group discussed that many countries globally are already implementing MDSR as a key strategy for addressing maternal mortality, guided by a task team within the Ministry of Health. It was noted that the new guide and tools support countries to build on existing MDSR and maternal mortality or near-miss audit platforms to also capture stillbirths and neonatal deaths, linking to national health goals and mortality reduction targets.

Next steps

The guide and tools will be released in mid-2016 with accompanying briefs, online training sessions, and other dissemination opportunities. With regards to the ENAP metrics study, it was emphasised that each death needs to have treatment and management information produced. The working group discussed the introduction of the perinatal audit tools in the facilities and also testing the ENAP coverage metrics as well as integrating with ongoing WHO quality of care efforts.

Birth weight measurement for all facility births, Session C6

Group work session C6 on Day 2 focused upon birth weight measurement for all facility births. Many of the proposed ENAP indicators for coverage, content and quality of care require accurate recording of birthweight, e.g. for KMC to identify those in need of the intervention. In view of this, the ENAP metric process identified a major data gap for accurate birthweight measurement and recording, and dedicated a parallel work stream to improving birthweight measurement in facilities.

Background

Around 20 million babies worldwide each year are estimated to be born with low birthweight (LBW), e.g. birthweight <2,500g. These babies are at higher risk of death, both as stillbirths, in the neonatal period, and also throughout infancy and early childhood. In addition to the increased risk of mortality, these babies are also at higher risk of morbidity during the neonatal period and infancy, and of long term developmental and physical health (including growth and cardiovascular effects) consequences. The primary underlying causes of low birthweight are intra-uterine growth restriction, preterm birth, or a combination of the two. At a population level both of these conditions are strongly associated with maternal factors e.g. maternal age, nutritional status, physical health, infection and lifestyle factors. As such low birthweight is a critical indicator for both the health of the mother and future risk for the baby. The UN nutrition goals in 2012 set a target to reduce LBW by 30% by 2025 – but no clear process for tracking this progress was set.

To adequately assess the size of the burden, and to track the effect of programmatic interventions for LBW babies, more accurate data on birthweight will be required. Current estimates of low birthweight in high mortality settings have relied upon household surveys with substantial associated methodological issues for this outcome, including reliance on maternal recall of perception of size at birth and post-hoc adjustments for heaping. With >60% of all births now in facilities, recording an accurate birthweight on these should be feasible, and would assist both with recognition of individual risk e.g. need for extra care for small, or exceptionally large infants, but also in monitoring population low birth rates, and providing disaggregated data on neonatal outcomes including morbidity and mortality.

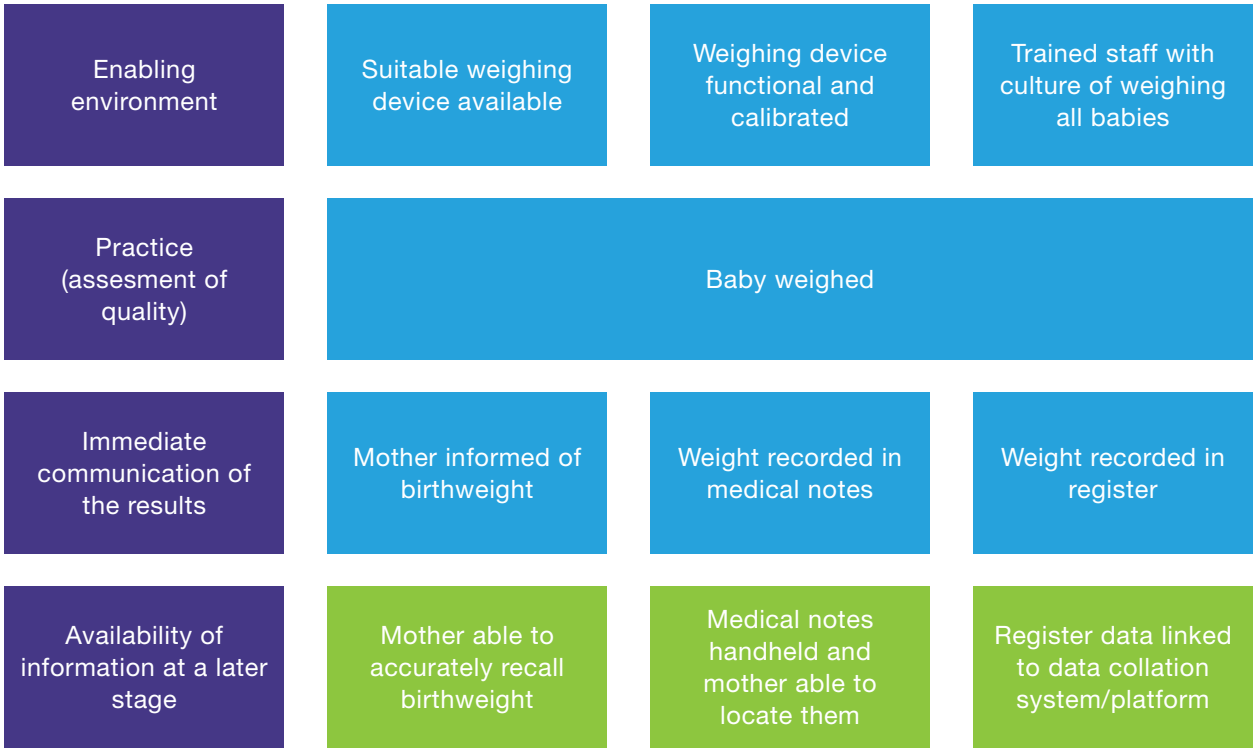
Available evidence suggests that despite this, an accurate birthweight for facility births is not universally recorded, and when recorded is not always compiled into registers to allow collation and use for action. Further work is required to undertake a review of the literature and program data to understand barriers weighing and recording birthweight for facility births, and to understand how these can be addressed to allow recording of accurate birthweight for all.

Current status of birth weight measurement for all facility births

The participants first discussed the current status of birth weight measurement for all facility births. In their experience, it was found that there is a weighing device (either digital scale or other scale) at most health facilities. Despite this, not all babies born in these facilities are weighed and sometimes the weighing device is not correctly used, for example failure to calibrate the scale properly. It was noted that birth weight is often not recorded promptly or correctly in medical notes and registers, but that mothers are usually informed about their baby's birth weight. Further, countries often have systems in place, such as baby cards that have details on birth weight, immunisation status and others, but enforcement is lacking. It is recognised that there are not many training tools for health workers on birth weight measurement. A web-based search of training tools for birthweight measurement in neonates yielded only one job aide from All India Institute of Medical Sciences (AIIMS).

Some of the identified necessary factors for recording of accurate birthweight measurement in facilities are detailed below (see Figure 5) and were discussed further at the meeting.

