

# 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 <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/02/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/01/2019	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**  
NCT00070720

**Secondary identifying numbers**  
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)

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/09/2003

**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

**Age group**

Adult

**Sex**

Female

**Target number of participants**

24 public hospitals

**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)

**Sponsor details**

6100 Executive Boulevard

Room 4B05H

Rockville, MD

United States of America

20852

+1 301 402 0830

wrightl@mail.nih.gov

**Sponsor type**

Government

**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, 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

## Publication and dissemination plan

Not provided at time of registration

**Intention to publish date**

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

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

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