

PRE-EMPT

improving pre-eclampsia/eclampsia care across the continuum

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a place of mind



PRE-EMPT

Pre-eclampsia and eclampsia
monitoring, prevention & treatment



Pre-eclampsia defined

- **Definition (classical)**
 - Hypertension
 - sBP ≥ 140 mmHg and/or dBP ≥ 90 mmHg
 - Significant proteinuria
 - ≥ 300 mg protein/24 hours
 - ≥ 30 mg protein/mmol creatinine on spot urinary protein:creatinine ratio
 - $\geq ++$ dipstick proteinuria
- **This paradigm does not fully recognise the systemic nature of pre-eclampsia**

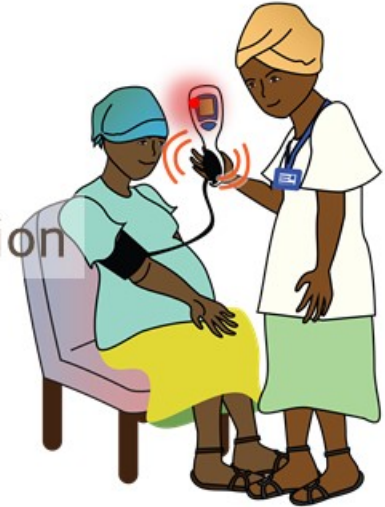
Pre-eclampsia redefined

pre-eclampsia is more than hypertension & proteinuria

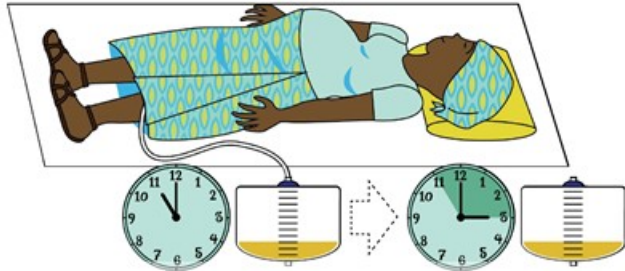


proteinuria

hypertension

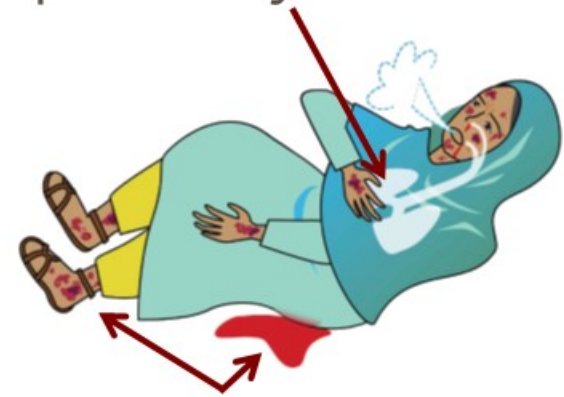


pre-eclampsia



acute renal failure

pulmonary oedema



DIC/abruption



eclampsia



stroke

- **Five objectives**
 - **Prevention**
 - **Monitoring**
 - **Treatment**
 - **Global Pregnancy CoLaboratory**
 - **Knowledge translation**

Prevention

the Calcium And Pre-eclampsia trial

PI: Justus Hofmeyr



Argentina
3 sites
(RHR)

Cape Town
2 sites

Harare

Johannesburg

East London

Calcium And Pregnancy (CAP) Trial

- **Rationale**

- In diet-deficient (calcium <600mg/d) women, calcium supplementation (≥ 1000 mg/d) in 2nd half of pregnancy decreases the incidence of pre-eclampsia
 - i.e., proteinuric GH (RR 0.68 [95% CI 0.49, 0.94])
- Is the reduction in pre-eclampsia an epiphenomenon of decreasing BP by 3-5mmHg?
- Might calcium mask risks (e.g., HELLP)?
- Might earlier (preconceptional & early pregnancy) calcium have greater effect?

