

# **Urogenital Fistula Management**

## ***Healthcare Delivery in LMICs: Morals and Ethics***

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# Incidence of Fistula

Main Aetiology is Obstetric Injury

Maternal Mortality Rates (in a lifetime)  
**For every woman that dies.....**

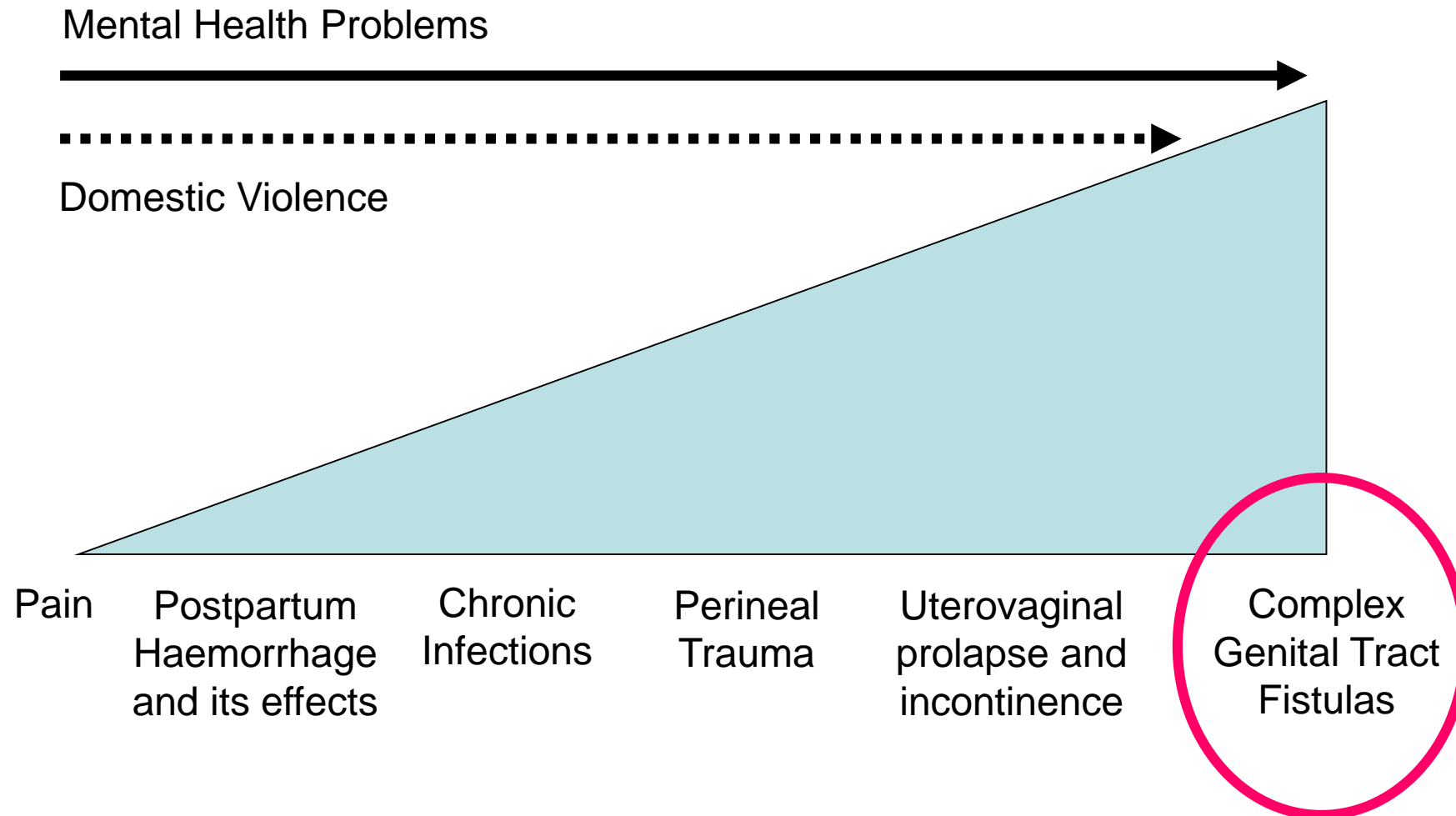
Scandinavia 1:300000

**20 will suffer crippling morbidity**  
Africa 1:12

NB: No. of women who die annually in West Africa equals all those who died in Korean conflict in 1950s



