

A photograph of a person's legs in a wheelchair on a wet, reflective floor. The person is wearing a dark blue skirt and red sandals. The floor is highly reflective, showing distorted reflections of the person and the wheelchair. The overall tone is somber and clinical.

OPERATION **FISTULA**

PILOT PROGRAM REPORT – 2012 - 2015



ON AVERAGE, PATIENTS SPENT

6.4 YEARS

WITH A DEBILITATING
INJURY THAT TOOK

80 MINUTES

TO FIX



OPERATION FISTULA

In 2012, Operation Fistula launched a pilot program to provide performance-based funding to African surgeons treating women with obstetric fistula (a condition defined at the end of this report).

A landmark survey had revealed that more than 55% of treatment organizations were treating fewer than 50 women per year. These low volume providers are critical to reaching a population of fistula patients that is widely dispersed. However, the small scale of these organizations meant that they were beyond the reach of existing funding organizations.

To bridge this gap, we developed an innovative financing structure that granted funds directly to surgeons who successfully treated patients. We replaced unwieldy administrative reporting requirements with a streamlined, workable system. Our one page patient record had 71 data fields which gave us unprecedented visibility into treatment. We distributed funds as soon as surgeons provided these concise, but complete, patient treatment records.

This simple solution had astounding results.

From October 2012 to October 2014, Operation Fistula funded treatment of 752 patients in four countries. We treated four times more than our original patient target. In meeting the demand for funding, our innovative methods enabled us to deliver exceptional value for money in terms of efficiency (\$190-\$288 per surgery) and cost-effectiveness (\$17.93-\$27.22 per DALY, or disability-adjusted life year, averted). We realized that our interventions are alongside vaccinations as amongst the most cost-effective global health interventions possible.

The data has completely transformed how we think about fistula. We believe that what we achieved and what it taught us have potentially game-changing implications for the field of fistula repair specifically and global surgery more broadly. This report shares these findings.

WHAT IS OPFISTULA

Operation Fistula is revolutionizing fistula care for women everywhere to ensure the money spent on fistula delivers the most effective results. We believe doing so will also reveal ways to radically increase quality surgical capacity in developing countries.

OUR CORE VALUES:

Everything starts and ends with the patients.
Each and every action must serve them.

We focus on doing the work, not selling it.
Smart money will find the most impactful projects.

We welcome scrutiny.
Constant criticism drives continuous improvement.



WHAT WE ACHIEVED

OUR MISSION IN THIS PROJECT WAS TO
BUILD SURGICAL CAPACITY BY PROVIDING
FUNDING TO SURGEONS BEYOND THE REACH
OF OTHER FUNDING ORGANIZATIONS.

THIS MEANT DEVELOPING A MECHANISM
TO REMOTELY EVALUATE SAFETY AND QUALITY
IN PLACES WE HAD NEVER VISITED WITH
PEOPLE WE HAD NEVER MET.

This pioneering scope required an adaptive style of project management that compelled us to experiment to find best practices and then to tirelessly test and improve them. We borrowed the concept of rapid prototyping to develop management protocols, tested them in the field, and adapted them for continuous improvement. This methodology is embedded in every dimension of this project and our organization and it is still very much ongoing.

Having rapid prototyping and continuous improvement become part of our organizational DNA is perhaps the most powerful achievement in this project.

Our impact objectives are outlined below. When we set these objectives, we really had little idea of the challenges and opportunities that implementation of such a pioneering project would entail. We set ambitious targets that would push us to deliver at a meaningful scale given our limited resources.

21

SURGEONS FUNDED

GOAL 1: ACTIVATE 5 PARTNERSHIPS IN 3 COUNTRIES

WE ACTIVATED 21 PARTNERSHIPS IN 4 COUNTRIES

9 of these surgeons received direct funding while the other 12 were funded through partnerships with grassroots organizations and UNFPA Madagascar. Our pioneering partnership with UNFPA Madagascar represented the first time the UNFPA has accepted conditional funding for fistula.