A new review

low-dose calcium and pre-eclampsia prevention

- **Data collection and analysis**
 - Randomised and quasi-randomised trials of low-dose calcium (<1g /day), with/without other supplements.
- **Main results**
 - Pre-eclampsia reduced consistently (9 trials, n=2234, RR 0.38 [0.28-0.52])
- **Conclusions**
 - Limited data consistent with reducing the risk of pre-eclampsia & have implications for current WHO guidelines and their global implementation

Calcium And Pregnancy (CAP) Trial



- **Trial design**
 - Placebo-controlled RCT
- **Population**
 - South Africa, Zimbabwe, & Argentina
 - Women who have previously experienced severe pre-eclampsia or eclampsia (\pm perinatal loss), who are planning another pregnancy
- **Enrolment (before pregnancy) until 20wk GA**
 - Intervention: Calcium supplementation (500mg/d)
 - Control: Placebo
- **Both arms to receive Ca²⁺ from 20⁺⁰wk**
- **Outcomes**
 - Primary: pre-eclampsia (proteinuric GH)
 - Secondary

Calcium And Pregnancy (CAP) Trial

ARTICLE IN PRESS

Pregnancy Hypertension: An International Journal of Women's Cardiovascular Health xxx (2015) xxx–xxx



Contents lists available at ScienceDirect

Pregnancy Hypertension: An International Journal of Women's Cardiovascular Health

journal homepage: www.elsevier.com/locate/preghy



Original Article

The effect of calcium supplementation on blood pressure in non-pregnant women with previous pre-eclampsia: An exploratory, randomized placebo controlled study

G.J. Hofmeyr^{a,b}, A.H. Seuc^c, A.P. Betrán^c, T.D. Purnat^d, A. Ciganda^e, S.P. Munjanja^f, S. Manyame^f, M. Singata^g, S. Fawcus^{h,i}, K. Frank^j, D.R. Hall^k, G. Cormick^{e,*}, J.M. Roberts^l, E.F. Bergel^e, S.K. Drebit^m, P. Von Dadelszen^m, J.M. Belizan^e, on behalf of the Calcium and Pre-eclampsia Study Group

	Calcium			Placebo			Difference	
	N	Mean	SD	N	Mean	SD	MD	95% CI
<i>With severe pre-eclampsia in previous pregnancy</i>								
Week after randomization	105	12.4	1.2	112	12.5	1.5		
Systolic BP (mmHg)	105	-6	14.7	112	-2.8	15.6	3.2	-0.9–7.3
Diastolic BP (mmHg)	105	-2.6	10.9	112	0.8	11.3	3.4*	0.4–6.4
<i>Without severe pre-eclampsia in previous pregnancy</i>								
Week after randomization	76	12.4	1.4	74	12.6	1.8		
Systolic BP (mmHg)	76	-1.4	14.3	74	-2.4	12.4	-1.1	-5.4–3.3
Diastolic BP (mmHg)	76	1.7	12.2	74	-0.6	11.4	-2.3	-6.1–1.5

* Statistically significant.

