



Iatrogenic Fistula: An Urgent Quality of Care Challenge

WHAT IS FISTULA?

A genital fistula is an abnormal opening in the upper or lower female genital tract that causes uncontrollable, constant leakage of urine and/or feces. Obstetric fistula is usually caused by several days of obstructed labor without timely medical intervention. Iatrogenic fistula is caused by surgical error, most often during cesarean section. Traumatic fistula is caused by injury—for instance, through sexual violence, female genital mutilation, or accidents.

Background

Access to skilled care at birth has expanded dramatically in the past decade, and 73% of births worldwide are now attended by trained health personnel (WHO, 2016a). However, most countries failed to meet the Millennium Development Goal for maternal mortality reduction by 2015, and there are still nearly 300,000 maternal deaths annually (UN, 2015; WHO, 2015). Quality of care may need to improve to achieve the reductions in maternal and newborn mortality targeted by the current Sustainable Development Goals (UN, 2016).

Evidence is emerging that maternal morbidity is related to quality of care challenges: Iatrogenic causes appear to contribute significantly to the burden of genital fistula in low-income countries. A review of 5,959 fistula cases from 11 Sub-Saharan African and South Asian countries classified 13% as caused by errors during medical procedures (Raassen, Ngongo, & Mahendeka, 2014). Eighty percent of these iatrogenic fistula cases occurred after procedures to address obstetric complications—frequently cesarean section, hysterectomy, and repair of ruptured uterus. These procedures were performed by all cadres of health staff.

Equally troubling, a study at a large fistula repair site in the Democratic Republic of the Congo (DRC) found that 74% of clients began their labor at a health center or hospital. Of these, 82% delivered at a health center or hospital, and only 26% were transferred from home or health center to a hospital. This study's findings suggest that quality of care, particularly the ability to identify and manage prolonged or obstructed labor in a timely manner, is inadequate at many health facilities (Benfield et al., 2015).

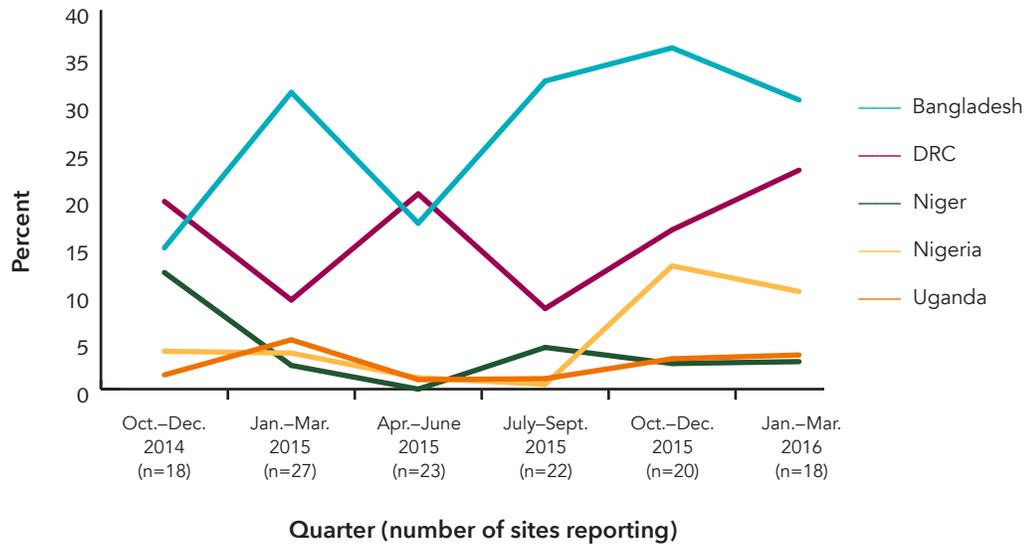
The Fistula Care Plus (FC+) project has sought to raise awareness about this important issue, documenting current trends and perceptions related to iatrogenic fistula and identifying actions that partners can take to address the problem.

