

# Implementation of a Surgical Safety Toolkit in Bangladesh:

## Program Learning from Routine Client Tracker Data

### BACKGROUND

Accessible, affordable, acceptable, and quality surgical care is fundamental to achieving the Sustainable Development Goals. Inadequate access to safe surgical care contributes to preventable death, disability, and financial hardship. Of the more than 130 million women who give birth every year, at least one in three will experience some type of complication that will require a medical or surgical intervention. It is estimated that there are nearly 300,000 maternal deaths annually and that maternal morbidities or disabilities affect 15–20 million women each year (WHO 2019; Koblinsky et al. 2012).

Prolonged/obstructed labor (P/OL) has been termed the most disabling maternal complication (Dolea and AbouZahr 2003). Neglected P/OL can result in female genital fistula, as can unsafe obstetric or gynecological surgery. An estimated 1–2 million women around the world are living with fistula, and there are thousands of new cases every year (Adler et al. 2013). The *Fistula Care Plus* (FC+) project, funded by the United States Agency for International Development (USAID) and implemented by EngenderHealth, seeks to strengthen health system capacity for fistula prevention, detection, treatment, and reintegration in priority countries.

### FC+ IN BANGLADESH

According to the Bangladesh Maternal Mortality and Healthcare Survey, there are approximately 20,000 women currently living with fistula in Bangladesh (MEASURE Evaluation et al. 2018). In Bangladesh, FC+ works to support fistula repairs and to prevent fistula through various interventions, including support for voluntary family planning (FP), clinical capacity building, and community outreach and education. In recent years, FC+ has supported approximately half of all annual fistula repair surgeries in Bangladesh and has mobilized national professional groups, government agencies, civil society platforms, and media institutions to engage in and strengthen strategies to prevent and treat fistula. Through these efforts, FC+ has brought attention to emerging aspects of fistula care, including the crisis of iatrogenic fistula and the need for recommendations related to persistent fistula-related disorders. From 2013 to 2019, FC+ in Bangladesh supported 1,537 surgical fistula repairs, trained 19 fistula surgeons,

and delivered 112,769 couple-years of protection through voluntary FP services. Additionally, to promote healthy behaviors and fistula care, FC+ conducted in-person and mass media education efforts, which have reached more than 1.7 million people.

### FC+ SURGICAL SAFETY TOOLKIT (SST)

While there are existing programs to expand access to surgical repair in many countries with fistula burdens, assuring and improving the quality of these services remains an important need. High-quality data about fistula services are also needed to better manage coverage of surgical care and improve clinical decision-making. In 2016, in response to identified gaps in clinical records, challenges in understanding clinical data trends, and clinical staff requests at project-supported facilities, FC+ developed and introduced the Surgical Safety Toolkit (SST).

The SST is a set of clinical trackers and quality assurance checklists designed to support the provision of surgical care for fistula and pelvic organ prolapse (POP) at a minimum acceptable standard in low-resource settings, as outlined by global actors such as the World Health Organization (WHO) and the Lancet Commission on Global Surgery. The SST also supports routine monitoring of surgical service delivery processes and fistula and POP care quality.

The SST includes a client tracker of clinical outcomes for surgical and nonsurgical care for fistula, POP, and incontinence; a surgical skills tracker to document the value (return on investment) of clinician training for fistula, prolapse, and incontinence; and a sentinel event tracker to identify trends of near-miss morbidity events that will augment the existing system of mortality review and inform future quality improvement support to facilities. The SST also guides and supports staff teamwork behaviors with seven surgical safety checklists covering topics ranging from candidacy for surgery to daily postoperative care to discharge follow-up planning. FC+ designed the checklists, which are integrated within the client tracker, to respond to requests from project-supported sites that identified and shared gaps from within facility care systems. These checklists are universal, so they can be used for any type of surgery offered by health facilities.



SST components are further described in Table 1. The full SST is available online.<sup>1</sup> FC+ also partnered with Medical Aid Films to create a video to introduce the SST to providers.<sup>2</sup>

### SST IMPLEMENTATION IN BANGLADESH

Seven project-supported fistula repair sites (including governmental and private hospitals) in Bangladesh implemented the SST as part of routine clinical monitoring at between April 2017 and June 2019. Following a pilot activity in early 2016, FC+ hosted an SST launch workshop in March 2017 in partnership with the International Society of Fistula Surgeons (ISOFS). Implementation teams from participating sites joined the workshop; these included surgeons, anesthesiologists, nurses, clinical secretaries, and program administrators. The orientation workshop emphasized the importance of safe surgery and

clinical quality, and provided an introduction to and training on the various components of the SST, including the video guide created by Medical Aid Films. The training included a practical component during which participants practiced completing the client tracker in a group session, interviewing one another as clients, and reviewing the client record.