Monitoring

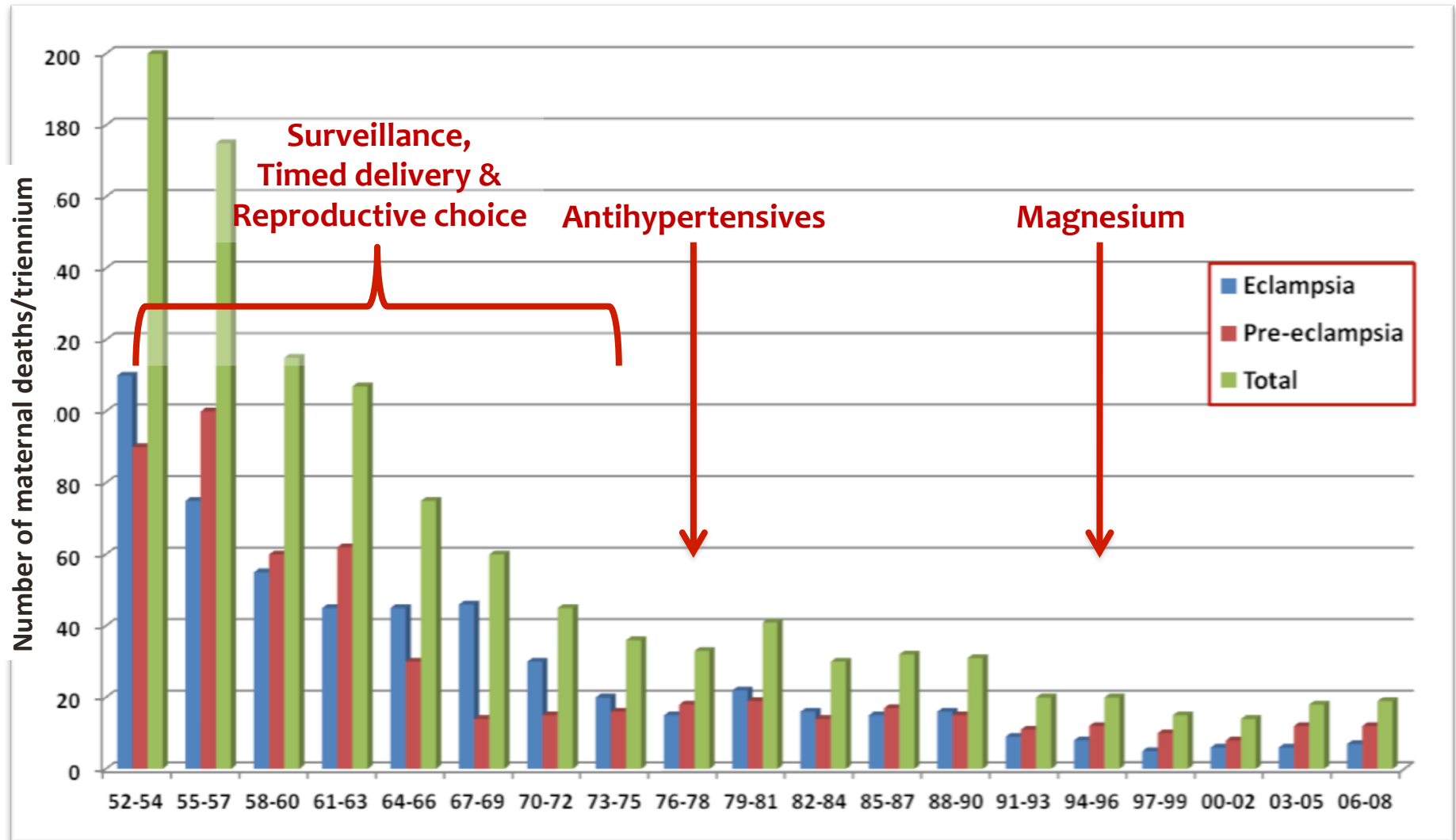
the miniPIERS model: development & validation

PI: Peter von Dadelszen



Maternal death from pre-eclampsia

by diagnosis – UK; 1952 – 2008



Data from CEMD ,UK

PIERS combined adverse maternal outcome

One or more of maternal morbidity or mortality:

Maternal death

Eclampsia (≥ 1)

Glasgow coma score < 13

CVA/RIND/TIA

Cortical blindness/retinal detachment/PRES

Positive inotropic support

Infusion of a 3rd parenteral antihypertensive

Myocardial ischaemia/infarction

SpO₂ $< 90\%$; $\geq 50\%$ FiO₂ for > 1 hr; pulmonary oedema

Intubation (other than for C/S)

Transfusion of any blood product

Platelets $< 50 \times 10^9/L$ with no transfusion

Hepatic dysfunction

Hepatic haematoma/rupture

Acute renal insufficiency (no prior renal disease)

