Short-term catheterization following fistula repair surgery: Improving women’s experience and increasing health system capacity

Vandana Tripathi
Deputy Director, Fistula Care Plus | EngenderHealth
Fistula Care *Plus* at EngenderHealth

- **Goal**: To strengthen health system capacity for fistula prevention, detection, treatment, and reintegration in priority countries in Sub-Saharan Africa and South Asia
- **Duration**: 2013-2018
- **USAID-funded** follow-on to Fistula Care project, which supported 23,860 repairs in 14 countries, trained over 23,000 individuals in support of fistula prevention and treatment
Catheterization following fistula repair surgery

- Duration of bladder drainage via indwelling urinary catheter after fistula repair surgery varies widely.
  - 5 days to >6 weeks
- Assumption behind prolonged catheterization is that the bladder heals better “at rest.”
  - Current practices based on custom rather than evidence
  - Some research suggests that allowing bladder to begin filling and emptying sooner may be beneficial to bladder healing.
What does prolonged catheterization mean for women and health systems?

- Requires longer hospitalization
- Involves greater discomfort for women
- Increases risk of healthcare-associated infection
- Involves more intensive nursing care
- Decreases facility capacity for treating other patients
- Increases cost of services
Research study: 7 vs. 14 day catheterization

| Objective: | Examine whether 7 day bladder catheterization is not inferior to 14 day bladder catheterization among women with simple fistula |
| Design: | Non-inferiority randomized controlled trial (RCT) |
| Intervention: | Duration of bladder catheterization |
| Arms: | Experimental = catheter removal on day 7 post-repair  
Control = catheter removal on day 14 post-repair |
| Endpoint: | Fistula repair breakdown anytime after day 7 after bladder catheter removal up to three months following surgery |
| Investigators: | Mark Barone, EngenderHealth (PI)  
Ahmet Metin Gulmezoglu, World Health Organization  
Steve Arrowsmith, Fistula Consulting LLC  
Joseph Ruminjo, EngenderHealth  
Co-investigators from each country site |
Research study, cont.

| Sample size: | 512 women with simple fistula |
| Sites: | 8 sites in 8 countries in Africa |
| Ethical review: | World Health Organization and locally in each country |
| Time frame: | January 2012 – August 2013 |
Study countries and sites

Niger
Maternité central de Zinder

Guinea
L'Hôpital Préfectoral de Kissidougou

Sierra Leone
Aberdeen Women’s Centre

Nigeria
National Obstetric Fistula Centre Abakaliki

Uganda
Kagando Hospital

Ethiopia
Gondar University Hospital

DR Congo
Hôpital Saint Joseph

Kenya
Kenyatta National Hospital
Study participants and outcomes

Pre-Surgery Screening
N=1007

Post-Surgery Screening
N=948

7-Day Post-Surgery Screening
N=557

Randomized
N=524

7 day catheterization
N=261

Main outcome observed
N=250

14 day catheterization
N=263

Main outcome observed
N=251

59 excluded pre-surgery:
- 1 pregnant
- 3 fistula radiation induced
- 22 did not consent to participate
- 32 could not return for follow-up
- 26 other reasons

391 excluded post-surgery:
- 381 fistula not simple
- 23 dye test positive
- 10 other reasons

34 excluded at randomization:
- 10 did not consent to continue
- 30 dye test positive

23 excluded:
- 22 Lost to follow-up
- 1 mistakenly randomized
Non-inferiority of 7 day catheterization

**Repair breakdown after 7 days after catheter removal through 3 month follow-up**

<table>
<thead>
<tr>
<th>7-day group (N=250)</th>
<th>14-day group (N=251)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 (4.0%)</td>
<td>8 (3.2%)</td>
</tr>
</tbody>
</table>

Event rate difference for percentage of women experiencing repair breakdown:

- 7 day better: -2.8%
- 14 day better: 4.5%

Non-inferiority margin: 10%
### Secondary outcomes

<table>
<thead>
<tr>
<th>Secondary Outcome</th>
<th>Randomization Group</th>
<th>RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7-day (n=261)</td>
<td>14-day (n=262)</td>
</tr>
<tr>
<td>Infection</td>
<td>8 (3.1%)</td>
<td>16 (6.1%)</td>
</tr>
<tr>
<td>Febrile episodes</td>
<td>5 (1.9%)</td>
<td>10 (3.8%)</td>
</tr>
<tr>
<td>Catheter blockage</td>
<td>5 (1.9%)</td>
<td>11 (4.2%)</td>
</tr>
<tr>
<td>Urinary retention during hospitalization</td>
<td>31 (11.9%)</td>
<td>25 (9.5%)</td>
</tr>
<tr>
<td>Residual incontinence - 3 month follow-up</td>
<td>9 (3.6%)</td>
<td>6 (2.4%)</td>
</tr>
</tbody>
</table>
7 day catheterization is safe and effective for managing women following repair of simple fistula without a significant increased risk of repair breakdown or residual incontinence.

Possible impacts of a shift to 7 day catheterization:
- Less discomfort to women
- Reduced hospital stays
- Lower cost per repair
- Increased capacity for treating fistula patients
Moving from research to action

• Results submitted to *The Lancet*
  – **Study authors:** MA Barone, M Widmer, S Arrowsmith, J Ruminjo, A Seuc, E Landry, T Barry, D Danladi, L Djangnikpo, T Gbawuru-Mansarya, I Harou, A Lewis, M Muleta, D Nembunzu, R Olupot, I Sunday-Adeoye, WK Wakasiaka, S Landoulsi, A Delamou, L Were, V Frajzyngier, K Beattie, A Metin Gülmezoglu

• Dissemination of findings through professional associations (ICM, FIGO)
### Collaborators (listed alphabetically)

#### Country co-investigators (current & former)
- Thierno Hamidou Barry
- Dantani Danladi
- Lucien Djangnikpo
- Tagie Gbawuru-Mansaray
- Harou Issoufa
- Weston Khisa
- Alyona Lewis
- Mulu Muleta
- Dolorès Nembunzu
- Robert Olupot
- Ileogben Sunday-Adeoye

#### EngenderHealth
- Steve Arrowsmith
- Mark Barone
- Karen Beattie
- Sarah Burgess
- Alex Delamou
- Vera Frajzyngier
- Evie Landry
- Chloe Manchester
- Joseph Ruminjo
- Lilian Were

#### World Health Organization
- Lucio Fersurella
- A. Metin Gülmezoglu
- Catherine Kiener
- Sihem Landoulsi
- Olivier Sarfati
- Armand Seuc
- Mariana Widmer

#### IntraHealth International
- Kate Stratten
- Aynalem Yigzaw

#### WAHA International
- Sinan Khaddaj
- Marina Ricci

#### Research Assistants
- Kelvin Chukwuemeka
- Bernadette Fofanah
- Aboubacar Tahirou
- Jacques Kolie
- Cele Manianga
- Sylvia Nyakato
- Millicent Oundo
- Fiseha Terefe Yinesu