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Reducing surgical site infections and mortality among obstetric surgical patients in Tanzania: a pre-evaluation and postevaluation of a multicomponent safe surgery intervention

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ABSTRACT

Introduction Despite ongoing maternal health interventions, maternal deaths in Tanzania remain high. One of the main causes of maternal mortality includes postoperative infections. Surgical site infection (SSI) rates are higher in low/middle-income countries (LMICs), such as Tanzania, compared with high-income countries. We evaluated the impact of a multicomponent safe surgery intervention in Tanzania, hypothesising it would (1) increase adherence to safety practices, such as the WHO Surgical Safety Checklist (SSC), (2) reduce SSI rates following caesarean section (CS) and (3) reduce CS-related perioperative mortality rates (POMRs).

Methods We conducted a pre-cross-sectional/post-cross-sectional study design to evaluate WHO SSC utilisation, SSI rates and CS-related POMR before and 18 months after implementation. Our interventions included training of inter-professional surgical teams, promoting use of the WHO SSC and introducing an infection prevention (IP) bundle for all CS patients. We assessed use of WHO SSC and SSI rates through random sampling of 279 individual CS patient files. We reviewed registers and ward round reports to obtain the number of CS performed and CS-related deaths. We compared proportions of individuals with a characteristic of interest during pre-implementation and post implementation using the two-proportion z-test at $p \le 0.05$ using STATA V.15.

Results The SSC utilisation rate for CS increased from 3.7% (5 out of 136) to 95.1% (136 out of 143) with $p<0.001$. Likewise, the proportion of women with SSI after CS reduced from 14% during baseline to 1% ($p=0.002$). The change in SSI rate after the implementation of the safe surgery interventions is statistically significant ($p<0.001$). The CS-related POMR decreased by 38.5% ($p=0.6$) after the implementation of safe surgery interventions.

Conclusion Our findings show that our intervention led to improved utilisation of the WHO SSC, reduced SSIs and a drop in CS-related POMR. We recommend replication of the interventions in other LMICs.

Key questions

What is already known?

- Postoperative complications are a significant contributor to mortality among surgical patients in low/middle-income countries.
- Use of the WHO Surgical Safety Checklist (SSC) reduces the risk of complications and death from surgery and enhances patient safety by promoting team work and communication among surgical team members.
- Several studies have provided evidence on the significance of global recommended best practices to reduce caesarean section (CS)-related complications.
- These practices include infection prevention (IP) bundles, use of Joel-Cohen incision, and implementation of Early Recovery After Surgery protocols.

What are the new findings?

- The implementation of the global recommended best practices to reduce CS related complications in low-resource settings such as Tanzania is feasible.
- Inter-disciplinary team-based approach enhances the acceptance and utilisation of the WHO SSC among surgical service providers.

What do the new findings imply?

- We demonstrated that a multicomponent team-based approach is effective in promoting WHO SSC adoption, reducing surgical complications and improving patient outcomes along with incorporating evidence-based clinical updates, for example, the IP bundle.
- Based on this evidence, it is therefore possible to scale up these interventions in other low-resource setting including Tanzania and achieve the reduction in caesarean related complications and mortality.

INTRODUCTION

Despite ongoing maternal health interventions, the number of maternal deaths in Tanzania remains high and stagnant.[1] The most common causes of maternal death in Tanzania, and in low/middle-income countries (LMICs), are haemorrhage, hypertensive disorders and infection.[2 3] In addition, the risk of maternal death is significantly higher among women who undergo caesarean section (CS), especially in LMICs, with the most common causes of maternal death during or after CS due to postpartum haemorrhage (32.0%), infection/sepsis (22.0%) and anaesthesia-related causes (14%).[4] Yet, timely and safe CS can prevent nearly 100 000 maternal deaths worldwide each year, or approximately 30.0% of all maternal deaths.[5]

Postoperative complications are a significant contributor to mortality rates among surgical patients in LMICs,[6] with infections occurring in up to 24.0% of cases.[7] Studies in Tanzania have reported high surgical site infection (SSI) rates ranging from 21.3% to 48.0% among patients undergoing surgery, including CS.[8–13] These rates are 5–18 times higher than rates in high-income countries.