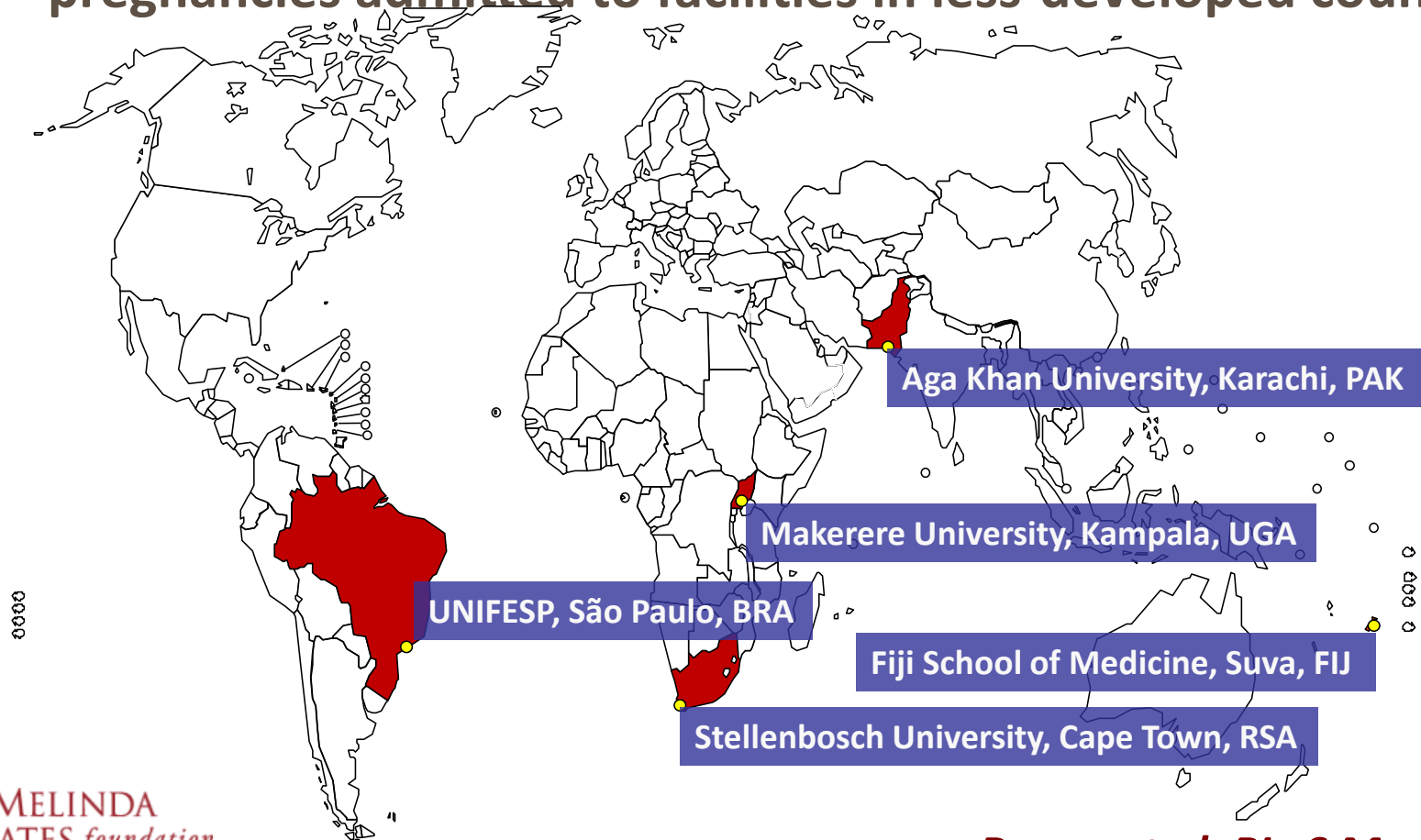
Acute renal failure (prior renal disease)

Placental abruption

Other (ascites/Bell's palsy)

- **Study design**

- miniPIERS recruited 2081 women with HDP-complicated pregnancies admitted to facilities in less-developed countries