Following the launch, FC+ staff conducted follow-up orientation visits to supported sites to ensure they were comfortable with and had the necessary capacity to begin implementing the SST. An FC+ clinical associate who served as the primary mentor regularly visited the facilities to provide on-site implementation support. Facility staff anonymized and entered routine client data documented through the SST into a customized database. FC+ staff reviewed these data during site visits and provided feedback to facility providers and managers during routine meetings in order to optimize use of the data for clinical decision-making.

1 View the full SST at <https://fistulacare.org/resources/fistula-services/>.  
 2 View the video at <https://www.medicalaidfilms.org/film/the-fistula-care-plus-surgical-safety-toolkit/>.

Table 1: SST Components

Component	Purpose
<b>Client Tracker Form and Database</b>	The client tracker is a tool that clinicians can use to collect information on client care related to fistula, POP, incontinence, and other genital tract conditions. The tool is organized into 11 sections: (1) quality assurance required data, (2) obstetrics and gynecology profile, (3) pertinent history, (4) staging and diagnosis, (5) admission, (6) nonsurgical procedures and outcomes, (7) surgical procedures and outcomes, (8) complications and sentinel events, (9) discharge, (10) safety checklists completed, and (11) FP counseling sessions. The form is available in a PDF version, to be printed and completed as a hard copy, as well as in an Excel version, which allows clinicians to record data into a client database.
<b>Surgical Safety Checklists</b>	There are seven safety checklists that providers can reference throughout the stages of care for clients dealing with fistula, POP, incontinence, or other genital tract conditions. The safety checklists include: (1) surgical candidacy, (2) preoperative clearance, (3) WHO surgical safety, (4) operation report, (5) client transport, (6) post-operative daily care, and (7) discharge summary. Each of the checklists, except the WHO surgical safety checklist, has an accompanying adaptable medical record form template that clinicians may find useful in documenting their clients' progress throughout care.
<b>Sentinel Events Tracker</b>	The sentinel events tracker includes instructions on how facilities can report deaths/mortalities and morbidities related to fistula, POP, incontinence, and other genital tract conditions. The tracker also provides a worksheet for calculating the number of morbidities each month, as well as forms for reporting mortalities and morbidities to facility supervisors.
<b>Trainee Skills Tracker</b>	Surgical trainees can use the trainee skills tracker to monitor their progress in sequential training sessions for fistula, POP, incontinence, and other genital tract issues. The tracker contains four skill-based modules: (1) outpatient evaluation and nonsurgical management; (2) fistula repair; (3) POP and incontinence treatment; and (4) crosscutting intraoperative decision-making, surgical finesse, and healthcare team leadership skills. The tracker is available as a PDF, which can be printed and completed for a single training session, and as an excel version, which allows trainees to track their progress across multiple training sessions within each module.
<b>Informed Consent in Fistula Care Booklet</b>	Informed consent is a critical component of quality fistula care. This booklet for service administrators, clinical staff, and supervisors provides guidance on how to counsel clients before fistula surgery and includes a sample consent form. Clients and their families may also find the booklet helpful in making informed decisions.



## PROGRAM LEARNING: FINDINGS FROM SST CLIENT TRACKER DATA

From April 2017 to June 2019, project-supported facilities recorded data from 725<sup>3</sup> clients using the SST client tracker. Table 2 presents a summary of client characteristics recorded in the client tracker database.

The average client age at the time of assessment was 37.6 years. The majority of clients were between the ages of 26 and 45 (56%). The number of times clients had given birth ranged from 0 to 12, with an average of 3; 22% of these were stillbirths (n=474). Clients reported an average of two living children at the time of the assessment. Nearly all (95%, n=692) client records included data on the number of prior surgeries the client had undergone for incontinence; 75% had not undergone previous surgeries for incontinence; 18% had one previous surgery; 5% had two; and 2% had three or more.

Of the 725 recorded cases, 511 (70%) included a fistula diagnosis, 36 (5%) included a POP diagnosis, 214 (30%) included incontinence/urinary and colorectal diagnoses, and 158 (22%) included a genital tract diagnosis. There were 11 cases (2%) diagnosed with both fistula and POP.