## The Scope of the Problem

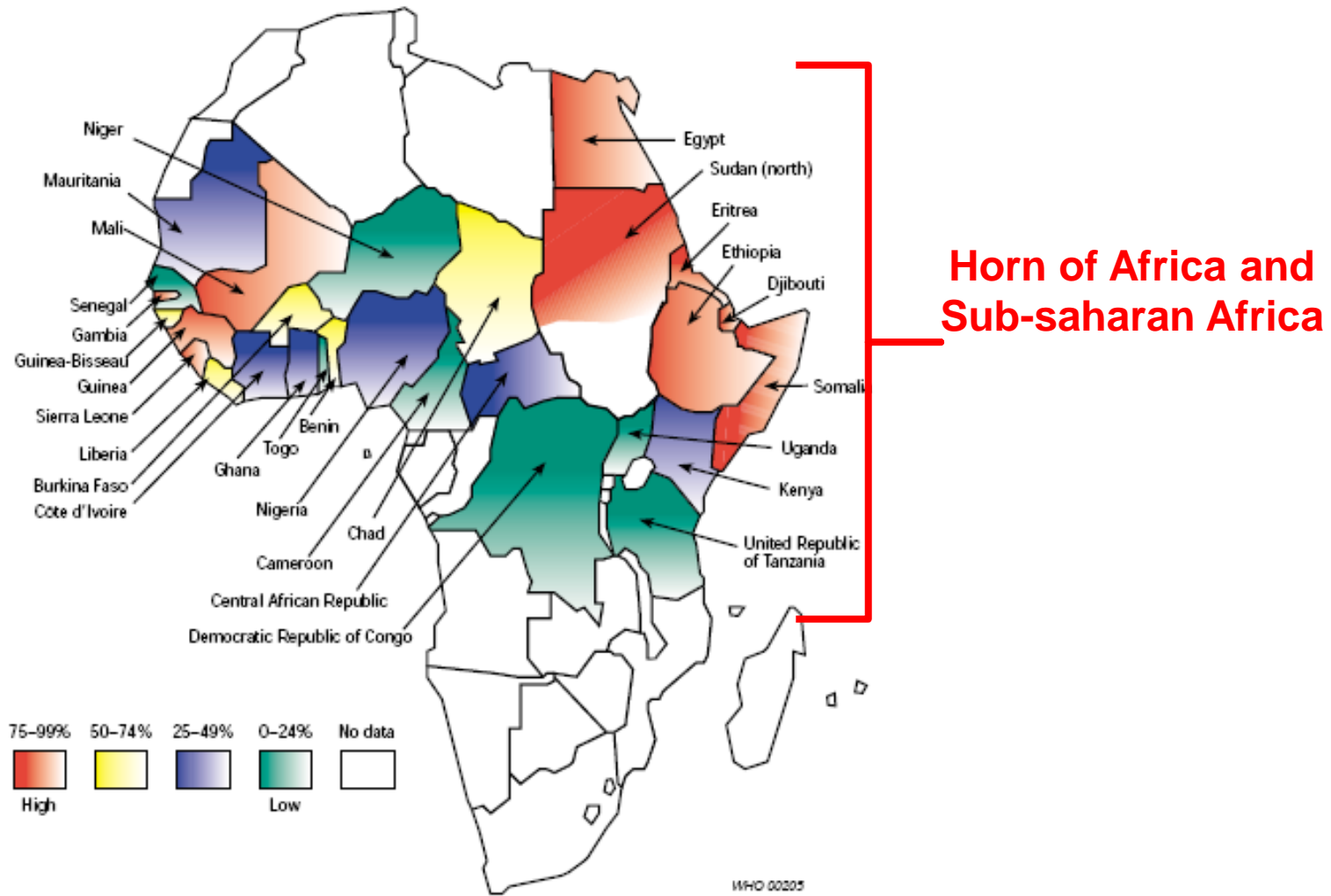


A major health problem in **low and middle income countries** as a consequence of obstructed labour

In developed countries GTF are usually iatrogenic or following radiotherapy or foreign body injury



Fig. 1 Prevalence of female genital mutilation in Africa



# Quality of Life Impact

## **Physical**

- Losing bladder/ bowel control
- Pain
- Dealing with chronic infections

## **Social**

- Embarrassment
- Affects lifestyle and avoidance of activities
- Impact on all relationships
- Increased dependence on caregivers

## **Personal**

- Mental Health secondary to divorce, etc
- Domestic Violence

**What are the issues?**

# Who is doing the work?

- Single clinician
- Working in isolation
- Access to other disciplines limited
- Certain cross-disciplines do not exist
- But gradually,
  - Patient outcomes affected
  - Patients expectations taken into account