Figure 5. Draft conceptual framework for birthweight measurement in facilities



Maternal recall of birthweight at exit interview

Household surveys continue to provide population based information regarding low birthweight. Surveys typically use three methods to assess birthweight. All mothers are asked about their perception of the size at birth (maternal perceived size), in addition for mothers reporting that their baby was weighed at birth the hand held health card with a recorded birthweight is reviewed (Card), or mothers asked to recall the birthweight of babies who were weighed at birth, but for whom no birthweight documentation is available at the time of the interview (Recall). The accuracy of maternal recall has not been systematically assessed. As part of the exit interviews planned for this facility based testing work, questions could be developed to assess the accuracy of maternal recall of birthweight on discharge. Low accuracy of recall on discharge would suggest that maternal recall may be unlikely to be a useful method to assess birthweight several years after the event, and consideration could be given to methods to improve recall for use in household surveys.

At the workshop, it was suggested to consider adding questions to the exit recall interview of mothers to ensure gathering data about the inclusion of birth weight measurement for facility births. The two questions suggested included 'were you informed of the weight of your baby at birth?' and to ask the birthweight question as in the standard core DHS survey module.

Areas for future research and next steps

Through the group work, participants discussed possible areas for research on birth weight measurement for all facility births. The following areas were suggested through the discussion and will be followed up during the formative research phase:

- Comparison between gold standard birthweight with medical digital scales and alternative available scales (industrial/ other) in terms of costs, accuracy, robustness and other factors.
- Formative research to better understand current practice and barriers/ facilitators to weighing babies.
- Develop a standardised tool with basic training and job aides to improve birthweight measurement and recording.
- Test what is the feasibility, acceptability and effectiveness of a basic training package with digital scales to improve birthweight measurement in facilities.
- How do mothers perceive the value of knowing birthweight? How can the culture demand for birthweight be improved in the population – mother held documentation e.g. birth certificate with weight, other innovations.

- What innovations could improve maternal recall of the birth weight?

Birth certificate and registration for all facility births, Session C5

Group work session C5 on Day 2 focused upon birth certificate and registration for all facility births. Many of the proposed ENAP indicators for coverage, content and quality of care can be obtained through birth certificates and registrations. In view of this, the ENAP metric process identified a major data gap for follow through of birth certificates and registrations, and dedicated a parallel work stream to improving birth certificate and registration in facilities.

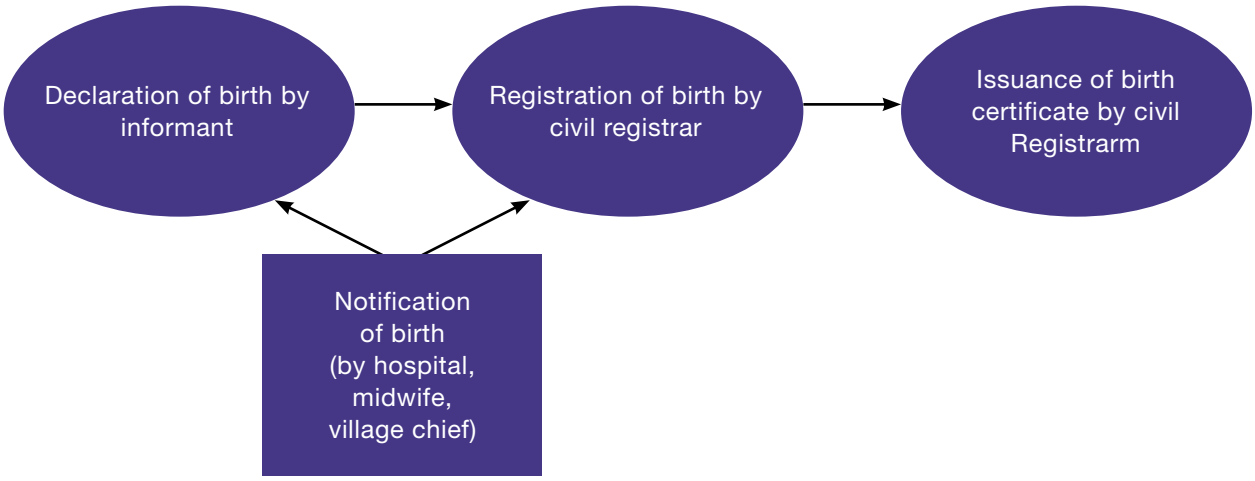
Background

Birth registration is the continuous, permanent and universal recording, within the civil registry, of the occurrence and characteristics of births in accordance with the legal requirements of a country.

A birth certificate is a vital record that documents the birth of a child. In some cases the issuance of a birth certificate automatically follows birth registration, although in others a separate application must be made.

See Figure 6 below noting the series of events involved in the birth registration and certificate process.

Figure 6. Birth certificate and registration process



Typically, the notification of a birth is made by an individual or institution to the registrar of vital events in a country. The notification role is usually played by health institution and birth attendants, and in a limited number of cases by a local government official, such as a village chief. The processes from notification to registration to certification vary widely from country to country. However, the benefit of interoperability/ collaboration between health systems and civil registration systems for both systems are more widely recognised and are becoming a major focus across several global initiatives (see below).

Funders

The working group discussed various funders that are showing strong leadership with funding initiatives for improving birth certificates and registrations. Global Affairs Canada (GAC) was identified as a major funder, in addition to NORAD, DFAT, European Union and DFID. It was noted that GAVI is supporting both birth registration and immunisation in GAVI grants, and Bloomberg with Data 2x, a CRVS initiative in Asia Pacific with UN ESCAP. Further, it was discussed that Bill & Melinda Gates Foundation funded CHAMPS initiative with CDC and Emory on Cause of Death (MITS).

Global Agencies and Working Groups

In addition to funders, the workshop group identified the following key global agencies and working groups demonstrating leadership for improving birth certificates and registrations:

- Canadian Centre of Excellence for CRVS (funded by GAC)
- UNICEF: BR4MNCH, CHD and specific country office projects focusing mainly on Birth Registration

- WHO, CDC and USAID focusing on Death Registration and Cause of Death
- World Bank: Global Financing Facility (GFF) and Regional Banks (UNECA, IADB) Global CRVS Scaling up Investment Plan 2015-2024 (Decade of CRVS)
- CRVS Working Group GA (also acts as CRVS group for Health Data Collaborative, current chair WB)
- INDEPTH: HDSS focusing on death registration & cause of death (audit) at surveillance sites
- EWEC Global Strategy and ENAP and EPMM
- Regional Ministerial Groups: APAI-CRVS (UNECA, UNICEF, WHO) & Regional Steering Group CRVS in Asia & Pacific (UN ESCAP, UNICEF, WHO)

Recommendations and next steps to close the gap

During the session, a few key points were discussed to explore closing of the birth registration gap through the facility-based metrics research. It was recommended to focus upon strategies to increase coverage of birth certificates that target facility births e.g. making health workers responsible for notification and linked to birth registers with increased use of ICT solutions. The use of incentives was recommended to promote birth registration and certification, either generally or especially for facility births. It also was recommended to look at barriers to overcome in order to ensure more compliance, e.g. parents have to go to another place, long queues, official or unofficial charges, long distances. Finally, it was recommended to compile a list of major initiatives working on improving birth certificates coverage and quality that may have relevant learning and key organisations and/or people to follow up with to find out more relevant information. UNICEF will ensure linkage and communication from relevant birth registration initiatives and ENAP Metrics Group.