A review of aggregated routine client tracker data provided important insights into the profiles of the 511 clients diagnosed

with fistula, including their FP needs and fistula etiologies and outcomes. The etiology of diagnosed fistula cases was nearly evenly divided between iatrogenic and obstetric (due to P/OL) causes—47% and 43%, respectively. An additional 7% of cases reported P/OL, but the assessing surgeon was unable to determine whether the fistula was due to iatrogenic or obstetric causes. The few remaining cases with identified etiology were caused by congenital defect (1%), trauma (1%), and indeterminate causes (<1%).<sup>6</sup>

Nearly half (45%) of cases were assessed by the operating surgeon to be complex and eligible for surgical repair, with an additional 1% of cases graded as complex and ineligible for repair. Nearly a quarter (23%) of cases were identified as moderate in complexity and 28% were identified as simple. Only 1% of cases were recorded as indeterminate in complexity. Complexity was not recorded in the remaining 3% of cases.

Of cases with an identified obstetric etiology, 60% were graded as complex and eligible for surgery, compared with 30% of iatrogenic cases. In contrast, 38% of iatrogenic cases were graded as simple, compared to 19% of obstetric cases. Figure 1 illustrates the graded complexity of diagnosed fistula cases, by etiology.

Of the 511 fistula surgical repairs recorded during this period, most were urinary-only fistula (90%) and most were closed at discharge (89%). Of the urinary-only fistula cases,

<sup>3</sup> The client tracker database contained anonymized records for 744 clients. After review and data cleaning, 19 records were removed from the final analysis due to data entry errors.

<sup>6</sup> Less than 1% of cases did not record etiology data.

**Table 2: Client Characteristics Summary**

	Client Age at Assessment	Total Births	Live Births	Prior Surgeries	Diagnosis <sup>4</sup>
Range	1–75	0–12	0–10	0–5	<b>N=725 cases</b>
Average	37.6	3	2	0	
Distribution	≤15: <1% 16–25: 19% 26–35: 29% 36–45: 27% 46–55: 17% ≥56: 7% N/A:* 1%	0: 2% 1: 19% 2: 25% 3: 20% 4: 16% 5: 7% 6: 5% 7: 2% 8: 2% ≥9: <1% N/A: 2%	0: 15% 1: 17% 2: 28% 3: 18% 4: 11% 5: 5% 6: 2% 7: 1% ≥8: <1% N/A: 2%	0: 75% 1: 18% 2: 5% 3: 2% ≥4: <1% N/A: 5%	Fistula: 70% (n=511) POP: 5% (n=36) Incontinence/urinary and colorectal diagnoses: 30% (n=214) Genital tract diagnoses: 22% (n=158) Both fistula and POP: 2% <sup>5</sup> (n=11)

\* N/A = not available

<sup>4</sup> These percentages sum to more than 100% because a woman could receive multiple diagnoses.

<sup>5</sup> These 2% of cases are also included in the percentages of the individual diagnoses of fistula and POP.

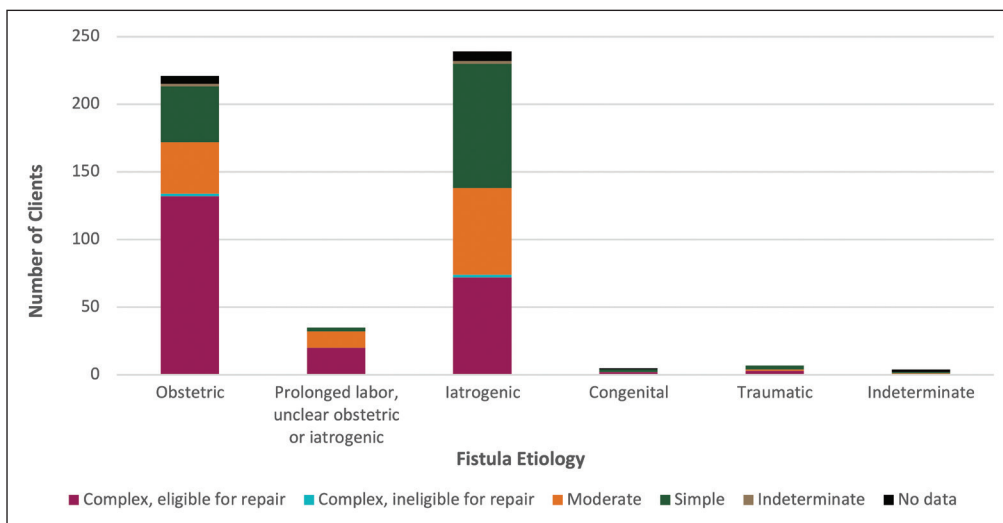


Figure 1: Fistula Etiology and Complexity (n=511 fistula cases)

90% (n=415) were closed at discharge—81% were closed and continent and 9% were closed and incontinent. Of the colorectal-only fistula cases, 84% (n=39) were closed at discharge—80% were closed and continent and 4% were closed and incontinent. Fistula that were both urinary and colorectal comprised 1% of all cases (n=6); 33% of these cases were closed and continent at discharge (17% cases were closed and incontinent) and 50% were not closed. Figure 2 presents surgical outcomes by type of fistula.

