

# Improving perinatal care in Latin America

<b>Submission date</b> 04/11/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/02/2005	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 28/01/2019	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Pierre Buekens

### Contact details

School of Public Health and Tropical Medicine  
Tulane University  
1440 Canal St  
Ste 2430  
New Orleans, LA  
United States of America  
70112  
+1 504 988 5397  
pbuekens@tulane.edu

## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT00070720

### Protocol serial number

GN 01

## Study information

Scientific Title

A behavioral intervention to improve obstetrical care.

### **Acronym**

GUIDELINES Trial

### **Study objectives**

The aim of this trial is to evaluate the effect of a multifaceted behavioural intervention on the use of two evidence-based birth practices, the selective use of episiotomies and active management of the third stage of labor (injection of 10 International Units of oxytocin).

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

The protocol was submitted and approved by the IRBs of the following institutions:

1. University of North Carolina at Chapel Hill (USA)
2. Tulane University (USA)
3. Research Triangle Institute (USA)
4. Pan American Health Organization (USA)
5. School of Medicine of the University of the Republic in Uruguay (Uruguay)
6. The University Hospital of Montevideo (Uruguay)
7. The Argentinean Society for Clinical Research (Argentina)

### **Primary study design**

Interventional

### **Study design**

Randomised controlled trial

### **Study type(s)**

Treatment

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

Episiotomy use; post-partum haemorrhage

### **Interventions**

Intervention group:

Evidence based clinical practice guidelines development workshop for opinion leaders. Opinion leaders will then use academic detailing, reminders, and feedback for dissemination and implementation of guidelines at the hospital level.

Control group:

Control hospitals will continue with their usual in-service training activities and will receive components of the intervention at the end of the study period.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Oxytocin

**Primary outcome(s)**

The rates of episiotomy and oxytocin use during the third stage of labor.

**Key secondary outcome(s)**

1. Perineal sutures
2. Postpartum haemorrhages
3. Birth attendants opinions

**Completion date**

01/09/2006

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

24 public hospitals in Argentina and Uruguay that had:

1. At least 1000 vaginal deliveries per year
2. No explicit policy for selective episiotomy or active management of third stage of labor

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Key exclusion criteria**

Does not comply with above inclusion criteria.

**Date of first enrolment**

01/09/2003

**Date of final enrolment**

01/09/2006

**Locations****Countries of recruitment**

Argentina

United States of America

Uruguay

**Study participating centre**  
**School of Public Health and Tropical Medicine**  
New Orleans, LA  
United States of America  
70112

## Sponsor information

### Organisation

National Institute of Child Health and Human Development (NICHD) (USA)

### ROR

<https://ror.org/04byxyr05>

## Funder(s)

### Funder type

Government

### Funder Name

National Institute of Child Health and Human Development (NICHD) (USA)

### Alternative Name(s)

NICHD

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United States of America

### Funder Name

Global Network for Women's and Children's Health Research (USA)

**Funder Name**

Bill and Melinda Gates Foundation (USA)

**Alternative Name(s)**

Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United States of America

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/05/2008	28/01/2019	Yes	No
<a href="#">Protocol article</a>	protocol	11/04/2005		Yes	No