Additional resources

The following additional resources were suggested:

A Passport to Protection: A guide to Birth Registration Programming – http://www.unicef.org/protection/files/UNICEF_Birth_Registration_Handbook.pdf

Global Civil Registration and Vital Statistics: Scaling up Investment Plan 2015 -2024 – http://www.who.int/healthinfo/civil_registration/WB-WHO_ScalingUp_InvestmentPlan_2015_2024.pdf?ua=1

Every Child's Birth Right: Inequities and trends in birth registration – http://www.unicef.org/publications/index_71514.html

KNOWLEDGE MANAGEMENT, Session B6

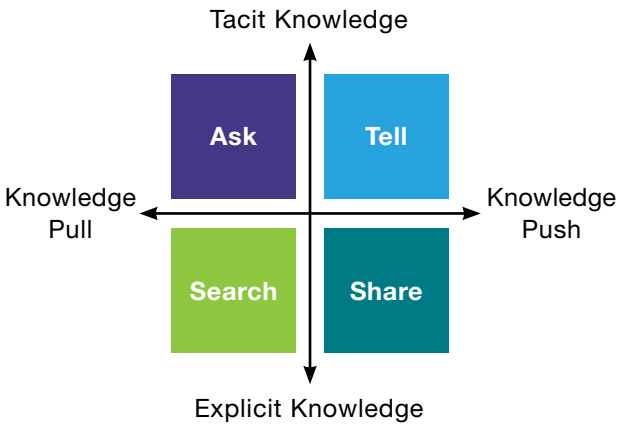
Working group B6 discussed the development of a knowledge management (KM) plan for this multi-stakeholder collaborative research study. Overall, it was emphasised that both the research process and forthcoming results will be widely disseminated at local, national and international levels. Throughout the research period, frequent social media updates such as blogs and news updates on consortium websites, including the Healthy Newborn Network (HNN), will share the research progress from the three country sites.

Background to knowledge management

An overview of knowledge management was provided to develop a common understanding of KM and basic KM principles and to generate ideas on how KM principles and approaches can be applied in the study context. KM, historically and primarily, is all about managing the knowledge of and in (and between) organisations. Knowledge comes in two forms: explicit knowledge that can be easily written down and tacit knowledge which exists primarily in people's minds and is developed through experience. KM addresses 3 key elements to facilitate knowledge exchange: people, processes and technologies.

KM ensures that we can push (or send) relevant knowledge and pull (or find) needed knowledge (See Figure 8). These KM processes ensure that we can capture learning for use in other and future work, connect people to enable knowledge exchange and apply knowledge to enable efficient and effective action. There are a number of obstacles that can hinder successful application to the domain of knowledge management, such as complexity, usability issues, adaptability to changes, servicing and development costs and inconsistency. It is therefore important to share and produce knowledge products, such as producing reports, briefs, journal articles, presentations, videos and sharing information at group meetings, online and on social media. It is also important to organise knowledge by holding after action reviews, developing, maintaining and uploading information to knowledge-sharing websites/systems and packaging essential information for stakeholders (i.e. academic papers, USBs, short reports, visual material). Ultimately, knowledge sharing activities are already part of the task at hand, but KM plans make this systematic and leverage their effectiveness. KM staff facilitate knowledge exchange, but knowledge sharing must be done by those that have and need the knowledge.

Figure 8. Tacit and explicit knowledge



Knowledge management during the research process

During the formative stage, it was discussed that the research design workshop report and research protocol will be published widely.

During the implementation phase and data collection, it was decided that

1. LSHTM will host an internal webpage to be used for the study tools and data, which will have limited availability, specifically to a national level advisory committee, the Metric's group, and to ENAP and EPMM partners. This process will allow for the cross-sharing of learning between country teams and the immediate personnel involved in and supporting the research.
2. LSHTM and the individual country teams will host periodic webinars on 1) the topics under analysis, 2) progress of activity, 3) presenting the results per country, 4) comparing results across study sites, and 5) learning from the process of data collection and study design etc.
3. Each country study team should appoint a knowledge management coordinator who is responsible to provide content for an internal webpage used for the study tools and data as set out at 1 above. This role, including how it will be appointed, will be discussed further with the country teams during the formative stage.
4. For each country team, the partner institutions hold at least two face-to-face seminars, one for staff before the data collection phase to raise awareness about the study's aims and one following the findings of the study.

5. The observers and study leads should engage in monthly or bi-monthly documentation of the reflections on the process of research as a valuable form of implementation research to document and inform the learning process.
6. It was also suggested to explore various online options and mobile applications to facilitate the ease of recording and sharing.

Following the analysis stage:

1. All research findings and tools developed will be available externally online, and the data module will be open access and accessible.
2. The results will be published in peer-reviewed journals and presented at national, regional and international conferences, seminars and workshops.
3. The findings will be shared widely within research and policy networks.
4. Briefs, including the study's recommendations and next steps, will be published linking to policy initiatives and WHA milestones to be disseminated at key UN events and to general public.
5. Nationally, the advisory committees will guide the dissemination plans in country and it will be important to scale-up and make recommendations to other countries.

Capacity building

During the study, it was discussed that:

1. A community of practice (COP) will be developed for the three country sites and study coordinators during the study with the aim to share information, knowledge and gather lessons learned. It was emphasised that the COP needs to be wider than a repository of tools alone and can include a discussion platform that is moderated and coordinated.
2. A study tour of study managers from the three sites should be planned to exchange and document lessons learned and at least one face-to-face Lesson Learning seminar be planned.
3. Further, the study can support at least two related PhD candidates, with a minimum of one from LMIC linked to the CIFF investment, and a teaching module will be established for data quality assessment/use, including use in Tanzania and Bangladesh.

Next steps

It will be important to discuss the knowledge management plan with the three country teams and refine as necessary to each country context. Options for sharing knowledge on various platforms, such as a COP, online, social media and through webinars, will need to be explored, planned and costed prior to implementation.