39%

**SURGICAL THROUGHPUT
IMPROVEMENT OVER
A 12 MONTH PERIOD**

GOAL 2: IMPROVE SURGICAL THROUGHPUT BY 30% IN A YEAR

WE IMPROVED THROUGHPUT BY 39%

In Malawi we improved local surgical capacity by 198% in the first year (from 49 to 146). In Madagascar, we encouraged local surgeons to treat fewer patients and focus on quality improvements. Throughput decreased by 9% over the group of Malagasy surgeons (from 152 to 138). In Mauritania, we had a slight increase in volume over a small number of patients.

752

PATIENT TREATMENTS FUNDED

GOAL 3: SUPPORT TREATMENT FOR 200 WOMEN WITH FISTULA

WE FUNDED TREATMENT FOR 752 WOMEN

This number so significantly exceeded our target because need demanded it. We reallocated budget to treat more patients and even mobilized additional resources to extend the pilot. At the time of writing this report, we continue to receive funding requests.

Our continuous improvement approach also delivered several unplanned achievements.

WE BUILT QUALITY CAPACITY BY FOCUSING THE RIGHT SURGEON ON THE RIGHT CASE

Most fistula patients have no hope of receiving effective treatment because most local fistula surgeons lack sufficient experience with cases that they ought to be able to manage. Experts come to the country and treat any case that arrives at the hospital. This means experts end up treating simple cases that local surgeons could effectively manage whilst also building their skills. This unmanaged treatment approach limits both quality and capacity.

Based on this logic, we encouraged our partners to apply their skills to the right cases. Local surgeons treated simple and intermediate cases and experts handled the difficult and complex cases. While we have no baseline data to quantify the relative impact, we believe this approach gives each woman the best chance of recovery while also developing the long-term quality of local treatment capacity. In our pilot, local surgeons had higher closure and continence rates than expert surgeons, which we read as an indication of skill-appropriate case selection.

HOW WE DEFINE SUCCESS

There are three outcomes in fistula surgery: 1) dry, where the woman's repair is successful, 2) closed, where the fistula is closed, but the woman has some residual incontinence, and 3) failed surgery. We report both "Dry" and "Closed" rates.

"Dry" occurs when the doctor reports that the patient is dry and/or the patient passes a dye test (where the bladder is filled with blue dye to identify any remaining fistula). "Closed" is when the patient passes a dye test, but the doctor reports that she is not dry. This means the fistula is repaired, but the patient still has some level of incontinence.

We also added survey questions for patients before and after treatment to gauge their view of the surgery's success. The next iteration of our form will include even more nuanced objective measures of success.

\$288
COST PER TREATED PATIENT



OUR EFFICIENCY FOCUS DELIVERED AN EXCEPTIONAL VALUE FOR MONEY

This is primarily due to the targeted and performance-driven funding we offered. By providing action-oriented incentives directly to the right people, we did not waste any resources on unnecessary overhead or underperformance. Increased volume of patients treated also absorbed greater project and organizational overhead.

Our total cost per treated patient, including all organizational overheads, came to \$288. Our pilot program had significant volunteer input and only variable labor, so we spent very little on administration and virtually nothing on fundraising. However, removing all organization costs and comparing grant cost per treated patient, Operation Fistula came in at \$190 per patient treated.



VALUE FOR MONEY

For us, value for money means maximizing the impact of all funds spent on fistula treatment. In our project, we gave \$142,592 in grants and spent an additional \$73,909, bringing our total costs to \$216,501. We use two indicators to evaluate our project's value for money: efficiency and cost-effectiveness.

Efficiency refers to cost per unit of output. Our output is the 752 patients treated. To calculate efficiency, we divide our grant and total costs by the 752 patients. Cost-effectiveness refers to the cost per unit of impact created. Our surgeries averted years of disability that the patient would have lived with had they not had the surgery. The number of years averted by our 752 surgeries totals 7,956. To calculate cost-effectiveness, we divide grant and total costs by the 7,956 DALYs averted.