Improving surgical outcomes in these settings is challenging due to multiple factors, including traditional hierarchies within surgical teams that lead to poor teamwork and communication, poor translation of global best practices into action in the local context, and limited use of data for action.[14] Poor teamwork and communication result in surgical errors and postoperative complications, thereby exerting a direct negative impact on patient outcomes.[15] It is, therefore, necessary to design innovative, team-based, context-specific interventions that address both technical and non-technical aspects of care. Such interventions can have a positive impact on patient outcomes and are urgently needed to address this challenge in LMICs.[14 16]

We evaluated the impact of a multicomponent safe surgery intervention in Tanzania, hypothesising it would (1) increase adherence to safety practices, such as the WHO Surgical Safety Checklist (SSC), (2) reduce SSI rates following CS and (3) reduce CS-related perioperative mortality rates (POMRs).

METHODS

Study design

This paper describes interventions and results from a multicomponent Safe Surgery 2020 project funded by the GE Foundation/ELMA Philanthropies and implemented in two regions, Kagera and Mara, in the Lake Zone of Tanzania. The project was implemented in 30 facilities providing Comprehensive Emergency Obstetric and Neonatal Care (CEmONC) services, from January 2018 to December 2020. A pre-cross-sectional/post-cross-sectional study design was used to evaluate WHO SSC utilisation (adherence to each step of the 3-phase tool), SSI rates and CS-related POMR using quantitative analysis before the intervention and, again, 18 months after implementation of the safe surgery interventions.

Study interventions

Our safe CS package of interventions included interprofessional surgical team training, promoting the adoption and use of the WHO SSC, and introducing the use of an infection prevention (IP) bundle for all CS patients (appropriate antibiotic prophylaxis, vaginal cleansing with povidone iodine immediately before CS and proper abdominal skin preparation).[17] The SSC was adopted specifically for CS and included the three components of the IP bundle. Neither the CS patients paid for the IP bundle nor the surgical team members were paid for providing IP bundle, as it was integrated to regular CS service provision. In addition, the facilities received regular ongoing blended (onsite and virtual) mentorship by interprofessional mentors, developed quality improvement action plans, and received registers, dashboards and coaching to strengthen data use at facility level.

We did not improve the record keeping prior to the study. However, the intervention itself did include a component of data strengthening and data use, and did improve data quality and reporting. Inter-disciplinary mentors were recruited from trained surgical providers at zonal referral hospital (Bugando Medical Centre), regional referral hospitals, some district hospitals and high-volume health centres. They received mentorship training, including how to conduct onsite mentorship visits, how to facilitate virtual mentorship sessions, and collect data on SSC use, diagnose and report SSIs and POMR. After receiving training, mentors provided quarterly onsite and remote mentorship support to ensure that knowledge and skills are transferred and maintained and service provision was properly documented in respective monitoring and evaluation tools. Mentors reinforced use of the SSC and coached all available surgical team members, including those who did not attend the training, on correct use of SSC and documentation. Mentors also reinforced clinical skills on the diagnosis, treatment of surgical complications, and reporting of SSIs and perioperative mortality. They also assessed the WHO SSC compliance and management of SSIs through direct observation and review of patient files to re-enforce the SSC use and appropriate reporting of SSIs. The intervention used routinely collected service and monitoring data, including data from (1) self-reported data entered into theatre registers by service providers and (2) audits of patient files and (3) direct observations of procedures conducted by the mentors.

The surgical teams received a 5-day training on leadership skills, focusing on patient safety, teamwork and communication, and a subsequent clinical training focusing on evidence-based updates on surgical skills (e.g., the Joel-Cohen incision), the use of the IP bundle (described in detail below) and simulation training on proper use of the SSC. The skills gained during these trainings were reinforced during onsite visits and virtual mentorship sessions.

The IP bundle for CS, which has been shown to improve surgical outcomes elsewhere,[18] was implemented in this project. This bundle included use of appropriate antibiotic prophylaxis 15–60 min before surgery (antibiotic choice according to national protocols), vaginal cleansing with povidone iodine for 30 s immediately before CS for women in labour or with ruptured membranes, and proper abdominal skin preparation with alcohol-based antiseptic solution or povidone iodine (based on availability). All women undergoing CS received this IP bundle as per standard operating procedure.