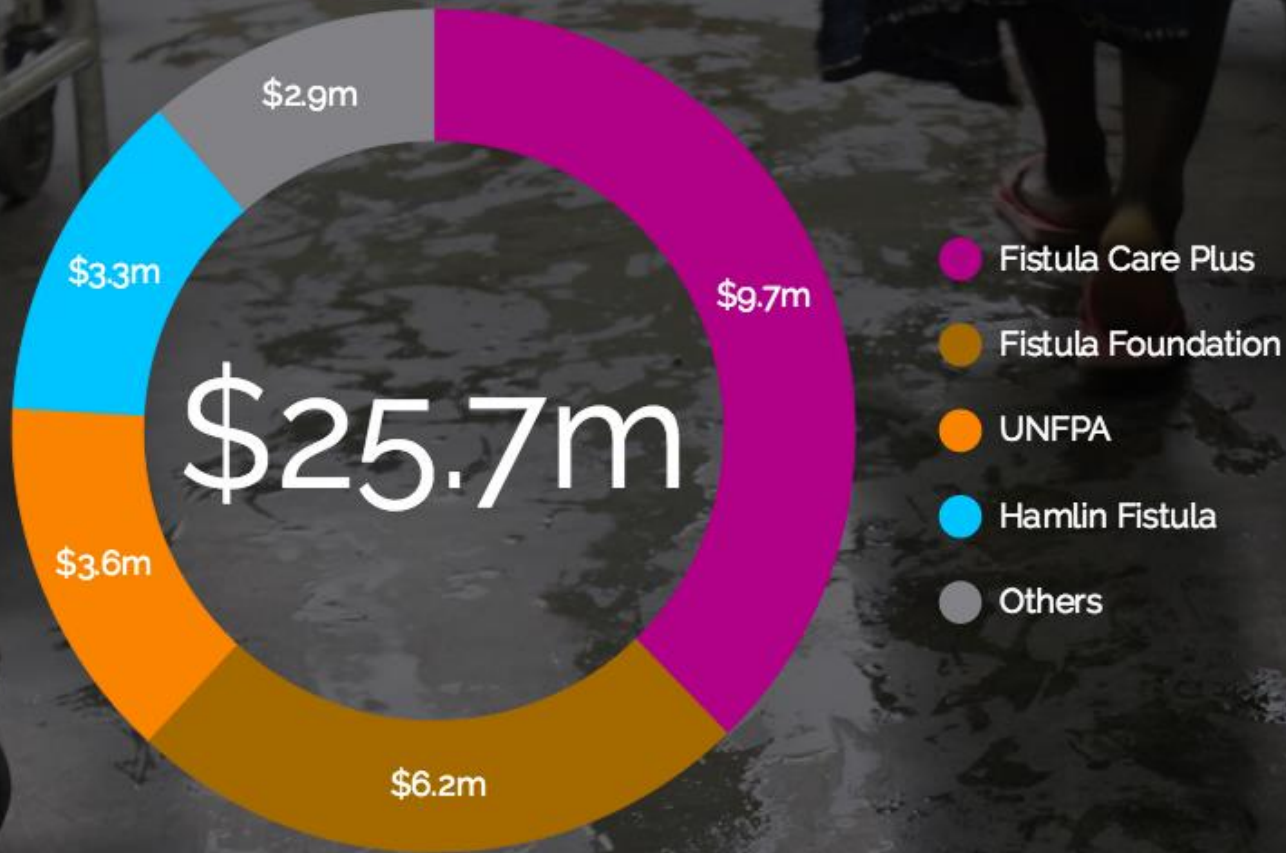
# Who are our patients?

- Demography
- Countries of origin
- Religions
- Culture
- Specific health problems?

# What factors affect our decisions?

- Racial practices
- Religious practices
- Entrenched cultural practices
- Critically, financial needs and control