Methods

In 2016, FC+ examined the distribution of iatrogenic fistula cases at project-supported fistula treatment sites, triangulating data from three sources: routine program monitoring and evaluation (M&E) data from fistula

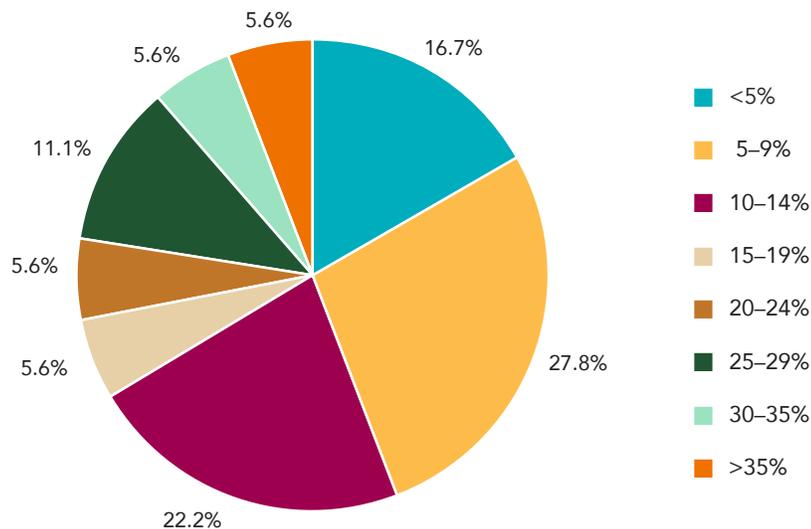
treatment sites in five countries; a survey of clinicians at these sites; and case reviews by FC+ partners and staff at selected sites in Bangladesh, the DRC, and Niger.

Figure 1: Percentage of fistula cases classified as iatrogenic* at FC+-supported treatment sites, by country, October 2014–March 2016



*Among all cases for which a cause could be documented

Figure 2: Percentage of fistula cases classified as iatrogenic at FC+-supported treatment sites, April 2016 (n=18)



Results

FC+ M&E Data

A review of six quarters of project M&E data found that iatrogenic fistula cases were treated at sites in each FC+ country, but that the proportion of cases identified as iatrogenic varied widely between countries and over time. Figure 1 illustrates the percentage of diagnosed fistula cases classified as iatrogenic by surgeons at FC+-supported treatment sites between October 2014 and March 2016. The proportion of fistula cases deemed iatrogenic is highest in Bangladesh, ranging from 15% to 36% in the six consecutive quarters reviewed and representing approximately one-third of cases in four of these quarters.

Clinician Survey

An online survey of fistula treatment sites conducted in April 2016 yielded responses from 18 sites: six in Nigeria, six in Bangladesh, three in Uganda, and three in the DRC. Of these sites, half treated fewer than 100 fistula cases per year, one-quarter treated 100–300, and the rest treated more than 300. Survey respondents were hospital-based clinicians, primarily

ob-gyns and fistula surgeons. Figure 2 illustrates clinicians' own estimates of the proportion of fistula cases they see that are iatrogenic. Approximately one-quarter of respondents reported that 25% or more of their cases were iatrogenic.

Surveyed clinicians also ranked five common ob-gyn procedures in terms of their contribution to iatrogenic fistula; averaging these rankings, cesarean section was perceived to be the most important cause and vaginal gynecological hysterectomy to be the least important (see Figure 3).

Clinicians also reported on how they determine that a fistula case is iatrogenic. Of responding sites, 35% used an algorithm proposed by Raassen et al. (2014) to classify iatrogenic fistula, and 53% used another definition. Respondents from the remaining sites did not know how iatrogenic cases were classified. Examples of reported criteria used to determine that a fistula is iatrogenic included “any ureteric injury,” “vault fistulas,” and “senior surgeon’s assessment.” Notably, 25% of respondents considered fistula directly caused by injuries during female genital mutilation (FGM) to be iatrogenic (see box, page 6).