GRANT COST

\$142,592

TOTAL COST

\$216,501

EFFICIENCY

\$190 - \$288

PER PATIENT

Output

752
patients

COST-EFFECTIVENESS

\$18 - \$27

PER DALY AVERTED

Impact

7,956
DALYs



OUR COST-EFFECTIVENESS SETS US ALONGSIDE HEALTH INTERVENTIONS WITH THE HIGHEST POSSIBLE SOCIAL RETURNS

Using the DALY (disability-adjusted life year), we can determine our impact and cost-effectiveness in even broader terms. DALY is a standard health metric that allows comparisons of the burden of disease across conditions. We calculated a “no frills” DALY and assessed DALY averted for our patients.

On average, each patient lost 2.2 years of healthy life due to the disability of fistula. The disability weights used to calculate DALY give some insight into how hard it is to live with fistula. Rectovaginal Fistula (disability weight of 0.492) is just less than terminal cancer (0.508) and amputation of both legs without treatment (0.494).

Vesicovaginal Fistula (VVF) ranks 49th (0.338). Left untreated, the years of life lost due to both disabilities would continue to rise. The surgeries we funded averted an astounding 7,956 DALYs (or 10.6 years per patient). In other words, every woman we treated gained back, on average, 10.6 years of healthy life that would otherwise have been lost to living with fistula.

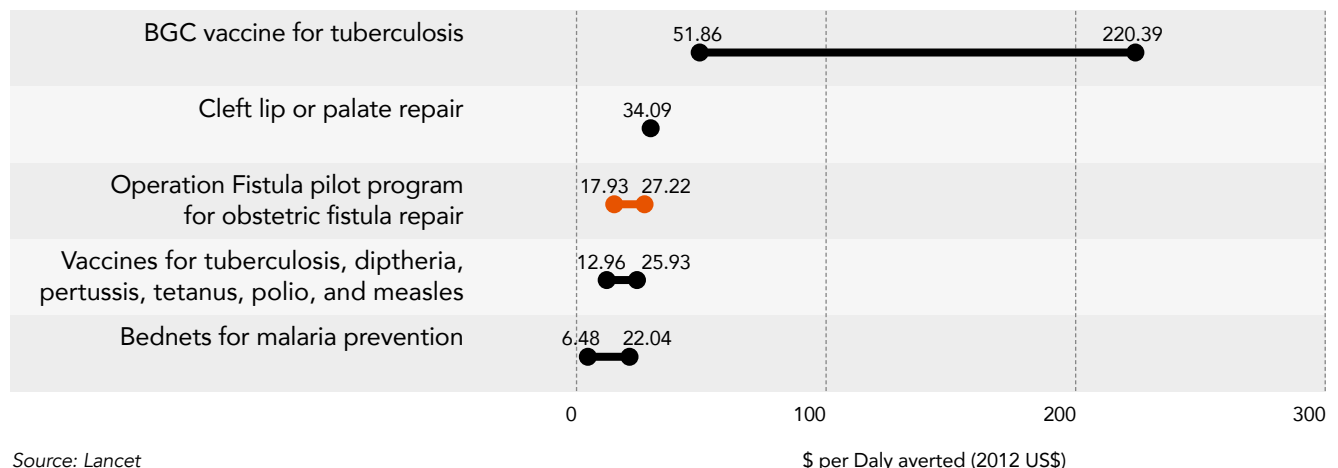
DALY can also help us understand our cost-effectiveness compared to other health interventions. The 7,956 DALYs averted cost between \$17.93 and \$27.22 (grant cost and total cost per DALY averted, respectively). This puts our fistula effort in the same cost-effectiveness range as vaccines.

WHAT IS A DALY?