CONCLUSION AND NEXT STEPS

The purpose of the workshop was to enable a technical review of the plans for ENAP metrics facility-based research and to bring together researchers who are/have undertaken similar work, as well as relevant experts to ensure programmatic relevance, with results appropriately targeted for wide use in national data platforms at a later stage. Through the plenary sessions and 17 working groups, each of the five core intervention indicators were discussed, alongside essential data collection processes, tools and other health systems work.

In each of the five intervention working groups, the group discussed a numerator, denominator and began to draft a set of structured clinical observation checklists during the workshop based on international standards, including WHO-approved guidelines for the relevant interventions of interest. Each intervention checklist focuses on the agreed numerator measure and the key data points to enable the collection of data for the target population denominator analysis, and where appropriate for a subset of observations. The checklists also include a few of the observations of content of care or timing (objective 3) noted during the discussions so that it is possible to validate select components of effective coverage.

The working groups discussed the use of observers and filming, and especially highlighted the important ethical, cultural and contextual issues. For the primary purpose of this research, it was determined that the use of clinical observers is the 'gold standard,' and that filming will have utility to answer a specific question regarding objective 3 for one of the five interventions, resuscitation procedures, and possibly for PSBI and KMC.

Discussion throughout the workshop emphasised the need for the strengthening of HMIS for newborn health interventions, closely linking with DHIS 2 in the three country sites. Recommendations were provided for the statistical design and the analysis planning for the numerators and denominators, and it was agreed that positive predictive value was a more useful indicator to assess validity and accuracy.

Further, in addition to the five interventions and research methods, the participants discussed birthweight, gestational age, birth certificate registration, perinatal audit and service readiness intervention for small and sick newborns as other essential health systems work that will be integrated into to the facility based research. In particular, birthweight and gestational age were highlighted across the working groups as important cross cutting issues.

Following the workshop, the extensive discussions and input from participants during the plenary sessions and 17 working groups will continue to be reflected upon and integrated into the remaining gaps in the final research protocol and related checklists. The research protocol and the related tools, including the three observer checklists (the Labour ward observer checklist, the KMC ward observer checklist and the PSBI Assessment and Treatment site observer checklist) and the maternal recall survey, will continue to be refined during the formative and piloting phases and will be published widely once finalised following the research.

These next steps will be coordinated by the ENAP metrics coordination team and will ensure ongoing multi-partner collaborative teamwork by seeking further consultations and participatory input from all the participants. Through this open participatory collaborative process, the aim is to have shared ownership of practical, realistic and measurable ENAP core indicators that can then be scaled up to achieve the essential ENAP 2030 targets for neonatal mortality and stillbirth rates of ≤ 12 per 1,000 births whilst ensuring high, equitable coverage with evidence-based interventions.

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ANNEX 1: Meeting agenda

WEDNESDAY 20TH APRIL 2016			Responsible
09:00-1030 **Beaumont**	**PLENARY 1** **Opening**	***Chair WHO*** ***Opening welcomes*** ***CIFF perspective*** ***Introductions*** ***ENAP measurement improvement roadmap*** • Milestones and progress to date, links to other work • Workshop aims, objectives & outputs	Jon Simon Matthews Mathai, Joy Lawn, Simon Azariah All participants Joy Lawn
10:30-11:00	*Coffee Break*		
11:00-13:00 **Beaumont**	**PLENARY 2** **Overview of research protocol and sites**	***Chair UNICEF*** ***Facility-based testing research*** • Main research question for the 5 indicators to test sensitivity/specificity of recorded data • Additional research on quality/content and principles for prioritising • Comparison of denominator options (40 mins with blocks for discussion) ***Use of observers and training, check-lists*** (20 mins including discussion) ***Use of film records; remit, analysis and challenges*** (20 mins including discussion)	Agbessi Amouzou Hattie Ruysen, Hannah Blencowe, Sarah Moxon Barbara Rawlins & Tariq Azim Allisyn Moran and KC Ashish
	Group Photo!		
13.00-14:00	*Lunch*	*Restaurant Main Section* *(Side meeting – Measurement agenda for Beyond Survival with Cally Tann, Ashok Deorari et al)*	
14:00-15:00 Grp 1 & 2: Beaumont Grp 3 & 4: Buckingham 4 Grp 5: Buckingham 5	**GROUP WORK A**	**Intervention specific indicator group work** 1. Uterotonics 2. KMC 3. Resuscitation 4. Treatment of PSBI 5. Antenatal corticosteroids (note sample size is underpowered for ACS, and focus will be GA metrics and safe use) **Indicator group *Task 1: Primary research question and tools*** To review the protocol for primary research question (sensitivity and specificity of the coverage measure for denominator) and to consider place of observation, finalise a checklist for observers, and measurement of the primary outcome (data from register/ other reporting forms or records).	**Facilitators** Allisyn Moran & Rima Jolivet Goldy Mazia & Sarah Moxon KC Ashish & Hattie Ruysen Troy Jacobs & Steve Wall Alfred Osoti, Jim Litch, Joy Lawn

15:00-15:15	*Tea Break*		
15:15-18:00 Grp 1 & 2: Beaumont Grp 3 & 4: Buckingham 4 Grp 5: Buckingham 5	**GROUP WORK A cont.**	**Indicator group work task 2: True Denominator** To consider measurement of the true denominator and make comments on how to evaluate / address denominator issues specific to this indicator. **Indicator group work task 3: Additional questions** To consider additional questions regarding effective coverage such as content, completion etc. (e.g. antibiotic therapy completion, or how continuous is KMC) and prioritise a few that could be included in this research	
19:00	*Banquet Dinner Beaumont*		

THURSDAY 21ST APRIL 2016			**Responsible**
08:30-09:00 **Beaumont**	**Overview of research sites**	***Introduction to the Country teams and testing sites*** Bangladesh Tanzania	Shams El Arifeen Theopista Johns & Mary Azayo
09:00-1030 **Beaumont**	**PLENARY 3**	***Chair (UNFPA)*** ***Group work feedback*** 10 mins each and 5 for discussion Discussions regarding implications (eg. observers-trained/untrained, use of films etc.)	Luc de Bernis
10:30-11:00	*Coffee Break*		
11.00-13:00 Grp 1 & 2: Beaumont Grp 3 & 4: Buckingham 4 Grp 5 & 6: Buckingham 5	**GROUP WORK B** *(Methods)*	**Methods group work** 1. Analysis planning for denominator options for testing 2. Training observers 3. Filming, including ethics, methods, and analysis 4. Pre-discharge interviews to assess maternal recall 5. Qualitative health-worker interviews to assess barriers and facilitators to data recording 6. Knowledge management/dissemination	Hannah Blencowe, Simon Cousens & Angela Baschieri Barbara Rawlins & Tariq Azim Allisyn Moran & KC Ashish Agbessi Amouzou & Kavita Singh Lara Vaz & Ann Marie Bergh Olive Cocoman & Dorothy Boggs (supported by Mary Kinney)
13.00-14:00	*Lunch*	*Restaurant Main Section* *(Side meeting – Metrics for chlorhexidine Cord Cleansing with Trish Coffey, Allisyn Moran et al)*	