## Estimated Annual Spending



**Estimated Fistula  
Backlog**

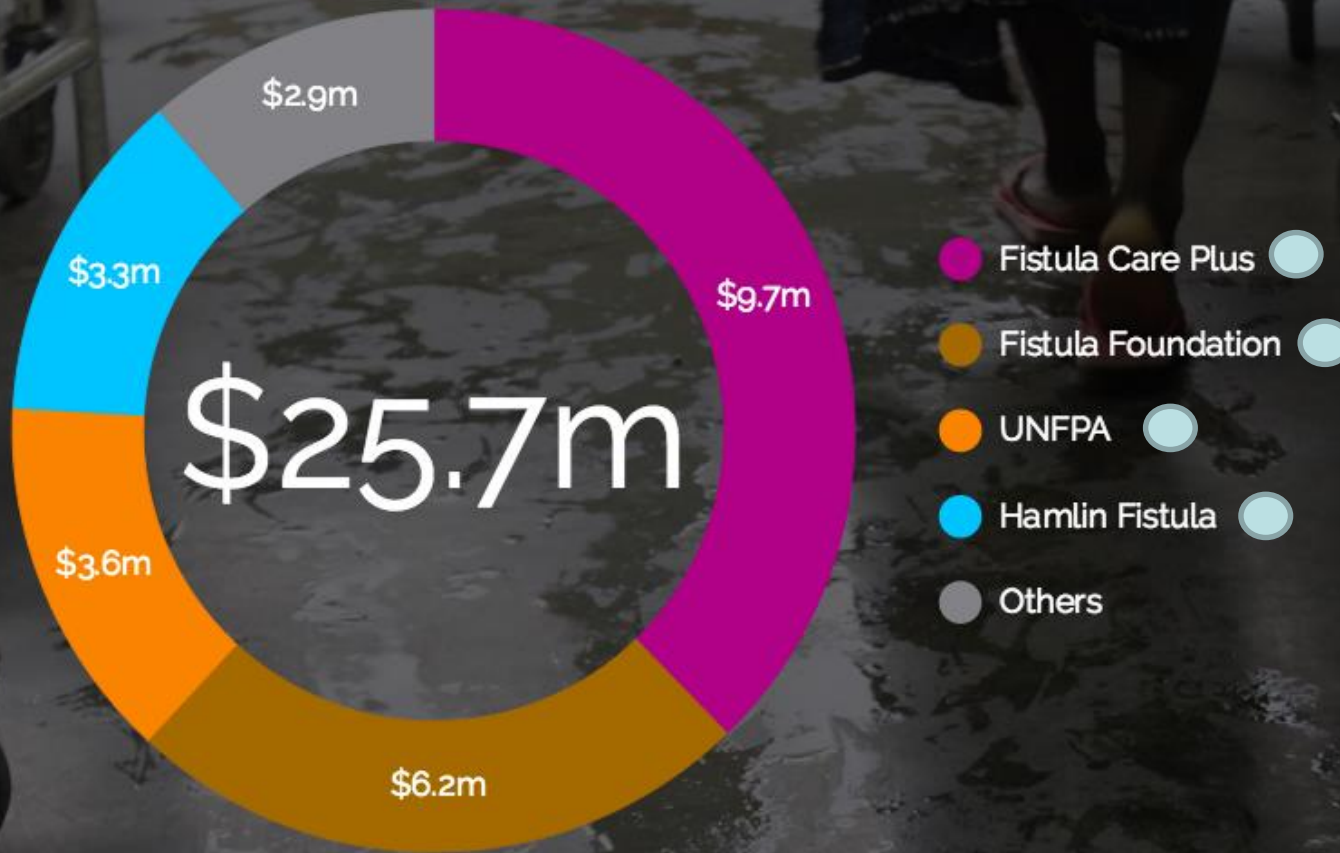
**2 MILLION  
WOMEN**

## Obstetric Fistula

**Estimated cost of  
surgery  
\$300**

**Thus, this will  
ONLY treat 90000  
women**

## Estimated Annual Spending



**G4 Alliance**

**Gates  
Foundation**

**Pharma  
Companies**

# Obstetric Fistula

**Professional  
Societies**

**African/Asian  
Fundors**

**WHO**

# **Where are we in the developing world?**

- Need for investigative resources
- Need for increased trained manpower – medical and paramedical
- Better operating facilities
- Integration of services
- Collaboration of clinicians across the continent, as in GTF
- Regular audit and publications

# What are the pitfalls?

- Poor communication
- Consideration of political position of governments and NGO
- Financial contributions
- Corporate responsibility
- Recognition of individuals and institutions

**How do we prioritise?**

# The Morality of Funding in LMICs

- LMICs funding relationship to morality has to be debated
- It is often stated that funding in LMICs is with a view to ensuring the 'common good'
- However:

The question of the 'common good' is slightly more specific than that of just morality

The idea of a common good is usually associated with Utilitarianism, and as is always attractive with this school of thought, their definition is relatively straightforward.

***They would simply say that: 'the common good provides the greatest amount of good for the greatest amount of people'***



# But, who determines the 'common good'

- The patient
  - Do they have a choice?
- The society
  - Who decides they can access care?
- The government's policy
  - Does it allow access?
  - Is it free?
- The funder
  - Whose interest does it serve?