The disability-adjusted life year (DALY) is a measure of disease burden. Put simply DALY is the number of years lost due to ill-health, disability or early death. In the field of public health, DALY is used to understand which health conditions are most affecting society. DALY can also be used in health impact assessment to evaluate how the use of resources has impacted people.

DALY essentially combines the burden of living with disability and the early death it might cause. Because fistula does not directly shorten lives, we are most interested in the burden of living with disability, which is calculated by multiplying a disability weight by the number of years someone has the disability. For example, a woman who had rectovaginal fistula for 10 years, would have lost 4.92 years of healthy life due to the disability.

\$ PER DALY AVERTED





**7,956
DALYS**

AVERTED BY THE SURGERIES FUNDED
(OR 10.6 YEARS PER PATIENT)



WHAT WE LEARNED

WHILE WE EXCEEDED ALL OF OUR GOALS AND
ACHIEVED EXCEPTIONAL OUTCOMES, OUR
PILOT PROGRAM ALSO REVEALED SEVERAL
IMPORTANT PROGRAMMATIC INSIGHTS
THAT WILL GREATLY IMPROVE OUR FUTURE
PROJECTIONS AND STRATEGY.

ABOUT THE PATIENTS:

68%

OF WOMEN HAD
THEIR FIRST PREGNANCY
AS TEENAGERS AND

62%

OF THESE GIRLS WITHIN 3
YEARS OF THEIR FIRST PERIOD

C-SECTION CAUSED
FISTULA FOR

31%

OF WOMEN WHO HAD THEM

The average patient was 30.4 years old when she arrived at treatment and had lived with fistula for 6.4 years before treatment. Small in stature at 149 cm (4'10") tall and weighing 46 kg (101 lbs), many women (24%) had body mass index measures that indicated severe malnutrition.

Our 752 patients reported 2,466 pregnancies (3.3 on average), with only 1,125 children still living (46%). 38% of pregnancies ended in stillbirth and 8% in early neonatal

death. While causative delivery occurred at age 24 on average, the majority of women became wives and mothers much earlier.

The average age at marriage was 17.9 years and 59% who reported husband ages indicated that their husbands were 5 or more years older. 68% of women had their first pregnancy as teenage girls and 62% of these girls had first pregnancies within 3 years of their first menstruation.



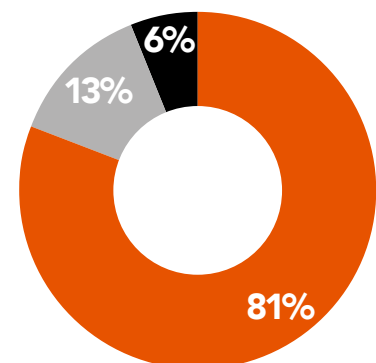
ABOUT DELIVERIES THAT CAUSED FISTULA:

The average woman had a labor that lasted 3 days. While it is often assumed that women get fistula because they cannot reach healthcare, only 23% of our patients had causative delivery at home. 14% reached a health center and an astounding 63% had the causative delivery at the hospital. This indicates that timing or quality of care at the facility may be an issue. In fact, surgery at the hospital caused 13% of the fistula cases our program treated.

Of the 402 women who delivered the causative birth in hospital, 192 of them (48%) had either an instrumental or caesarean delivery (c-section) or a hysterectomy. C-section caused

fistula for 28% - nearly 1 in 3 - of the 133 women who received this operative intervention at the hospital. Additionally, 64% or 9 of the 14 c-sections done at health centers resulted in fistula. Hysterectomy showed equally bad quality indicators as 38% of the 14 women who received hysterectomy got the fistula from the procedure. Lack of surgical quality is a major driver of fistula.

The vast majority (81%) of causative deliveries resulted in stillbirth. Only 13% of babies born in the causative delivery survived infancy. Of the 36 early neonatal deaths, 50% were born and died at the hospital.