14:00-16:00 Grp 1 & 2: Beaumont Grp 3 & 4: Buckingham 4 Grp 5 & 6: Buckingham 5	**GROUP WORK C (Systems)**	**Systems and integration group work** 1. Statistical design issues (eg AUC), data collection, database design and checks, plan for analysis 2. Service readiness for small & sick newborns (linked to EmOC) 3. Perinatal audit (linked to MDSR) 4. DHIS platforms and linking to these from the start 5. Birth certificate registration for all facility births 6. Birth weight measurement for all facility births	Joanna Schellenberg, Simon Cousens & Shams El-Arifeen Sarah Moxon & Queen Dube Matthews Mathai & Florina Sebanescu Ola Titlestad & Wilfred Senyoni Debra Jackson & Joy Lawn Hannah Blencowe & Ashok Deorari
16:00-16:15	*Tea Break*		
16:15-17:30 **Beaumont**	**Plenary 4**	**Chair** **Feedback from group work** 5 mins each and 5 for discussion **Planning ahead, take home actions** • Review of meeting objectives and expected outcomes • Finalising and publishing research protocol, tools • Timeline and key dates until end of 2018 • Ideas for more capacity building and how to fund this • Intentional linking to wider uptake of findings • Later phase of feasibility testing, big picture planning	Suzanne Fournier Joy Lawn and Hattie Ruysen
19:00	*Dinner*	*Beaumont : For all still staying at the hotel*	

ADDITIONAL ADD-ON MEETINGS

FRIDAY 22ND APRIL 2016		
PURPOSE:	**Consider workshop outputs and undertake more detailed country planning**	
PARTICIPANTS:	Bangladesh and Tanzania country teams with ENAP/EPMM coordination group and one/ two representatives from the indicator specific groups	
09:15-10:30 **Buckingham 4**	**Meeting/ discussion**	Implications from workshop Review of workshop outputs Overview of timelines for Bangladesh and Tanzania Agreement on next steps to finalise protocol and tools and plan IRB sub-missions Identification of remaining gaps or new items needed Brief overview of plans for measurement of service readiness for small and sick newborns
10:30-10:45	*Coffee Break*	

10:45-12:45 **Buckingham 4**	**Small group Meetings**	**Planning for Bangladesh research sites** Implications from workshop for research design/sites Timeline, work plans, key dates eg country stakeholders, HFA etc • Planning IRB submission, addressing ethical issues • Database and data analysis planning, DHIS2 platforms and linking • Planning later work for » Birth certificates » Birth weight measurement » Perinatal audit **Planning for Tanzania research sites** • Next steps to select/inform teams following RFA • Implications from workshop for research design/sites • Timeline, work plans, key dates eg country stakeholders, HFA etc • Planning IRB submission, addressing ethical issues • Database and data analysis planning, DHIS2 platforms and linking • Planning later work for » Birth certificates » Birth weight measurement » Perinatal audit **Planning for Malawi service readiness small and sick newborns** • Planning for data extraction, management and analysis • Process and timeline for ethics submission and in Malawi • Overall timeline and key dates • After lunch: • Small meeting with Queen Dube to discuss clinical care tools for small and sick newborns **Intervention specific teams additional time as needed to plan for** • Uterotonics • KMC • Resuscitation • Treatment of PSBI • Antenatal corticosteroids
12:45-14:00	*Lunch*	*Restaurant Main Section*

ANNEX 2: Participants

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ANNEX 3: Working group facilitators and participants

WORKING GROUP	FACILITATORS	PARTICIPANTS
DAY 1, SESSION A		
1. Uterotonics	Allisyn Moran & Rima Jolivet	Georgia Gore-Langton, Gaurav Sharma, Elahi Chowdhury, Matthews Mathai, Luc De Bernis, Agbessi Amouzou, Honorati Masanja, Wilfred Senyoni
2. KMC	Goldy Mazia & Sarah Moxon	Theopista John, Simon Cousens, Suzanne Fournier, Lara Vaz, Kate Milner, Shams El Arifeen, Ashok Deorari, Queen Dube, Dyson Likomwa, Anne-Marie Bergh, Amanda Cleeve, Debra Jackson
3. Resuscitation	KC Ashish & Hattie Ruysen	Angela Baschieri, Maya Kohli Lynch, Tariq Azim, Mary Azayo, Michel Brun, Trish Coffey, Mary Drake, Vladimir Gordeev, Indira Narayanan, Barbara Rawlins, Kavita Singh, Tazeen Tahsina, Ola Titlestad, Ly Nguyen
4. Treatment of PSBI	Troy Jacobs & Steve Wall	Hannah Blencowe, Rubayet Sayed, Nalini Singhal, Tamar Chitashvili, Juan Dewez, Ehsan Rahman, Jon Simon, Amira Khan, A I Ayede, Jai Das, Joanna Schellenberg
5. Antenatal corticosteroids	Alfred Osoti, Jim Litch, Joy Lawn	Cally Tann, Dorothy Boggs, Florina Sebabescu, Olive Cocoman
DAY 2, SESSION B		
1. Denominator options for testing.	Hannah Blencowe, Simon Cousens & Angela Baschieri	Vladimir Gordeev, Joy Lawn, Michel Brun, Tamar Chitashvili, Mary Drake, Tazeen Tahsina, Ola Titlestad, Matthews Mathai, Luc De Bernis, Florina Sebanescu, Jai Das, Alfred Osoti
2. Training observers	Barbara Rawlins & Tariq Azim	Mary Azayo, I. Ayede, Amanda Cleeve, Goldie Mazia, Indira Narayanan
3. Filming, including ethics, methods, and analysis	Allisyn Moran & Ashish KC	Gaurav Sharma, Nalini Singhal, Shams El Arifeen, Joanna Schellenberg, Queen Dube
4. Pre-discharge interviews to assess maternal recall	Agbessi Amouzou & Kavita Singh	Hattie Ruysen, Amira Khan, Rubayet Sayed, Theopista John
5. Qualitative health-worker interviews to assess barriers and facilitators to data recording	Lara Vaz & Anne Marie Bergh	Susan Niermeyer, Juan Dewez, Sarah Moxon
6. Knowledge management/ dissemination	Olive Cocoman & Dorothy Boggs	Georgia Gore-Langton, Troy Jacobs, Wilfred Senyoni, Ashok Deorari, Debra Jackson