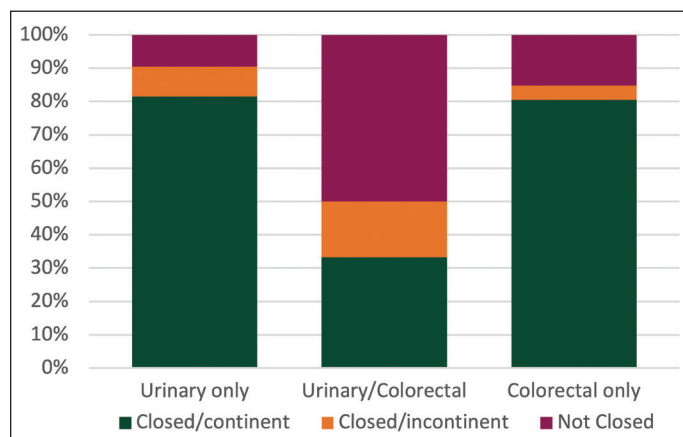


Figure 2: Type of Fistula and Surgical Outcome

Fistula repairs that were graded as moderate or simple by the operating surgeon had more successful outcomes: 95% of moderate cases were closed at discharge (91% closed and continent) and 96% of simple cases were closed at discharge (90% closed and continent), compared with 84% of complex cases (72% closed and continent). Figure 3 presents surgical outcomes by graded complexity of fistula.

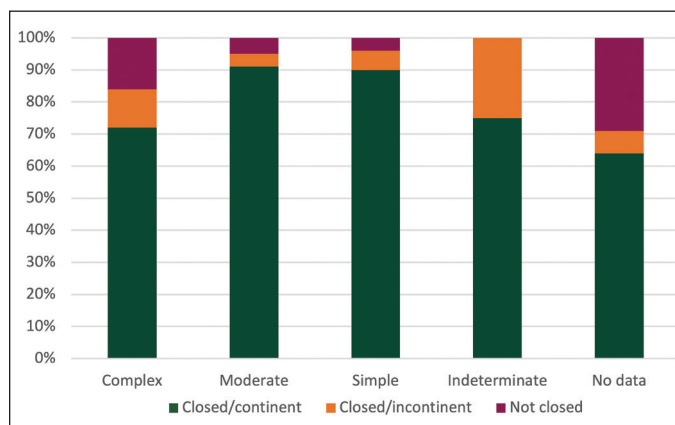


Figure 3: Fistula Complexity and Surgical Outcomes

In Bangladesh, providers assess clients' eligibility for voluntary FP services through several screening factors during the counseling process. Screening factors include the following: a client must have an intact uterus, be under the age of 50, and not be menopausal. Of the 725 clients documented in the client tracker database, 45% (n=328) were not pre- or postmenopausal, had an intact uterus, and were under 50. Of those 328 clients who met the eligibility criteria for FP services, 157 were diagnosed with a fistula. All fistula clients (100%, n=157) received at least one FP counseling session during the four possible counseling opportunities as they progressed from admission to pretreatment to posttreatment to discharge.

At admission, 85% (n=134) of the 157 eligible fistula clients expressed a desire to obtain an FP method. Nearly one-third (30%, n=47) reported currently using a method. Oral

contraceptives (47%, n=22) and injectables (19%, n=9) were most popular, followed by tubal ligation (13%, n=6), implants (9%, n=4), abstinence (9%, n=4), vasectomy (2%, n=1), and withdrawal (2%, n=1). Of these current contraceptive users, 15% (n=7) reported needing method renewal at admission, nearly all of whom were clients using oral contraceptives or injectables. Although 24 clients indicated a desire for tubal ligation to be performed during their surgical procedure, only two (8%) were completed.

At time of discharge, 90% (n=141) of the 157 fistula clients who met the initial FP screening criteria were counseled and deemed eligible for an FP method. It is unclear from the aggregated SST data what criteria deemed the remaining 10% ineligible at discharge; however, it is likely related to the client's current relationship status, a consideration in contraceptive eligibility screening in Bangladesh. Of those deemed eligible for an FP method, 60% (n=84) chose one at discharge—43% chose oral contraceptives, 39% chose abstinence, 8% chose injectables, 5% chose implants, 2% chose male condoms, and 1% each chose tubal ligation and vasectomy. See Figure 4.