During clinical training and subsequent ongoing mentorship, surgical teams were trained on the use of surgical techniques that have been shown to reduce the risk of postoperative complications and speed recovery, such as the Joel-Cohen Incision[19] and implementation of Early Recovery After Surgery (ERAS) protocols.[20 21] In each health facility, six surgical team members (including the surgeon, assistant surgeon, anaesthetist, theatre nurse, postnatal ward nurse and midwife) were trained together on the project interventions.

This paper describes the impact of the safe surgery intervention in improving surgical outcomes in 30 health facilities in the Lake Zone of Tanzania. Our study addressed three hypotheses around the change that would occur following implementation of the safe CS: (1) increase adherence to safety practices, such as the WHO SSC, (2) reduce SSI rates following CS and (3) reduce CS-related POMR

We present the results prior to and after 18 months of implementation of the interventions described in this study.

Study setting

The study was administered to surgical teams in 30 out of the 40 health facilities (15 health facilities in each region) in Kagera and Mara regions in Tanzania that were providing CEmONC services. The 10 remaining facilities were excluded in this study because they received a more comprehensive intervention package and are the subject of a separate evaluation. The surgical teams in these 30 facilities attended the clinical and leadership trainings as described above. The health facilities are located in both urban and rural settings and are at multiple levels of the health system, including regional referral hospitals, district hospitals, designated district hospitals and health centres. In each facility, six members of the surgical team: surgeon, assistant surgeon, theatre nurse, anaesthetist, labour ward nurse and postnatal ward nurse, were trained together on the evidence-based clinical package, including the proper use of the SSC and IP bundle. The teams were then supported by trained mentors with every other month in-person visits to ensure adherence to the intervention package.

Study population, sample size and selection

We collected data from individual patient files of women who received CS services and the paper-based registers where surgeries and respective surgical outcomes were recorded. The patient files and ward round notes were used to obtain the SSC utilisation rates and SSI rates. The paper-based registers were used capture to CS volume and CS-related maternal deaths.

A total of 1239 and 3033 CS were recorded in the operating theatre (OT) register during the baseline and 18 months after implementation respectively each for a period of 3 months.

This study was part of the larger study where a convenient sample of 20 patient files per site were randomly sampled for both the pre and post, 5 of which are relevant to the CS analysis of this paper. To sample the CS files, the list of all CS clients was obtained from the OT register, and assigned a consecutive number from 1 to N. With the use of random number tables, the four to five CS patient files were sampled per site depending on availability of the files. We randomly sampled 279 CS patient files (136 and 143 for baseline and end line, respectively), representing 4–5 CS patients' files from each facility. The files for women undergoing CS services and postoperative care were reviewed to determine the rates of SSC utilisation, SSI and CS-related mortality.

The diagnosis of SSIs was made by physicians, who were specifically trained on using the Centers for Disease Control and Prevention's (CDC) SSI definition.[22] The physician reviewed the clinical notes that were recorded in the CS patient files during the pre-implementation and post implementation, and made diagnoses based on when the information provided met CDC's criteria. We assessed the presence or absence of SSI for the period of the post-op (surgery) days up to the time the patient was discharged from the health facility.

We reviewed the OT register, where the CS surgeries are recorded routinely, to obtain the aggregate number of CS performed from January to March 2018 (pre-implementation) and from September to November 2019 (post implementation).

We reviewed the inpatient register and ward round reports to obtain the number of CS-related deaths for the period of January to March 2018 and September to November 2019. This study has been reviewed and received Non-Human Subject Research Determination notice.

Data analysis

To understand the changes in SSC utilisation rates, SSI rates, CS-related POMR for the 3 months during the pre-implementation and post implementation of the interventions, we compared the proportions of individuals with a characteristic of interest during pre-implementation against the proportion of individuals with same variable post implementation. The variables of interest are categorical (WHO SSC utilisation, SSI rate, and CS-related POMR).

The null hypothesis Ho, was that the pre-implementation and post implementation proportions of the characteristic of interest are the same for each of the categorical variables, meaning the difference was equal to zero. We compared the proportions of individuals with a characteristic of interest during pre-implementation against the post implementation using the two-proportion z-test at $p \leq 0.05$ using STATA V.15.