DAY 2, SESSION C		
1. Data collection, database design and checks, plan for analysis	Joanna Schellenberg, Simon Cousens & Shams El-Arifeen	Vladimir Gordeev, Angela Baschieri, Ashish Kc, Tariq Azim, Tamar Chitashvili, Honorati Masanja.
2. Service readiness for small & sick newborns (linked to EmOC)	Sarah Moxon & Queen Dube	Georgia Gore-Langton, Lara Vaz, Juan Dewez, Ehsan Rahman, Queen Dube, Nalini Singhal, Anne-Marie Bergh, Michel Brun, Mary Azayo, Steve Wall, Rubayet Sayet, Indira Narayanan, Al Ayede,
3. Perinatal audit (linked to MDSR)	Matthews Mathai, Florina Sebanescu	Theophista Johns, Luc De Burnis, Jon Simon
4. DHIS platforms and linking to these from the start	Ola Titlestad & Wilfred Senyoni	Steve Wall, Agbessi Amouzou, Rima Jolivet, Hattie Ruysen, Olive Cocoman, Theopista Johns.
5. Birth certificate registration for all facility births	Debra Jackson & Joy Lawn	Tazeen Tahsina, Dorothy Boggs
6. Birth weight measurement for all facility births	Hannah Blencowe & Ashok Deorari	Gaurav Sharma

ANNEX 4: Process for protocol development

ENAP Management Group:
Co-Chairs UNICEF & WHO
(Kim Dickson & Anthony Costello)
MX Group includes all co-chairs for ENAP coordination groups - Advocacy, Implementation, Metrics, Research + Key Donor representatives)
Coordinator sitting in PMNCH

ENAP Metrics Group:
Co-Chairs WHO & LSHTM (Matthews Mathai & Joy Lawn)

ENAP Implementation Group:
Co-Chairs WHO & UNICEF

ENAP Research Group:
Co-Chairs WHO & AKU (Rajiv Bhal)

ENAP Advocacy Group:
Co-Chairs PMNCH, Save the Children & United Nations Foundation

ENAP Metrics coordination Group:
Bill & Melinda Gates Foundation
CIFF
Save the Children/Saving Newborn Lives
UNICEF
USAID
London School of Hygiene and Tropical Medicine
WHO

Feedback at each stage

MNH Techincal Advisory Group
Aim to align this within the WHO led Maternal and Newbord Metrics Advisory Group (Including EPMM)

PROCESS FOR DEVELOPMENT OF ENAP METRICS & EPMM FACILITY BASED COVERAGE RESEARCH PROTOCOLS

1 **Validation Protocol Group** *(slightly different group for feasability testing):*

Purpose -
Develop first draft GENERAL protocol TO GUIDE facility based validation of ENAP coverage indicators:

Participants: Require epi and stats expertise in order to design a robust validation including: sample size, with specific reference to sensitivity and specificity etc.

LSHTM (Joy & Hattie); Statistician (Simon Cousens); Country team leads (Shams for Bangladesh, Tanzania TBC); WHO (Matthews); ICM/UNICEF (Agbessi); IDEAS (Tanya M); USAID (Allisyn); UNICEF Nepal (KC Ashish); Save the Children (Lara)

Newborn Resus group
Lead Links via UNICEF KC Ashish + Hattie Ruysen

Antenatal corticosteroid group
Lead Links via UNCOLSC (Joy Lawn), WHO (Josh Vogel/Alfred Osoto) and GAP (Jim Litch)

Tanzania
Research team and national partners

2 **Technical consultation**
Design Workshop focused on key methodological outputs plus review from Intervention Specific working groups.

Purpose -
To provide detailed review of protocol in accordance with intervention specific expertise.

Participants:
> 60 methods, intervention and measurement experts during 2 day workshop.

Kangaroo Mother Care group
Lead Links via KMC acceleration grp + thru Sarah Moxon and Goldy Mazia

Treatment of Infection task team:
Lead Links via SATTS with WHO & SNL (Steve Wall/ Qazi) + Deb Sitrin

Oxytocin task team:
Lead Links via EPMM, Allisyn Moran + Rima Jolivet

Bangladesh
Research team and national partners

3 **BROAD CONSULTATION**

4 **DISSEMINATION AND SHARING OF PROTOCOLS and RELATED TOOLS**

Part of Multi-partner Measurement Improvement Roadmap 2015-2020
www.everynewborn.org

ANNEX 5: Overview and gantt chart of key facility-based testing activities (2016-2017)

	May-16	Jun-16	Jul-16	Aug-16	Sep-16	Oct-16	Nov-16	Dec-16	Jan-17	Feb-17	Mar-17	Apr-17	May-17
TASK													
IRB Submission													
Draft of validation protocol for facility-based indicator testing completed ahead of IRB submission (final protocol will be open access for other groups to use/adapt)	■	■											
Adapt generic protocol and tools to local context	■	■											
Submit for local ethical approval	■	■											
Submit for LSHTM ethical approval			■	■	■								
Formative Phase													
Selection of study sites (high through-put facilitates providing ACS, resus, KMC & treatment for suspected PSBI)	■	■											
Map all relevant metrics research or implementation work (including collating tools & protocols), identifying potential linkages for catalysing use at scale (e.g. DHIS-2)		■	■	■									
Database structure established for sharing facility-based metrics testing data across sites with initial data.				■	■	■	■	■	■				
Formative HFA, register review and health data flow assessment					■	■	■	■					
Establish database for sharing facility-based metrics testing data across sites with initial data					■	■	■	■					
Preliminary analysis following HFA and health facility data flow and context evaluations commenced (to ensure database design and planning are refined accordingly)								■	■				

ACTIVITY GANTT 2016-2017 CONT.	May-16	Jun-16	Jul-16	Aug-16	Sep-16	Oct-16	Nov-16	Dec-16		Jan-17	Feb-17	Mar-17	Apr-17	May-17
TASK														
Facility-based testing (observer data collection phase)														
Initiate pilot testing with observers in situ														
Synthesis learning to date and refine standard operating procedures, data collection tools and database design														
Move into facilitate based data collection phase														
Start technical work to refine indicators for use in HMIS, & with related IT technologies .e.g. DHIS-2														

ANNEX 6: DRAFT Research protocol (version 2 September 2016)

Please contact enapmetrics@lshtm.ac.uk to request a copy of the draft research protocol "Testing the recording of priority facility-based, maternal and newborn coverage indicators for use in health management information systems" (version 2 September 2016). The research protocol will continue to be refined during the formative and piloting phases and will be published widely once finalised following the research.

