Title: Global Maternal Sepsis Study (GLOSS)

A review of the global maternal sepsis study protocol was done. The study was conducted in partnership with the State Institute of Health and family Welfare (SIHFW), Haryana and Post Graduate Institute of Medical education and Research (PGI) Chandigarh under a memorandum of understanding with PGIMER.

Identification of study districts and institutions: Identification of study districts and institutions was done in a meeting held with partners. Two districts (Panchkula and Ambala), where deliveries take place and the number of cases of maternal sepsis and infections that are likely to be seen during one week of the study, were selected. There are 169 healthcare facilities in the two districts, with 49 facilities providing maternity care. There are 11 intensive care units, however, the serious maternity cases are referred to only 2 hospitals in the government sector. Private hospitals and nursing homes handle over 50% of deliveries. Based on available data, it was found that 35% of deliveries occur at district and sub-district hospitals, 10% at health centres, and 5% at tertiary institutions in the government sector. Six institutions from government hospitals in the two districts were selected for the study, while smaller health centres were excluded due to logistical challenges. The two tertiary institutions where seriously ill cases are referred (i.e. PGI and Government Medical College and Hospital Chandigarh), were also included. The selection of the two districts was based on geographical proximity, familiarity, and working relationships. The population, estimated number of live births, and live births in the selected hospitals were communicated to GLOSS for approval. The challenge was that most women in tertiary centres come from Chandigarh, Punjab, Haryana, Himachal Pradesh and other neighboring states, but plans were made to accurately include them in order to capture cases of maternal sepsis. Even though these are referral institutions the identification of women from these districts was relatively easy since there is an operational electronic registration system in these two hospitals that identifies the residential address of the clients.

Table 1. Estimated population and annual births in the two districts and facilities selected for the study.

District	Population (approx.)	Estimated live births/ year in the area	Number of live births/ year in the hospitals selected
Panchkula	0.7 million	14000	District 8500
			Sub district 1320
Ambala	1.2 million	24000	District 4742
			Sub district 1914
			Sub district 700 Sub district 588
Chandigarh	(To cover cases from these two district)		PGIMER (tertiary) 6000 GMCH (tertiary) 7000

Pre-testing of maternal sepsis survey tools

The survey tools were pre-tested in district hospital Panchkula, which is a secondary level institution in the state. The staff at the hospital was briefed about pre-testing. The maternity ward, labour room, postnatal ward, private ward and Sick Neonatal care Unit of the hospital, where maternal and newborn in-patient services are provided, were visited. Pre-testing of the WHO study protocols was done on the women admitted in the District Hospital Panchkula on 7th and 8th September 2017 to screen all cases from the different locations in the hospital. The records of all these cases were reviewed daily for detection of maternal infection for one week. Suspected cases of infection were followed up for one week to determine the change until the time of discharge, referral or adverse outcome, if any. No case of maternal infection was identified. However, one case of pre-mature rupture of membranes and one suspected neo-natal sepsis case was identified. It was observed that routine antibiotics were being prescribed to all delivered women without undertaking laboratory investigations. Also, the case files were generally incomplete. Ethics approval for the study was obtained from PGIMER.

Advocacy: The advocacy poster on GLOSS maternal sepsis study in English was printed locally and was displayed in the eight facilities in the maternity wards and all other prominent locations in the hospitals and health centers prior to commencement of the study for sensitization of the hospital staff. The key messages from these posters was shared by the hospital staff with the clients who visit the facilities. The information from posters was translated into the local language and two specific messages were developed, providing guidance to clients and healthcare providers about the facilities to visit. Messages were sent to 1139 ASHAs (Accredited Social Health Activists, deployed by the state government), 57 facilitators, 6 block supervisors and 2 district coordinators. In addition, these messages were sent to 230 auxiliary nurse midwives (ANMs) and 45 lady health visitors. The messages were also sent to 2000 families where there are pregnant women in the two districts. The staff from SWACH also contacted all the ASHAs from the districts by phone to discuss identifying and referring maternal infections. The goal was to inform the community on a personal level and establish direct contact with them.