Definition of study outcomes

WHO SSC utilisation rate

- Proportion of CS where the WHO's SSC was correctly completed and filed in the patient file.
  - Numerator: number of CS where the SSC was correctly completed in the reporting period
  - Denominator: total number of CS in the reporting period

SSI rate

- Proportion of all CS patient files with a postoperative SSI within 30 days of operation, diagnosed during hospitalisation.
  - Numerator: number of SSIs diagnosed for all CS sampled files, in the reporting period.
  - Denominator: total number of CS patient files randomly sampled in the reporting period

CS-related POMR

- Proportion of all CS leading to in-hospital deaths among patients, within 30 days of the index procedure.
  - Numerator: total number of perioperative deaths (intraoperative and postoperative deaths (regardless of cause) in the reporting period.
  - Denominator: total number of CS performed in the reporting period.

Patient and public involvement

By design, the multicomponent safe surgery project was implementation research, which applied the theoretical knowledge and conceptual skills around safe CS and used existing data from the literature to develop the research questions. The research questions were informed by the processes of safe CS implementation and the results of implementation, including how to introduce potential solutions into a health system, and how to scale and sustain them. The intent was to understand what, why and how the multicomponent safe surgery interventions work in LMIC settings such as Tanzania and to test approaches to improve patient safety and surgical outcomes.

The study did not involve the patients in the design, recruitment or conduct of the study.

The study used secondary data analysis, by reviewing and analysing the CS data for WHO SSC utilisation and postoperative outcomes and complications that were routinely collected by healthcare providers while providing services in their facility.

The safe surgery project held a series of information dissemination meetings in Tanzania when the study results were available. Various stakeholders, including the health facility surgical teams, health facility staff, members of the Surgical Societies, Ministry of Health, Presidents Office, Regional Authority and Local Government and other relevant health professionals and community stakeholders, were involved. We will also widely disseminate the results at regional and global conferences.

If accepted for publication, we intend to more widely disseminate the study results to the global safe surgery community and other key stakeholders via regional and global conferences, as well as through webinars and community of practice platforms. This study will provide rigorous evidence to the global surgical community about the effectiveness of the multicomponent safe surgery intervention approach to improving surgical care quality. If successful, patients and other stakeholders could benefit from a quality improvement method that could improve surgical outcomes in Tanzania' Lake Zone region and other regions with similar contexts.

Table 1 Facility characteristics

	Number of facilities	Percentage
Facility level		
Health centre	16	53.3
District Hospital	14	46.7
Average caesarean section volume per month		
<20	7	23.3
20–50	10	33.3
>50	13	43.3
Number of beds		
<50	14	46.6
50–100	8	26.7
>100	8	26.7
Ownership		
Public	15	50.0
Faith based organisation (FBO)	14	46.6
Private	1	3.4

RESULTS

Health facilities characteristics

The bed capacity of the CEmONC facilities that implemented the project ranged from 15 to 200. The CS volume ranged from 3 to 60 CS monthly. The facilities had maximum of two operating rooms. Further description of the facilities is provided in table 1.

Changes in the utilisation rate of the SSC

The SSC utilisation rate among the women undergoing CS increased from 5 out of 136 (3.7%) during the pre-implementation period (January–March 2018) to 136 out of 143 (95.1%) after implementation of the leadership and safe CS trainings. The results show there was an improvement in the utilisation of the SSC for both Kagera and Mara regions. In Mara Region, the utilisation improved from 1.6% during baseline to 92.9%. In Kagera

Table 2 Per cent of caesarean section in which the Surgical Safety Checklist was used, by region and type of facility

	Pre-implementation (January–March 2018)		Post implementation (September–November 2019)		
	n	%	n	%	P value
Region					
Mara	1	1.6	65	92.9	<0.001
Kagera	4	5.4	71	97.3	<0.001
Type of facility					
Hospital	4	5.3	66	95.7	<0.001
Health centres	1	1.6	70	94.6	<0.001

Data source: C-section files.

region, the SSC utilisation increased from 5.4% during baseline to 97.3% after the project implementation. The improvement is statistically significant with a p value <0.001 across the regions and health facilities (table 2).

The SSC utilisation rate was higher in Kagera, 97.3% as compared with Mara region, 92.9%. Similarly, the improvement in the utilisation of the SSC was observed in both health centres and hospitals almost equally (85.7% vs 88.6%).