● Stillbirth
● Live birth
● Early neonatal death

ABOUT THE SURGERIES:

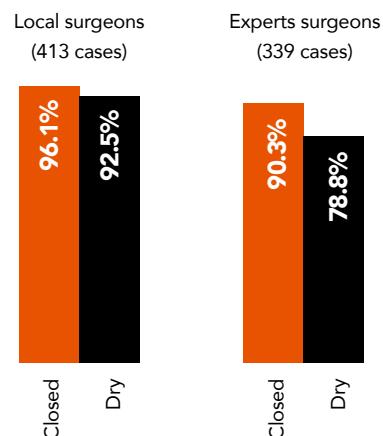
The vast majority (92%) of surgeries treated were vesicovaginal fistula, though we also had rectovaginal fistula and combination cases. The average corrective surgery took 80 minutes. Women spent an average 20 days in the hospital, with 14 of those days under catheterization. 15.8% of women reported having previous surgeries. Surgeons reported 4.4% complications and that 7.4% would require some future treatment.

Closed and Dry rates for the group were 93.5% and 86.3% respectively. As expected, local surgeons treating simpler cases outperformed experts treating complicated cases on both measures. Closed rates were 96.1% and 90.3% for Local and Expert

surgeons, respectively. Dry rates showed an even greater variance at 92.5% and 78.8%. As mentioned above, the variance is driven primarily by optimal case allocation where local surgeons managed simple and intermediate cases, while experts handled difficult and complicated cases.

94% of patients rated their overall satisfaction with the procedure at 8 or higher on a scale of 10. Patients that reported leaking “a large amount” of urine “all the time” did not rate their procedures as high as the group. Only 60% reported satisfaction at 8 or higher on a scale of 10. However, 88% reported satisfaction rates at 7 or above.