ANNEX 7. DRAFT Observer checklists and Maternal Recall Survey (version 2 September 2016)

Please contact enapmetrics@lshtm.ac.uk to request a copy to the Observer checklists, including the Labour Ward Observer checklist, the KMC observer checklist and the PSBI Assessment and Treatment site observer checklist, and the Maternal Recall Survey. The Labour ward checklist includes Immediate Uterotonic Administration, Essential Newborn Care, and Newborn Resuscitation and Antenatal Corticosteroid Verification Tools. The three observer checklists and maternal recall survey will continue to be refined during the formative and piloting phases and will be published widely once finalised following the research.

ANNEX 8. Advantages and disadvantages of clinical observers

The table below highlights the advantages and disadvantages of using clinicians versus non-clinicians for observing maternal newborn interventions.

		ADVANTAGES	DISADVANTAGES
Clinical Observers	**Logistics, training and cost**	Familiar with the maternal-newborn interventions that we aiming to observe and measure as part of the study.	May be challenging to recruit personnel with necessary skills/retain them especially important consideration in countries where health worker density is low.
		Require less training for the study, which will save costs on training and logistics in preparation for the study.	Experienced clinicians will be costly to employ for the duration of the survey. Despite clinical training, their experience of maternal-newborn interventions will vary depending on prior number of years or area of clinical expertise.
		Familiar with the hospital working context, and potentially have experience of the inner workings of the hospital.	May find themselves observing close or senior colleagues, there may be a power imbalance or bias introduced recording or observing inappropriate practices.

Continued next page...

		ADVANTAGES	DISADVANTAGES
Clinical Observers (continued)	**Ethics**	Experience of adhering to hospital procedures (e.g. infection control) and responding to patient needs in sensitive situations.	There will be frequent ethical dilemmas for clinical observers judging when to intervene, especially when observing poor quality practice, disrespectful practice or missed opportunities for interventions.
		Able to identify emergency situations and take appropriate actions as per study ethics protocol. This may lead to changes in practice. However, as the aim of this study is to observe the accuracy and precision of the recording of the interventions, this will not bias the aims of the study.	The presence of clinical observers may also influence the health worker recording of the practice, which could introduce bias to the study (e.g. health workers may be more likely to record their practice accurately when they are being observed by clinicians).
		Less likely to misinterpret, confuse or wrongly classify clinical interventions (e.g. will recognise different types of injections or identify when different terminology is used).	May still misinterpret, confuse or wrongly classify interventions despite clinical knowledge, or may bring their own "clinical judgment" bias into the study (e.g. base decisions on what they would do rather than the clinical guidelines or protocol).
Non-clinical observers	**Logistics, training, cost**	Less costly to employ for the duration of the study.	Basic training on essential newborn care and care of newborns with complications will be needed, which may require quite lengthy and costlier training.
		With appropriate training, could potentially follow a clinical algorithm or protocol without bringing any clinical judgement into the setting.	Observing maternal health interventions and identifying specific actions without prior clinical training will be challenging and there will be frequent situations where practices are misinterpreted, confused or wrongly classified (e.g. confusing different drugs or delivery modes).
	Ethics	Non clinicians are unlikely to be able to identify emergency situations. There will be less ethical concerns.	A detailed ethical protocol will still be needed in complex cases or in cases of disrespectful care or malpractice.

ANNEX 9. Overview of potential sources of bias, and solutions

POTENTIAL SOURCE OF BIAS	ESTIMATED EFFECT	MITIGATION OF POTENTIAL BIAS
Using observers- Hawthorne effect: Presence of observers and observer action will change health worker behaviours for routine documentation	Routine health worker documentation will improve / increase because documentation actions are being observed.	• Clearly communicate objectives of research to observers. • Training of observers to be discreet in observations and avoid prompting or commenting on recording practices. • Work with hospital management and health workers in the facility to ensure the benefits of the research are communicated and that the purpose is not to penalise or blame individuals for existing recording practices. • Use comparison of records of cases observed versus previous cases (2-3 cases) to assess possible Hawthorne effect on recording, but documenting whether quality of recording is similar.
Using observers – Hawthorne effect: Presence of observers and observer actions will change health worker practices	Routine health worker practices will improve because practices are being observed. Will increase (e.g. better adherence to clinical protocols).	• Not necessary to mitigate as not directly biasing research aims. • Ethical protocol needed for observer intervention in cases of emergency or malpractice.
Selection bias – during identification of the study population, higher volume facilities may not be representative of the general practices in health facilities	Practices, including routine documentation, may be different in higher volume facilities than in lower level health facilities.	• Carry out observations in more than one high volume facility. • Carry out context analysis to ensure that characteristics of the facility can be well described at the analysis stage.
Recall bias - maternal or health worker recall of events may be different depending on outcomes of patient	Adverse significant events may affect health worker and patient recall and recording.	• Masking of the intent of questions for mothers to minimise recall bias. • Potential bias should be acknowledged at analysis stage.
Transfer bias	Mothers or patients that die or that are referred are not included in exit interviews resulting in a fundamental difference between those included in the sub-study and those not. This will not affect main research aims.	• Systems in place to ensure that documentation for all patients, even those that are referred out, is included in the sub-study. • Describe this limitation at the analysis stage.
Misclassification bias – observers incorrectly identify interventions	An intervention that has/ or has not been occurred is incorrectly identified and therefore data collection is inaccurate.	• Use of trained clinical observers (rather than non-clinical observers) that are trained on clearly defined observation checklist. • Study supervision and quality checks in place.
Addition of supplementary routine registers and health worker training to complete these.	The provision of new materials and training will increase staff awareness, skill and motivation to complete routine records therefore increasing the number of correctly recorded indicators compared with observed practise. There is a risk you measure the outcome of using supplementary registers with training, rather than routine practise.	• Minimise need for supplementary register use by ensuring wherever possible that the included facilities are already implementing an adequate system for routine documentation and reporting. • Consider this potential source of bias during the analysis stage in order to utilise any relevant statistical methods to adjust. • Acknowledge and describe within the discussion and the limitations.