Figure 3: Clinicians' mean rankings of various procedures' perceived contribution to iatrogenic fistula, April 2016

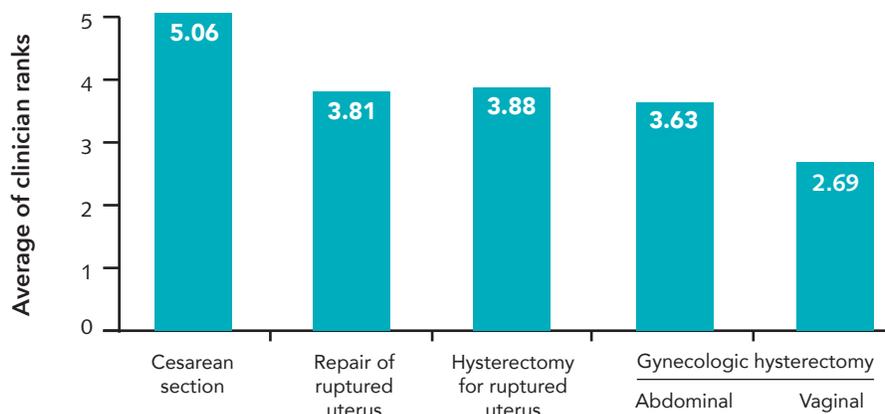


Table 1: Distribution of iatrogenic fistula cases in the DRC and Niger, by type and cause

Type of fistula	%	Primary causative procedure(s)
DRC		
Vesico-uterine	42.5	Cesarean section
Cervical	22	Subtotal hysterectomy
Ureteric	28	Hysterectomy (5%) Cesarean section (23%)
Urethro-vaginal	8.5	Symphysiotomy
Niger		
Vesico-cervico-uterine	58	Cesarean section/hysterectomy
Ureteric	28	Cesarean section/hysterectomy
Trigono-vaginal	7	Cesarean section
Urethro-vaginal	7	Forceps/ <i>yankan gishiri</i> *

* *Yankan gishiri* is a traditional remedy practiced by the Hausa and Fulani tribes in parts of Nigeria and Niger. It is a longitudinal cut made in the vaginal wall to treat numerous obstetric, reproductive, and urological ailments (Yola, 2011).

Case Reviews

FC+ partners and staff conducted reviews of fistula case records at repair sites in three countries in 2015. In Bangladesh, this review covered 248 fistula cases repaired at four hospitals between 2012 and 2014. In the DRC, 566 cases repaired at one Kinshasa hospital between January 2012 and March 2015 were reviewed. In Niger, the review encompassed 724 cases repaired at two national hospitals between January 2009 and September 2015.¹ Reviewers examined patient records to identify the cause of the fistula, as determined by the surgeon, and information about the causative procedure in iatrogenic cases.

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Procedures associated with iatrogenic fistula also varied among countries. Notably, in Bangladesh, 75% of iatrogenic fistula cases resulted from hysterectomy, whereas cesarean section was the more frequent cause in the DRC and Niger (Table 1).

¹ An in-depth analysis of a subset of these iatrogenic fistula cases has been published (Ganda et al., 2016).

A Call for Action

This FC+ review and triangulation of data suggests that medical procedures have become an important cause of fistula, ahead of trauma in most settings and lagging only behind obstetric causes. Country-specific reviews in DRC and Ethiopia have also found a substantial proportion of fistula cases to be related to surgical procedures, particularly cesarean section (Onsrud, Sjoveian, & Mukwege, 2011; Wright, Ayenachew, & Ballard, 2016). Given the preventability of fistula and the severity of its impact on women's health and well-being, these findings should be cause for alarm and action.