# E.g. Fistula

- The patient
  - No choice
- The society
  - The elder of the village usually
- The Government
  - Not always free and access depends on service provision
- The Funders
  - Their interest: donors, 'funders agenda', direction of delivery

**Is the answer, Research?**

# Ethics in Health Research in LMICs

- Health research plays a pivotal role in addressing inequities in health and human development
  - But, the research must be based on sound scientific and ethical principles.
- Although it is accepted that ethics play a central role in health research in developing countries
  - Much of the recent debate has focused on controversies surrounding internationally sponsored research
  - Much has taken place without adequate participation of the developing countries.
  - The relationship between ethical guidelines and regulations, and indigenously sponsored and public health research has not been adequately explored
- Fundamental principles of ethical health research, such as community participation, informed consent, and shared benefits and burdens must remain sacrosanct
  - But, other issues, such as standards of care and prior agreements, merit will need greater public debate.
  - In particular, the relationship of existing ethical guidelines to epidemiological and public health research merits further exploration

# Ethical principles and benchmarks for multinational clinical research 1

## Collaborative partnership

- Develop partnerships with researchers, makers of health policies, and the community.
- Involve partners in sharing responsibilities for determining the importance of health problem, assessing the value of research, planning, conducting, and overseeing research, and integrating research into the health-care system.
- Respect the community's values, culture, traditions, and social practices.
- Develop the capacity for researchers, makers of health policies, and the community to become full and equal partners in the research enterprise.
- Ensure that recruited participants and communities receive benefits from the conduct and results of research.
- Share fairly financial and other rewards of the research.

## Social value

- Specify the beneficiaries of the research—who.
- Assess the importance of the health problems being investigated and the prospective value of the research for each of the beneficiaries—what.
- Enhance the value of the research for each of the beneficiaries through dissemination of knowledge, product development, long-term research collaboration, and/or health system improvements.
- Prevent supplanting the extant health system infrastructure and services.

# Ethical principles and benchmarks for multinational clinical research 2

## Scientific validity

- Ensure that the scientific design of the research realizes social value for the primary beneficiaries of the research
- Ensure that the scientific design realizes the scientific objectives while guaranteeing research participants the health-care interventions to which they are entitled.
- Ensure that the research study is feasible within the social, political, and cultural context or with sustainable improvements in the local health-care and physical infrastructure.

## Fair selection of study population

- Select the study population to ensure scientific validity of the research.
- Select the study population to minimize the risks of the research and enhance other principles, especially collaborative partnership and social value.
- Identify and protect vulnerable populations.

## Favourable risk-benefit ratio

- Assess the potential risks and benefits of the research to the study population in the context of its health risks.
- Assess the risk-benefit ratio by comparing the net risks of the research project with the potential benefits derived from collaborative partnership, social value, and respect for study populations.

# Ethical principles and benchmarks for multinational clinical research 3

## Independent review

- Ensure public accountability through reviews mandated by laws and regulations.
- Ensure public accountability through transparency and reviews by other international and nongovernmental bodies, as appropriate.
- Ensure independence and competence of the reviews.

## Informed consent

- Involve the community in establishing recruitment procedures and incentives.
- Disclose information in culturally and linguistically appropriate formats.
- Implement supplementary community and familial consent procedures where culturally appropriate.
- Obtain consent in culturally and linguistically appropriate formats.
- Ensure the freedom to refuse or withdraw.

## Respect for recruited participants and study communities

- Develop and implement procedures to protect the confidentiality of recruited and enrolled participants.
- Ensure that participants know they can withdraw without penalty.
- Provide enrolled participants with information that arises in the course of the research study.
- Monitor and develop interventions for medical conditions, including research-related injuries, for enrolled participants at least as good as existing local norms.
- Inform participants and the study community of the results of the research

# Conclusion 1

- **Work in collaboration with donors, foundations, professional bodies and other partners, ensuring**
  - Transparency
  - Effective communication
  - Trust
- **Take ownership jointly on all projects**
  - Accepting and taking risks together
  - Looking for and formulating new solutions together
  - Adapting science and technology to 'fit' in with defined needs
- **Engage individuals, communities, NGOs, governments, the private sector**



## Conclusion 2

- The 'common good' agenda should be determined by LMICs, and funding should be a means to a designated end, not a primary determinant
- In order to support health research in LMICs that is both relevant and meaningful, the focus must be on developing health research that promotes equity and on developing local capacity in bioethics
- Only through such proactive measures can we address the emerging moral and ethical dilemmas and challenges that globalization and the genomics revolution will bring in their wake.

**Thank-you**