Changes in the proportion of women who had SSIs following CS

The proportion of women with SSIs after CS reduced from 13.9% during baseline to 0.7% after the implementation of safe CS interventions (table 3). The SSI rates were higher in Mara region (16.1%) during baseline as compared with 12.2% in Kagera region (table 3). The changes in SSI rate after the implementation of the safe surgery interventions is statistically significant in both health centres and hospitals (p=0.006 for health centres and p<0.001 for hospitals).

Changes in CS-related POMR

The CS-related POMR decreased by 38.5% over the 18 months of implementation of the safe CS project, decreasing from 0.16% (2 out of 1239) to 0.1% (3 out of 3,033) after the project implementation. However, the changes in the proportion of CS-related deaths are not statistically significant (p=0.6).

Table 3 Per cent of caesarean section with surgical site infection after C-section during pre-implementation and post implementation period, by region and by type of facility

	Pre-implementation (January–March 2018)		Post implementation (September–November 2019)		P value
	n	%	n	%	
Region					
Mara	10	16.1	1	1.4	0.002
Kagera	9	12.2	0	0.0	0.002
Type of facility					
Hospital	11	14.7	0	0.0	0.001
Health centre	8	13.1	1	1.4	0.006

Data source: C-section files.

Table 4 Per cent change in caesarean section-related perioperative mortality rate during pre-implementation and 18 months post implementation of the interventions, by region and by type of facility

	Pre-implementation (January–March 2018)		Post implementation (September–November 2019)		P value
	n	%	n	%	
Region					
Mara	1	0.3	2	0.2	0.7
Kagera	1	0.11	1	0.05	0.56
Type of facility					
Hospital	2	0.2	0	0.0	–
Health centre	0	0.0	3	0.4	–

Data source: paper-based registers.

In Mara region, the CS-related POMR decreased by a third, dropping from 0.3% (1 out of 336) during the pre-implementation period (January–March 2018) to 0.2% (2 out of 1076) after 18 months of safe surgery project implementation (September–November 2019). In Kagera region, the CS-related mortality rate has halved (0.11 vs 0.05) when comparing the pre-implementation (1 out of 903) against the 18 months after implementation of the project (1 out of 1957). However, the results are not statistically significant (p=0.56), see table 4.

DISCUSSION

Our findings revealed that after 18 months of implementing the safe CS project interventions in the 30 CEmONC health facilities in the Lake Zone of Tanzania, there was a significant increase in the use of the SSC. The adoption and adherence to the SSC in this project provides further evidence that it is feasible to introduce patient safety concepts and tools, such as the SSC, even in LMICs that may have limited resources.[23]

The SSC utilisation rate in this evaluation was quite high, at 95.1%, and this was higher than that found in Ethiopia or Uganda (39.7% and 80.0%, respectively), which represent similar LMIC settings.[24 25] These results from our 30 facilities are comparable with the results from the International Surgical Outcome study where the SSC was used in 89.9% of surgical patients.[17] We triangulated these results with routine data from the same facilities which also revealed a checklist utilisation rate of above 90.0%.[26] There was minimal variation in checklist use between hospitals and health centres, suggesting that health facility size did not significantly affect the adoption and utilisation of the SSC in the Lake Zone. These findings also show that the goal of promoting SSC use for patient safety at the facility level, as stipulated in the 2018 Tanzania National Surgical

Obstetric and Anesthesia Plan (NSOAP), can realistically be achieved and scaled up across other regions in the country.[27]

SSIs cause significant morbidity and mortality globally, and particularly in LMICs. These complications, despite being common, are often preventable. In this study, the SSI rate at baseline, before the intervention started, was 13.9%. This rate is similar to that reported by Mpogoro *et al* in a Lake Zone Referral Facility.[28] Higher rates have been reported elsewhere in Tanzania.[29] After 18 months of safe CS project implementation, this rate was markedly reduced to 0.7% (a reduction of 94.9%) with (p<0.001), showing that the interventions, including adopting the SSC to include the IP bundle and the updates on surgical technique, had a dramatic improvement in infection-related outcomes.