It is imperative that the fistula, global surgery, and maternal health communities of practice raise awareness about iatrogenic fistula and develop an advocacy network to promote solutions. Actions recommended to better understand the problem of iatrogenic fistula and address its causes include:

- Developing a consensus on the definition and classification of iatrogenic fistula
- Promoting consistent and complete documentation of fistula etiology across causes (obstetric, iatrogenic, traumatic, infection, cancer, congenital defect, other) at fistula treatment centers
- Implementing routine monitoring of iatrogenic fistula, potentially terming it a reportable sentinel event, and developing standardized data collection tools to document information, such as the causative procedure and provider cadre
- Facilitating high-quality surgical care, particularly safe cesarean section, in low-income countries, including through:
 - The full engagement of ob-gyns in the growing global surgery movement
 - Support for the development of a consensus “minimum acceptable standard of care” to create a

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framework for future national and regional quality assurance guidelines and policies (ACOG, 2010; Debas et al., 2015)

- Standardized training regimens for medical officers, surgical technicians, and other cadres, where task shifting of cesarean section away from ob-gyns is national policy, including: initial training in an optimal ob-gyn facility; follow-up training in an assigned practice site; and follow-up quality assurance, supervision, and retraining mechanisms
- Improvements in surgical and peri-operative team surgical safety training and use of safety tools such as the *Surgical Safety Checklist* (WHO, 2016b) and the *Emergency and Essential Surgery Education and Training Resources* (WHO, 2016c)
- Strengthened quality assurance systems, supervision, and work environment for surgical clinicians
- Strengthened postoperative monitoring and reporting of adverse events related to obstetric and gynecological care
- Improved decision making regarding obstetric and gynecological treatment options, particularly surgical procedures, and indications-based surgical record keeping

Issue in Focus: Varying Classification Criteria

The findings of the FC+ clinician survey indicate a need for a clear definition of the characteristics that indicate a fistula is iatrogenic. Three major issues appear to contribute to the current lack of consistency:

- Different surgeons interpret clinical history and presentation differently, and no consensus classification system exists. While some surgeons have adopted the algorithm proposed by Raassen et al. (2014), there is disagreement within the fistula community about this system's validity.
- Women who experience prolonged or obstructed labor but who eventually reach medical care represent a "gray area" in determining fistula causation. If a woman is in labor for several days at home, ultimately has a cesarean delivery, and then develops a fistula, it is difficult to be certain whether the fistula was caused by tissue damage during labor and/or injuries sustained during the medical procedure.
- There is also disagreement about whether a fistula caused by unintended injuries during FGM is most accurately labeled iatrogenic or traumatic. While such fistula cases, generally involving urethral or perineal/lower rectal injury, are not common, they have been reported by clinicians in multiple settings where FGM is widespread. The FC+ project and the International Federation of Gynecology and Obstetrics (FIGO) fistula surgery training



curriculum affirm that fistula directly resulting from FGM is traumatic (FIGO et al., 2012). However, fistula surgeons from both East and West Africa, who regard the practice of genital cutters to be an acquired skill, consider such fistula to be iatrogenic, as demonstrated by the clinician survey and earlier clinical consultations (Abrams et al., 2012).

Without a consistent approach to classifying fistula etiology, it is impossible to accurately track and compare iatrogenic fistula rates and to benchmark the occurrence of fistula at facilities conducting obstetric and other relevant surgical procedures.

Conclusion

An increase in iatrogenic fistula has important implications for the fistula, safe motherhood, and global surgery communities. Many countries have made dramatic progress toward the eradication of obstetric fistula. However, if iatrogenic fistula continues to occur at current rates, a substantial caseload of fistula cases will remain for years to come, even if fistula from prolonged and obstructed labor is eliminated. As access to emergency obstetric care and essential surgery expands in low- and middle-income countries, it is essential that adequate safety standards be established and maintained. In many low-resource settings, women have heeded the call to deliver at a health facility to prevent fistula and other adverse outcomes. It is imperative that the health system, in turn, deliver quality care to them.

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The *Fistula Care Plus* Project at EngenderHealth works to prevent fistula from occurring, treats and cares for women with fistula, and assists in their rehabilitation and reintegration. *Fistula Care Plus* partners with ministries of health, nongovernmental organizations, United Nations agencies, faith- and community-based organizations, and others, including more than 30 sites providing surgical fistula repair in Sub-Saharan Africa and South Asia. For more information about fistula and the *Fistula Care Plus* project, visit www.fistulacare.org.

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