

# Validation of the UDI- and IIQ-7 questionnaire in Lingala and Kikongo in an obstetric fistula population

<b>Submission date</b> 07/11/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/12/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/12/2016	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Obstetric fistula is a hole in the birth canal caused by prolonged and obstructed labour. If left untreated in a patient, this leads to incontinence (constant and uncontrollable leakage of urine or faeces). When obstetric fistula (OF) repair takes place, the results are usually assessed by the surgical team and the patient perspective is often neglected. Urogenital distress inventory (UDI-6) and the impact of incontinence questionnaire (IIQ-7) are two internationally-validated questionnaires.

The aim of this study is to translate them in two Congolese local languages (Lingala and Kikongo) and to check whether that they can be used to assess the symptoms and the impact of urinary incontinence on the quality of life in patients with obstetric fistula.

### Who can participate?

Female adults with fistula due to obstetric complications and able to fill in questionnaires

### What does the study involve?

Answering questionnaires

### What are the possible benefits and risks of participating?

Not provided at time of registration.

### Where is the study run from?

Saint Luc Hospital, Kisantu, Democratic Republic of Congo

### When is the study starting and how long is it expected to run for?

October 2013 to January 2017

### Who is funding the study?

Investigator led and funded. Incidental costs paid by Department of Urology, University Hospitals KU Leuven, Leuven, Belgium.

Who is the main contact?  
Professor Dirk De Ridder  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Dirk De Ridder

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## Additional identifiers

**Protocol serial number**  
UDIIIQ-1

## Study information

**Scientific Title**  
Validation of the UDI- and IIQ-7 questionnaire in Lingala and Kikongo in an obstetric fistula population - an observational study

**Study objectives**  
Urogenital distress inventory (UDI-6) and the impact of incontinence questionnaire (IIQ-7) are two internationally validated questionnaires on incontinence. It is hypothesised that these questionnaires can be translated and validated in two Congolese local languages (Lingala and Kikongo) and that they can be used to assess the symptoms and the impact on the quality of life of urinary incontinence in patients with obstetric vesicovaginal fistula.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Internal Review Board of the Hospital St. Luc, Kisantu, RD Congo

**Study design**  
Observational study

**Primary study design**

Observational

**Study type(s)**

Quality of life

**Health condition(s) or problem(s) studied**

Vesicovaginal fistula due to obstetric complications in a rural hospital in DR Congo

**Interventions**

Questionnaires, according to following methodologies.

- UDI-6 and IIQ-7 translated and undergoing content validity checks using focus groups.
- Final versions tested in a normal population and in an obstetric fistula population for internal consistency and test-retest reliability.
- Responsiveness tested in an obstetric fistula population and effect sizes calculated.

**Intervention Type**

Other

**Primary outcome(s)**

Validation parameters: Cronbach alpha, reliability, responsiveness

**Key secondary outcome(s)**

1. Fistula closure rate - number of healed fistula vs the number of persistent fistula after fistula surgery. This is assessed by clinical examination after 3 weeks.
2. Incontinence rate - number of patients with urinary incontinence ( stress and/or urgency incontinence) while the fistula is healed. This is assessed by clinical examination at 3 weeks and 3 months after surgery.

**Completion date**

01/01/2017

**Eligibility****Key inclusion criteria**

Female patient with a vesicovaginal fistula due to obstetric complications.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Key exclusion criteria**

1. Male
2. Unable to fill in a questionnaire
3. Fistula not due to obstetric complications

**Date of first enrolment**

01/10/2014

**Date of final enrolment**

31/12/2016

## Locations

**Countries of recruitment**

Congo, Democratic Republic

**Study participating centre**

Hôpital St. Luc

Kisantu

Inkisi

Province du Bas-Congo

Kisantu

Congo, Democratic Republic

NA

## Sponsor information

**Organisation**

KU Leuven - dept. of urology

**ROR**

<https://ror.org/05f950310>

## Funder(s)

**Funder type**

University/education

**Funder Name**

Investigator initiated and self funded

# Results and Publications

## **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from [dirk.deridder@uzleuven.be](mailto:dirk.deridder@uzleuven.be).

## **IPD sharing plan summary**

Available on request