### IMPLICATIONS FOR PROGRAM IMPROVEMENT

Since its inception, FC+ has gathered aggregated monitoring data on the volume of supported clinical services as reported by sites through a project-specific DHIS2 database. FC+ introduced the SST as an additional layer of routine monitoring to support quality assurance and more in-depth documentation of service data by clinical teams. FC+ compared information captured in the DHIS2 database and the SST

to assess the feasibility, acceptability, and sustainability of SST adoption. During the time period examined, the DHIS2 database recorded 601 fistula surgeries; in comparison, the SST client tracker database recorded 511 surgeries (85%). This suggests that clinical teams at supported sites were able to complete the additional documentation required by the SST in a majority of cases, although further support may be required to ensure consistent completion of these tools. Additionally, the fistula etiology distribution recorded in the DHIS2 database was very similar to that which was recorded in the SST client tracker database (e.g., 45% obstetric, 41% iatrogenic, and 2% traumatic in the FC+ DHIS2 database, compared to 43% obstetric, 47% iatrogenic, and 1% traumatic in the SST client tracker), indicating reasonable validity of SST data. The SST client tracker enables clinical staff at the facility level to conduct individual reviews of case management processes and outcomes, and this experience suggests that the SST can improve data available for clinical quality monitoring and improvement without introducing an unmanageable layer of additional data entry.

The findings of this preliminary review of aggregated SST client tracker data also suggest opportunities for program improvement. Only 8% of clients requesting tubal ligation received it during the same episode of care during which they received fistula repair. This may reflect a lack of site readiness or capacity to provide sterilization services, but the gap between client desire and method received suggests significant opportunities for expanding the availability of voluntary contraceptive services for fistula clients. Additionally, the greater choice of abstinence at discharge (39% compared

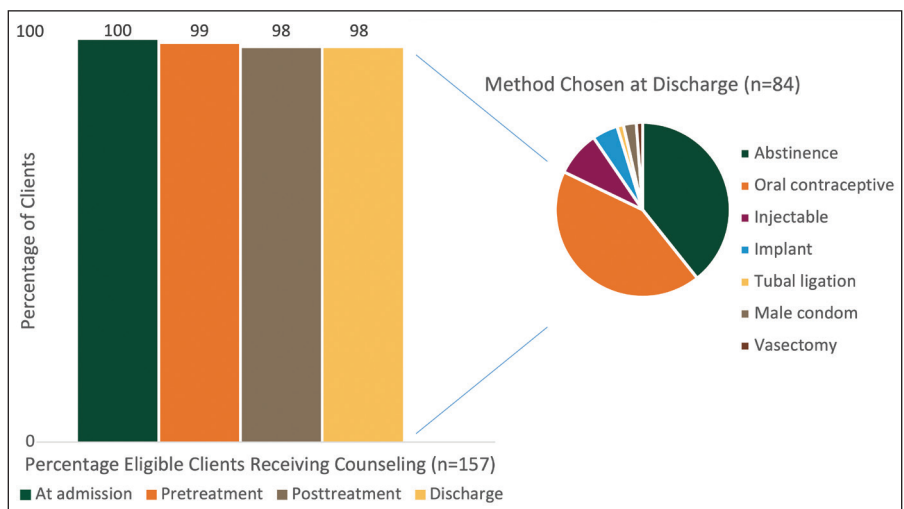


Figure 4: FP Counseling and Method Choice at Discharge

to 9%, respectively) may reflect counseling on abstaining from sexual activity during the post-operative healing period rather than adoption of abstinence for FP. This requires further exploration at supported sites; it may be useful to refine counseling messages to ensure additional follow-up or referral for FP services.

## CONCLUSION

FC+ partners in Bangladesh successfully implemented the SST toolkit as part of routine clinical monitoring and utilized the data on an ongoing basis to review clinical outcomes and client profiles. The SST is derived from global standards for safe surgical care with a focus on fistula-specific metrics. This toolkit can be used for routine documentation of surgical care processes for fistula and POP cases, as well as adapted for monitoring other types of surgical care. Available in both French and English, the SST can help surgeons and healthcare providers improve safety and quality of care around fistula surgery to ensure the best possible health outcomes for women.

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For more information about fistula and the *Fistula Care Plus* project, visit [www.fistulacare.org](http://www.fistulacare.org).

505 Ninth Street NW, Suite 601, Washington, DC 20004 · +1 (202) 902 2000 · [engenderhealth.org](http://engenderhealth.org)