Adaptation and adoption of the protocols

SWACH developed an internal form for tracking the number of maternal case files that were being screened. This form helped data collectors keep track of cases that were enrolled and also record the case files of discharged patients to determine the completion of enrolled cases. Case files were screened in various wards, including ANC, PNC, SNCUs, and the Labour room. The number of case files screened in each ward was recorded to ensure accurate identification and enrollment of cases of maternal infection.

Training of data collectors from PGI and GMCH

The data collectors and doctors from two tertiary referral institutions, PGIMER and GCMH, were trained at SWACH. The training sessions covered various aspects of the protocol, including inclusion formats, reporting formats, and case investigation forms. The materials, including printed and electronic formats, as well as PowerPoint presentations, were shared with the trainees. Follow-up meetings were held with staff from PGIMER and GCMH to address any issues or concerns. Various resources, such as PowerPoint presentations, flow charts, and data forms, were used during the training. A coordination strategy was also developed to ensure that daily logs were submitted by the data collectors using mobile phone technology (WhatsApp) to the country coordinator.

The data collectors for Panchkula and Ambala were chosen from local individuals with medical or sociology backgrounds, such as nurses. They underwent thorough training in the SWACH, utilizing GLOSS power point presentations, flow charts, and protocols. The training took place over a 6-day period starting on 8 November 2017. Additionally, a refresher training was held on 23 November to update the data collectors based on a meeting that took place on 21 November 2017.

Implementation of the protocol:

Each facility selected for the survey was briefed on the study and case files were collected and reviewed for inclusion in the study. The enrolled cases were assigned a participant number and informed about the study, after which verbal consent was obtained. The information from the case records was entered into individual client forms and a daily log was created for each enrolled case. The daily logs were electronically communicated to the country coordinator, who monitored this process and reminded data collectors if any logs were not received. The information from each facility was uploaded daily to CREP. Cases that were screened out the previous day and new cases were reviewed each day for possible inclusion in the study until the clients were discharged or left the facility. The enrolment of new cases ended after one week, but already enrolled cases were followed up until January 10, 2018, and the follow-up continued for cases that remained admitted. The enrolled cases were uploaded daily to CREP and updates were made as necessary. Cases that did not report were contacted daily for updated information. A total of 71 cases of suspected maternal infections were identified, but upon review, 36 cases were rejected due to insufficient evidence. The rejected

cases were communicated to the central system for appropriate corrections. Any discrepancies or errors in the data were corrected by the data manager, with assistance from the country coordinator and consultation with the case file if needed. By April 13, 2018, all queries had been responded to and resolved. The country coordinator also participated in other surveys and encouraged others to participate as well.

Challenges encountered and solutions adopted to address the challenges

1. Staff: Data collectors were of variable background. To overcome this, the staff at tertiary institutions was given orientation training and all the components of GLOSS package.

2. Training: Intensive step by step training combined with hands on experience and half day reorientation prior to survey. Response to queries raised by data collectors throughout the study.

3. Data management: Although it was estimated that about 150 hours would be required in reality about 250 hours were spent. Ongoing support and guidance from CREP WHO HQs country co coordinator helped sustain the motivation of data manager.

4. Other Problems:

- Case files at all levels were very elaborate but incomplete. Profile for basic investigations even in second level facility is inadequate e.g. differential blood cell count and lack of attention to band forms, urine microscopy. Local facility in charge were informed about the deficiencies before the study.
- Second and third generation antibiotics are prescribed, even though there was insufficient evidence of maternal infection. This problem could not be addressed due to common clinical practice behavior.
- Two facilities had no case of suspected maternal infection despite sufficient load of cases in one. The data collector teams intensified their screening procedures and reviewed each record twice.
- Partner facility staff did not participate in GLOSS post campaign survey. The staff members were reluctant to fill up on line form they were given these forms and requested to fill them These were then uploaded on the GLOSS platform.