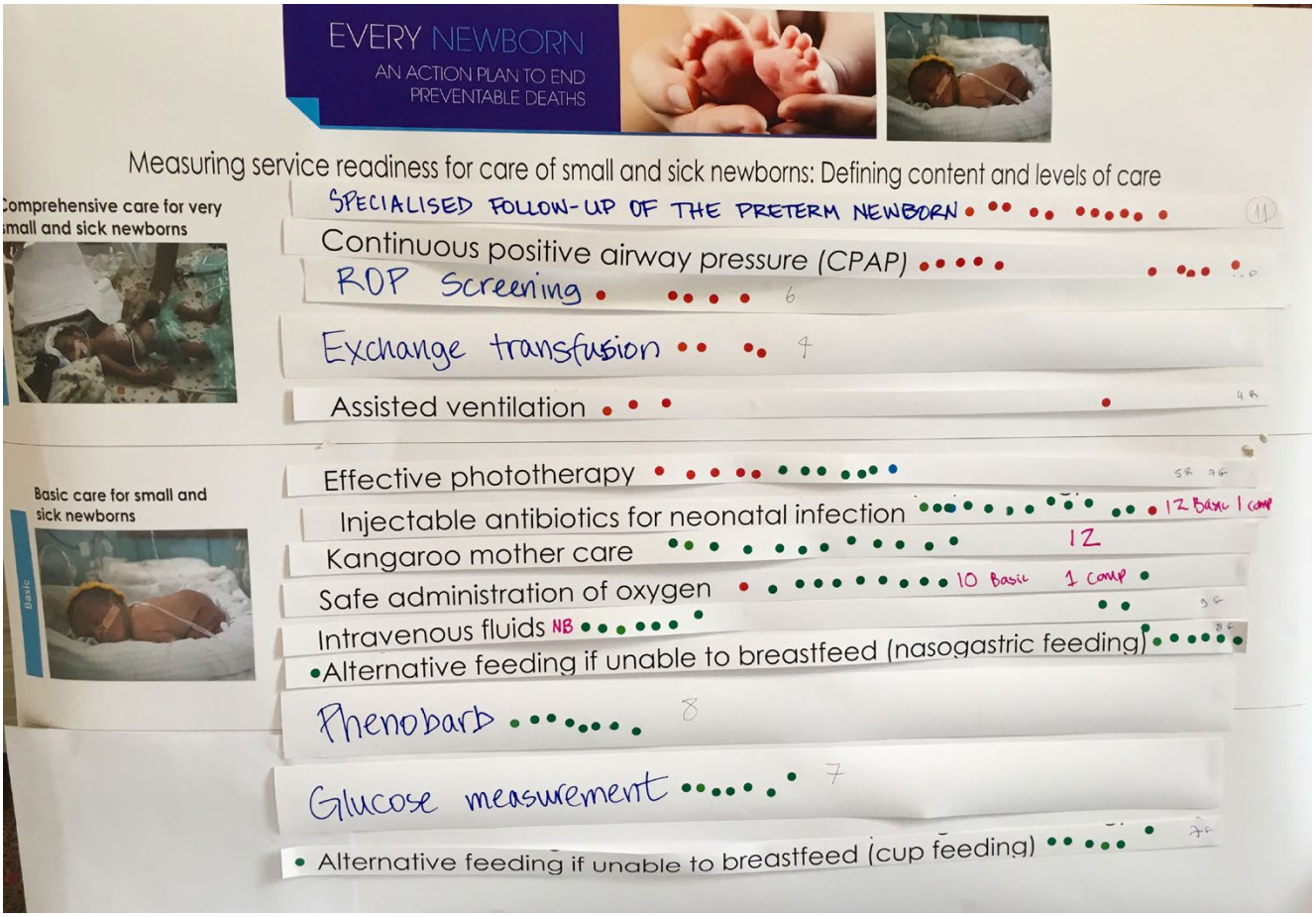
ANNEX 10. Signal functions for inpatient care of small and sick newborns

The group discussed an extensive list of signal functions for inpatient care of small and sick newborns during working group session C2. The text in red indicates additions to the original list and the text in italics indicates maternal interventions that are relevant for care of small and sick newborns.

SIGNAL FUNCTION	COMMENTS
Thermal care	Almost universal consensus that thermal care should be available and emphasised at all levels. For inpatient care combination of warmed cots, KMC, incubator will need to be considered.
Antibiotics for mother if preterm or prolonged PROM	All agreed that this is important to emphasise as a maternal intervention, but was not focus of discussion due to the timing of the intervention (before birth).
Antenatal corticosteroids	All agreed that this is important to emphasise as a maternal intervention, but was not focus of discussion due to the timing of the care (before birth).
Adverse significant events may affect health worker and patient recall and recording.	Masking of the intent of questions for mothers to minimise recall bias. Potential bias should be acknowledged at analysis stage.
Alternative feeding if baby unable to breastfeed (cup feeding and nasogastric tube feeding)	The original signal function only included cup feeding, but the group agreed that nasogastric feeding should be included as part of the signal function.
Safe oxygen therapy	Long discussion on safe oxygen and the need for the signal function to outline pulse oximetry, blenders and humidifiers and consistent O2 supply. Point made that need to stress importance of safe administration, just because a facility have O2 does not mean the facility is safe and ready to provide oxygen for newborns.
Management of hypoglycaemia	Particularly focused on glucose measurement etc.
Intravenous fluids	Safety and laboratory support.
Effective phototherapy	Management of bilirubin levels.
Intravenous antibiotics for the treatment of newborn infections	Sepsis management with infection treatment (IV) – challenges exist for IV antibiotics for week long courses/ two weeks and will need to be able to finish the course.
Kangaroo mother care, including follow up	Important that the signal function captures the facility readiness to provide follow up structures as well as the inpatient components of KMC
Management of seizures	Eg. phenobarbitone and associated care
Total parenteral nutrition (TPN)	General agreement that this should not be a signal function but formed important part of the discussion.
Continuous positive airway pressure (CPAP)	Many felt that although CPAP is becoming increasingly available, there was still a need for caution on widespread use at lower level without due attention to safety.
Mechanical ventilation	Require significant associated support and potential for long term damage means safety is critical.
Surfactant therapy	Concerns this was prohibitively expensive for many settings.

Retinopathy of prematurity (ROP) screening	Few settings able to do this, but would be important for higher level facilities to build into their care of preterm given the importance of ROP as a cause of preventable blindness.
Bronchopulmonary dysplasia screening	This was mentioned but most felt not feasible or realistic as a signal function.
Head ultrasound	Mentioned but limited discussion on this as an actual signal function.
Exchange transfusion	Many noted that CEmOC facilities can do blood transfusion but this should not be automatically assumed that these same facilities can carry out transfusions for newborns.
Haemodialysis	This was mentioned but most felt not feasible or realistic as a signal function.
Cooling	Group participants felt evidence for this strong, but still a relatively new intervention in higher income settings.
Mechanical ventilation	Many felt very few facilities will be able to do this in many low income settings
Specialised follow up of the small and sick newborn	The group emphasised the importance of this component of offering inpatient care and that services need to think about how to build this into their facility based care as part of their service readiness.

The image below shows the number of votes for each signal function by levels of care on the working group flip chart.



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