EXPERT VERSUS LOCAL SURGEONS

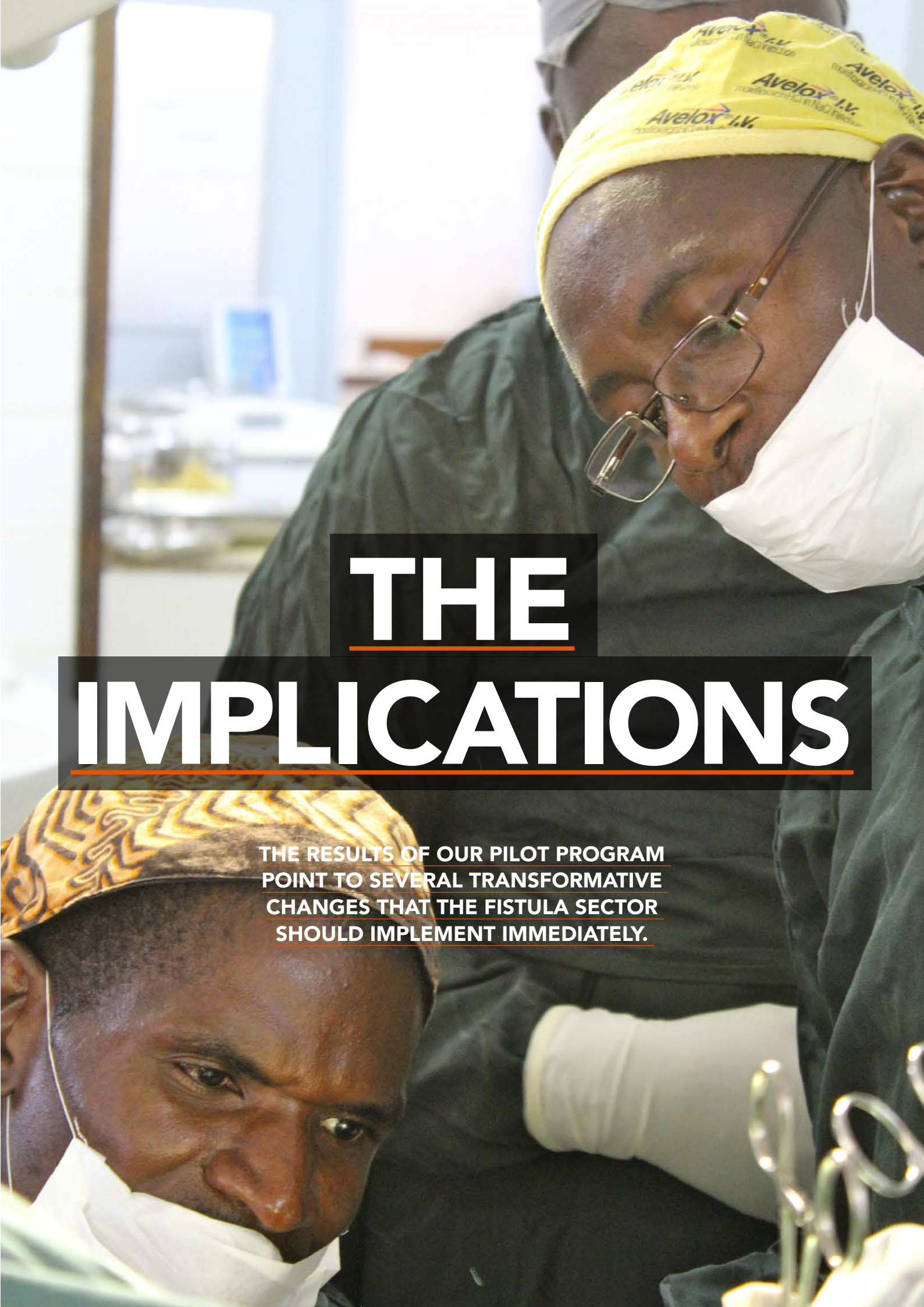


DATA COLLECTION

We believe in evidence-based management, so data collection is fundamental to us. We want enough data to objectively ensure safety and quality, while also understanding the patient and environment. But asking too many questions creates a burden for surgeons who should spend their time operating rather than completing paperwork. We try to get the richest view of what is happening by asking as few questions as possible. This is an art that we continue to develop.

We committed to having only one page (front and back) to collect data and we started by requesting 41 points of data. We went through four iterations of our form to strengthen and consolidate questions and add new data requests (like patient baseline and post surgical satisfaction). We currently collect 71 points of data and two photos of every patient.

Based on information from this report, we are working on the next iteration of our patient record form and expect significantly more insight from our form and process revisions.



THE IMPLICATIONS

THE RESULTS OF OUR PILOT PROGRAM
POINT TO SEVERAL TRANSFORMATIVE
CHANGES THAT THE FISTULA SECTOR
SHOULD IMPLEMENT IMMEDIATELY.

ALL FUNDING SHOULD BE DATA DRIVEN

We developed this model specifically to reach the majority of surgeons who were outside the reach of funders. In doing so, we endeavored to better understand outcomes and improve objectivity in measuring results by creating a patient level data system. The data collected from our patients drives our program, ensures traceability and visibility, and forces us to continually improve our service in response to patient outcomes and feedback.

The acceptable approach must be funding with full transparency and accountability. This approach drives quality improvements and capacity growth. By adopting our approach, funding organizations could not only treat more patients at a higher level of quality, but they could also increase the knowledge base of which best practices deliver the best results for patients.

**EVERY FISTULA
TREATMENT EFFORT
SHOULD COLLECT
DATA TO ENSURE
QUALITY OF CARE
AND INCREASE THE
KNOWLEDGE BASE
OF WHICH PRACTICES
DELIVER THE BEST
RESULTS FOR PATIENTS**

ENDING FISTULA REQUIRES BUILDING/IMPROVING SURGICAL CAPACITY

We have always known that c-section was a surgical measure that would prevent obstetric fistula. However, until our pilot program, we had no idea that the low-quality delivery of this and other surgical interventions could be such an enormous contributing cause of fistula. Based on our findings, we now believe that every fistula treatment effort should include efforts to build/improve surgical capacity for c-section and hysterectomy.