miniPIERS model

development & validation with bootstrapping

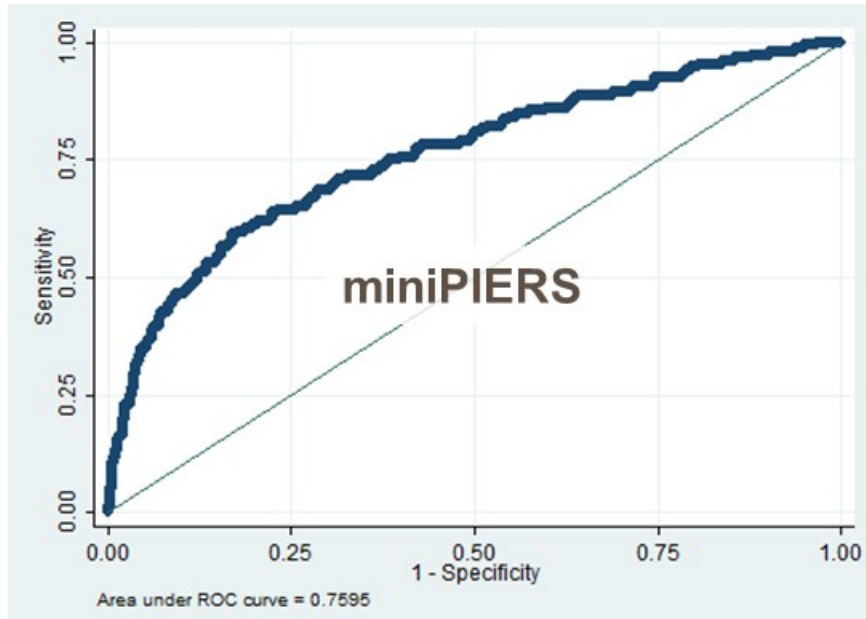


- **AUC ROC = 0.77 [95% CI 0.73, 0.81]**
- **Includes**
 - Parity (0, ≥ 1), gestational age, maternal chest pain/dyspnoea, maternal headache/visual disturbances, maternal abdominal pain with bleeding, sBP, and dipstick proteinuria
- **Dipstick proteinuria not a necessary component - included for face validity**
 - Highly predictive of perinatal mortality
 - 4+: OR = 7.1 [95% CI 3.3, 15.5]

miniPIERS model + SpO2

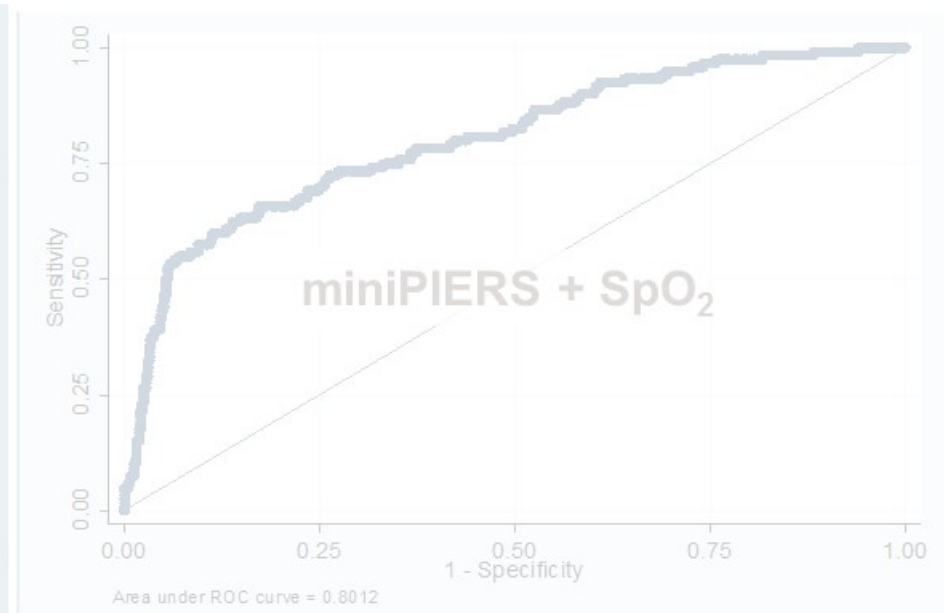


miniPIERS model + SpO₂



[AUC ROC 0.77 (95% CI 0.74, 0.80)]

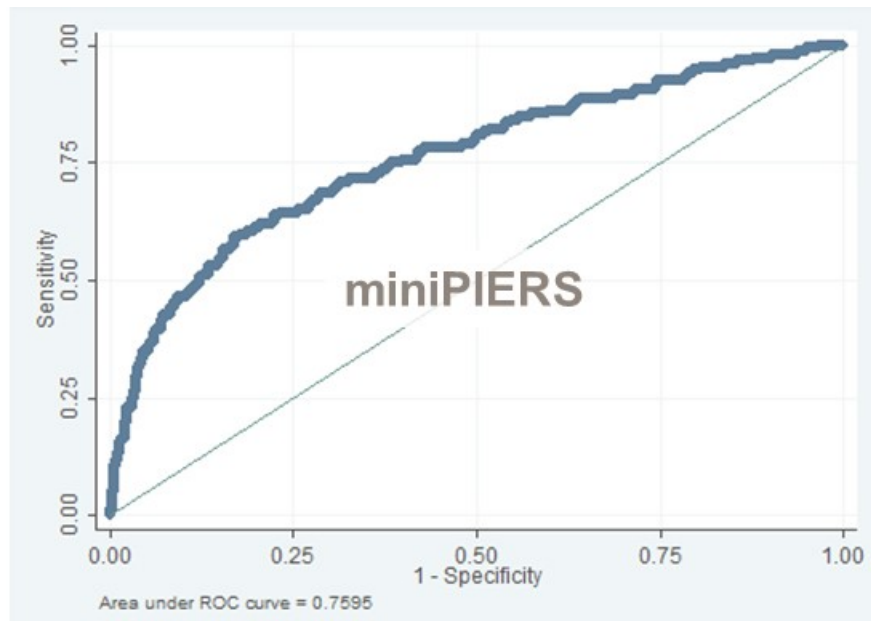
- High-risk group defined using a predicted probability $\geq 25\%$
- Identify 65% of women with adverse outcomes