Our results also show a 38.5% reduction in CS-related POMR in the study facilities. Although not statistically significant, these results show the potential impact of the safe CS interventions in reducing mortality related to surgical complications. Our findings are comparable with other studies reported elsewhere. Haynes *et al* documented a reduction in mortality rate from 1.5% to 0.8% in a global review of WHO SSC implementation.[30] Similar to our findings, a decline of mortality by 47.0% was reported in Brazilian Federal District.[31]

We believe that the significant decrease in the SSI and mortality rates resulted from the safe CS multicomponent clinical intervention implemented in this study. In addition to promoting use of the SSC to enhance patient safety and reduce errors, the project also introduced use of the IP bundle for CS, surgical skills updates and ERAS. Several studies have documented the evidence on the impact of the IP bundle for CS in reducing perioperative complications.[18 32 33] Literature on role of the IP bundle on reducing post CS SSIs in Tanzania is non-existent. Most facilities do not implement the evidence-based practices described in this paper as a package of intervention, as we did in this study. We found only one study that highlighted the role of instituting an Antimicrobial Stewardship Programme in a regional referral hospital that resulted into SSI rate reduction.[11]

Our study demonstrates that the evidence-based clinical practices demonstrated in various studies globally, can be implemented locally in Tanzania to improve patient outcomes. For example, antibiotic prophylaxis which is recommended for CS patients by WHO[34] and shown to be very effective in reducing post-CS infections in real settings[35 36] is not routinely used in most facilities. Before this study, none of the project facilities practiced vaginal cleansing for women undergoing CS despite evidence of its effectiveness as recommended by WHO and documented in literature.[37–39]

This study affirms the findings and recommendations by Chu *et al*[40] who assessed operative mortality in resource limited settings, and recommended implementation of surgical quality improvement programmes so as to improve patient outcomes.

CONCLUSION

It is evident the multicomponent safe surgery intervention has resulted into increased utilisation of the WHO in LMICs such as Tanzania. Despite the clear global evidence on use of the SSC in improving patient safety, its uptake at the moment, especially in LMICs has been very slow. This study provided evidence on the feasibility and best approach to use in adopting this tool in settings similar to our study facilities.

Additionally, the remarkable reduction in postoperative surgical complications provides further evidence on the impact of global best practices in reducing surgical infections in the clinical settings as evidenced by the results presented in this study.

Finally, we were able to show a reduction in the CS-related POMR, though the results are not statistically significant, demonstrating how the safe surgery interventions contributed to the improved safety and quality of surgery in these settings.

We recommend scale-up of such interventions countrywide to improve surgical outcomes among obstetric and other surgical patients, as outlined in the Tanzania NSOAP.

Implication for policy makers

This study provides tangible evidence to donors, funders and policy makers on the need to invest in well-designed surgical interventions as part of Universal Health Coverage and contribute to achieving the Sustainable Development Goals by 2030.[41]

It is prudent for national and subnational ministries/local governments to consider planning and budgeting for such interventions to ensure safety of surgical procedures in all health facilities that provide surgical care. Based on this evidence, some of these interventions such as use of the WHO SSC should be supported by ministry guidelines as a mandatory standard across all health facilities, rather than being left as optional for facilities to adopt or not. This could be included as the key performance indicator for surgical services as part of the national monitoring systems. It is not just about having the SSC, it is about implementation and how this safe CS intervention supports and enables that team-based implementation.

Such a shift in the paradigm is needed for successful implementation of safe surgery interventions and should be accompanied by inclusion of inter-disciplinary teams of providers and the necessary mentorship support to achieve the intended results.

Promising innovations, such as this multi-component safe surgery/safe CS intervention, can in the longer term, contribute to the reduction of mortalities related to surgery including maternal mortality.

Study limitations

The SSI rates may have been underestimated as the CS patients were discharged within three to 7 days post-surgery and there was no long-term follow-up after discharge. There may also be additional underestimation as SSI rates were determined through chart review, and not through direct observation.

There is a potential of under reporting of the CS-related POMR since patients were not followed up after discharge and may have been referred and reported in other health facilities that were not part of this study. Some of the ten health facilities that were not included in this study are regional referral hospitals and district hospitals.

Other factors beyond the project interventions may have influenced the results to some level because other ongoing support continued to be provided to health facilities by either other implementing partners or the government.

We did not improve the record keeping prior to the study, however, the intervention itself did include a component of data strengthening and data use, and did improve data quality and reporting.

There is also potential selection bias of sampling the CS files, as the complete list of CS patient was sometimes missing due to poor filing system at the health facilities. Some sampled files could not be located and required a lengthy process to find them.

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