Our internal data makes a compelling case, but recent research also supports the necessity of building surgical capacity. The Lancet Commission on Global Surgery released a report in April 2015 that claimed only 6% of the 313M surgical procedures done

each year occur in the poorest countries, where over 1/3 of the world population resides. The report recommends that all district-level hospitals should aim to provide c-section along with two other acute, high-value and general procedures (laparotomy and treatment of open fracture). A separate report from the Royal College of Obstetricians and Gynecologists shows that 37% of the burden of maternal and neonatal conditions can be averted by universal access to quality obstetric surgery at first level hospitals.

WE BUILT GOFER

A TOOL THAT WILL TRANSFORM THE WAY WE
COLLECT AND UNDERSTAND PATIENT DATA



SURGEONS CAN



COLLECT DATA ANYWHERE

Our data collection system works anywhere – online and off. GOFER's underlying technology was piloted, tested and refined in conflict zones.



ANALYZE WORK WITH EASE

Entered data is automatically analyzed using statistical best practices. GOFER provides data visualization dashboards that give you an unprecedented view into your work.



USE ANY DEVICE

The GOFER app will work on any Android or iOS device. GOFER also works through a web portal that you can access on any computer, anywhere.



KEEP DATA SECURE

Automatic end-to-end encryption. GOFER data security protocol meets and/or exceeds US FDA, HIPAA, and EU data security compliance.

FUNDING ORGANIZATIONS CAN



MANAGE GRANTS

Collect information from grantees with ease. Manage grants remotely with partners working in the most remote places on earth.



MONITOR PROGRAMS

Visibility provides unique insight into how your programs are evolving. It also lets you put additional funding where it can have the greatest impact.



ENSURE QUALITY OF CARE

Digital measurement allows a revolutionary view into quality of care. Ensure your funds are helping improve quality, expand capacity and deliver better results for more women.

DONORS CAN



SEE THE IMPACT OF THEIR FUNDING

Never before could a donor know exactly what effect their funding has had. GOFER allows donors to see the specific and systemic effect of their support.



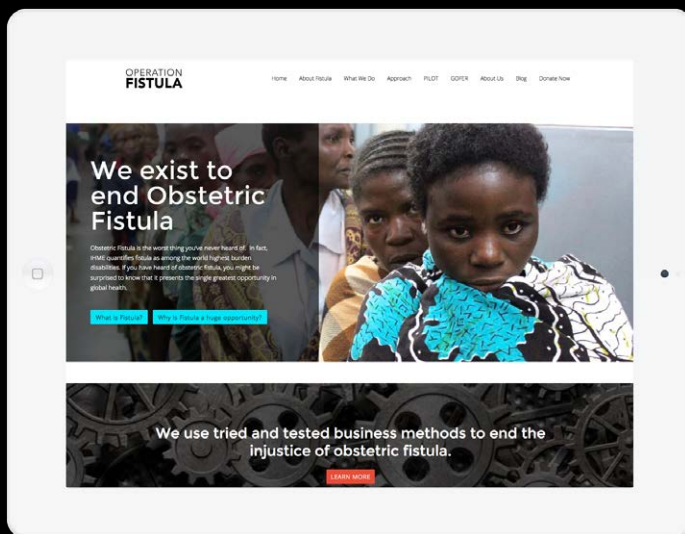
INCREASE CONFIDENCE AND INVEST MORE

Full transparency leads to higher accountability. Increased visibility and confidence will lead to higher investment.

LEARN MORE AT WWW.OPFISTULA.ORG/GOFER

WE USE TRIED AND TESTED BUSINESS METHODS TO END THE INJUSTICE OF FISTULA.

By mixing leading minds from a breadth of backgrounds, our movement offers the greatest chance to transform systems. Operation Fistula is composed of top entrepreneurs and corporate executives, women's health thought leaders, and expert surgeons.



**LEARN MORE AT
WWW.OPFISTULA.ORG**

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