[AUC ROC 0.80 (95% CI 0.76, 0.85)]

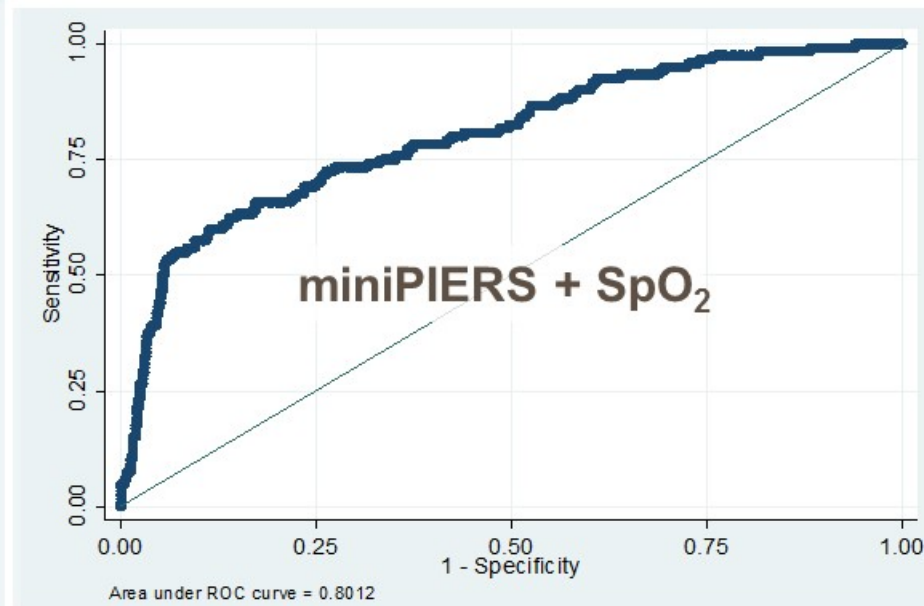
- High-risk group defined using a predicted probability $\geq 25\%$
- Identify 85% of women with adverse outcomes

miniPIERS model + SpO₂



[AUC ROC 0.77 (95% CI 0.74, 0.80)]

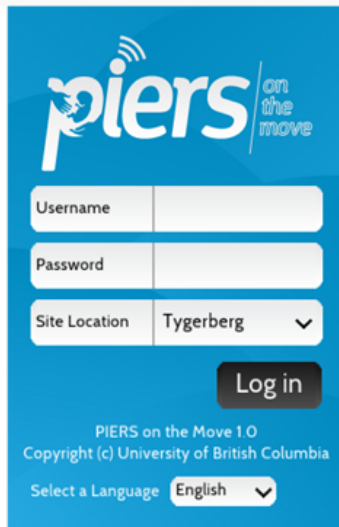
- High-risk group defined using a predicted probability $\geq 25\%$
- Identify 65% of women with adverse outcomes



[AUC ROC 0.80 (95% CI 0.76, 0.85)]

- High-risk group defined using a predicted probability $\geq 25\%$
- Identify 85% of women with adverse outcomes

PIERS on the Move



Username

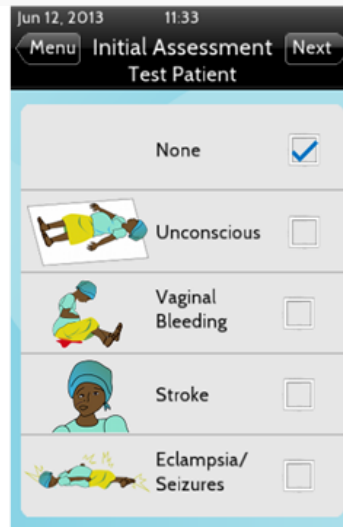
Password

Site Location Tygerberg

Log in

PIERS on the Move 1.0
Copyright (c) University of British Columbia

Select a Language English



Jun 12, 2013 11:33

Menu Initial Assessment Next

Test Patient

None

Unconscious

Vaginal Bleeding

Stroke

Eclampsia/Seizures



Jun 07, 2013 09:03

Back Characteristics Save

Weight Current 54 kg

Pre-Pregnancy 49.5 kg

Weight Gain 4.5 kg Change units

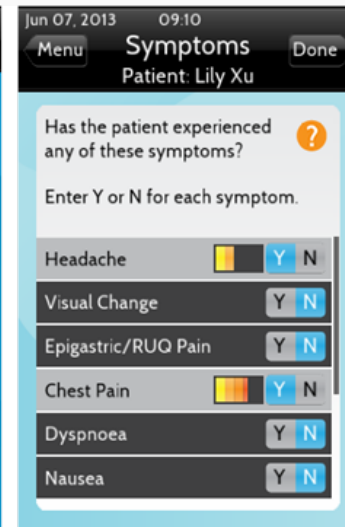
Gravidity 4 Parity 3

Number of Fetuses 2

Calculate EDD Current Method: Last Menstrual Period

Estimated Date of Delivery (EDD) 2013 11 22

Gestational Age 16 + 0



Jun 07, 2013 09:10

Menu Symptoms Done

Patient: Lily Xu

Has the patient experienced any of these symptoms?

Enter Y or N for each symptom.

Headache Y N

Visual Change Y N

Epigastric/RUQ Pain Y N

Chest Pain Y N

Dyspnoea Y N

Nausea Y N



Jun 07, 2013 09:18

Back Clinical Observations Done

Patient: Lily Xu

Maternal Status

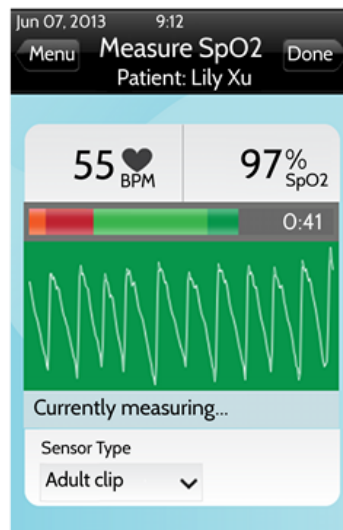
Symptoms

Signs

SpO2

Outcomes

Main Menu Patient Search Patient Menu Clinical Observ



Jun 07, 2013 9:12

Menu Measure SpO2 Done

Patient: Lily Xu

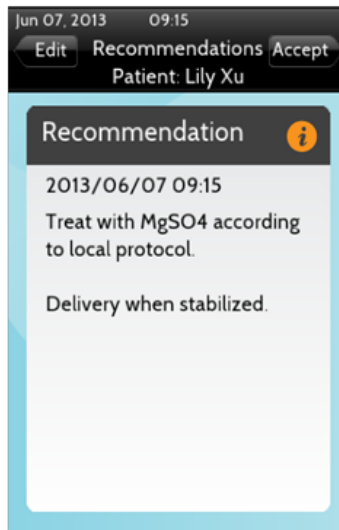
55 BPM

97% SpO2

0.41

Currently measuring...

Sensor Type Adult clip



Jun 07, 2013 09:15

Edit Recommendations Accept

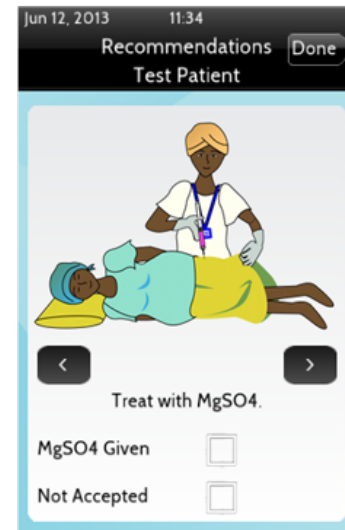
Patient: Lily Xu

Recommendation

2013/06/07 09:15

Treat with MgSO4 according to local protocol.

Delivery when stabilized.



Jun 12, 2013 11:34

Recommendations Done

Test Patient

Treat with MgSO4.

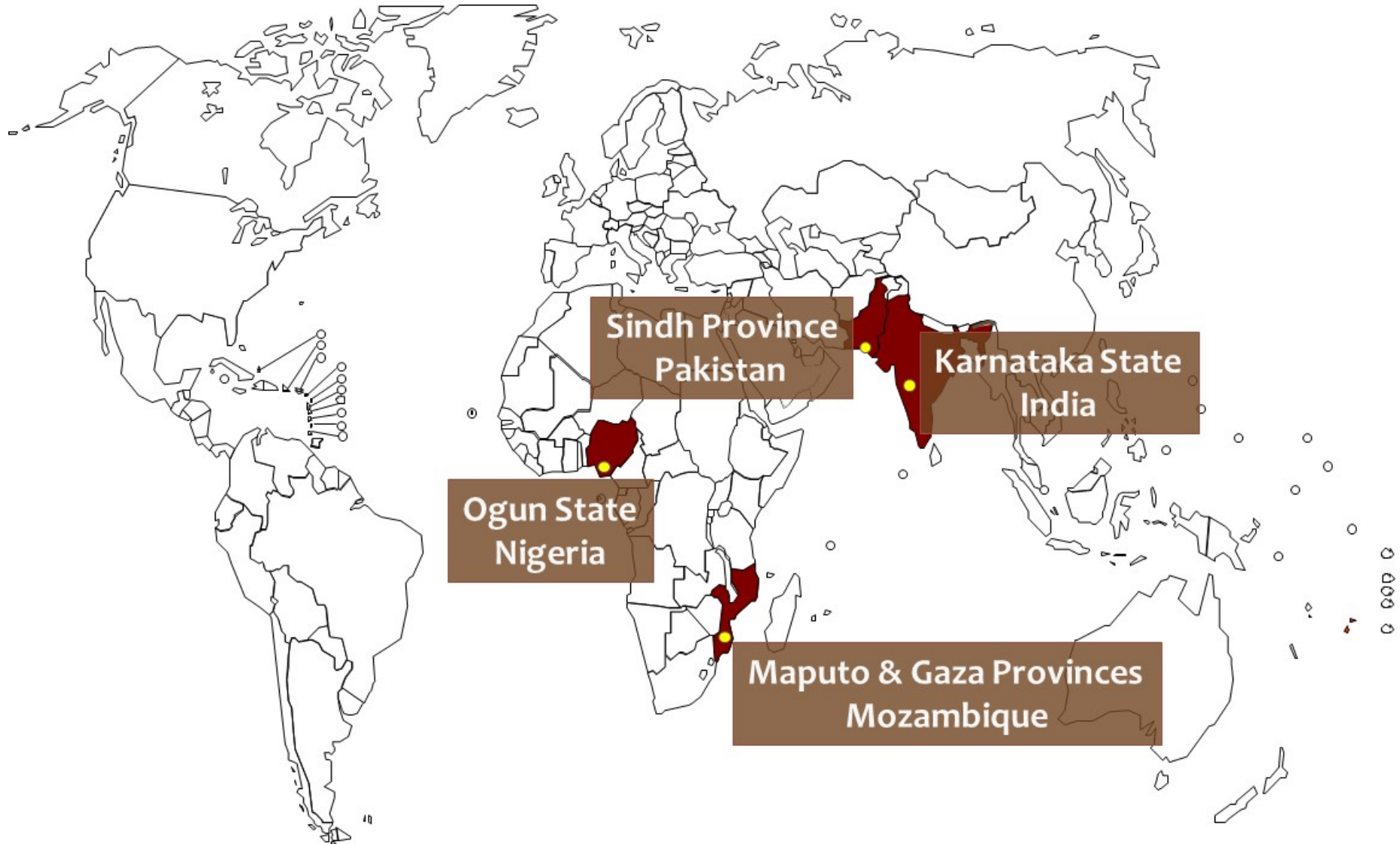
MgSO4 Given

Not Accepted

Treatment

the Community-Level Interventions in Pregnancy (CLIP) trials

PI: Peter von Dadelszen





CLIP Feasibility Studies

methods

- **Multiple methods of data collection employed to explore feasibility of the CLIP Trial**
 - **Focus Group Discussions**
 - **In Depth Interviews**
 - **Document Review**
 - **Participatory Observation**
 - **Facility Assessment**
 - **Self-Administered Questionnaires**
 - **Community Surveillance**

CLIP Feasibility Studies

publications



- **Three supplements to *BMC Reproductive Health***

- **December 2015**

- Mixed-methodology for assessing the feasibility of Community Level Interventions for Pre-eclampsia in South Asian and African contexts
- Community perceptions of pre-eclampsia (all four countries)
- Health care seeking behaviours for obstetric care (all four countries)

- **Women Deliver 2016**

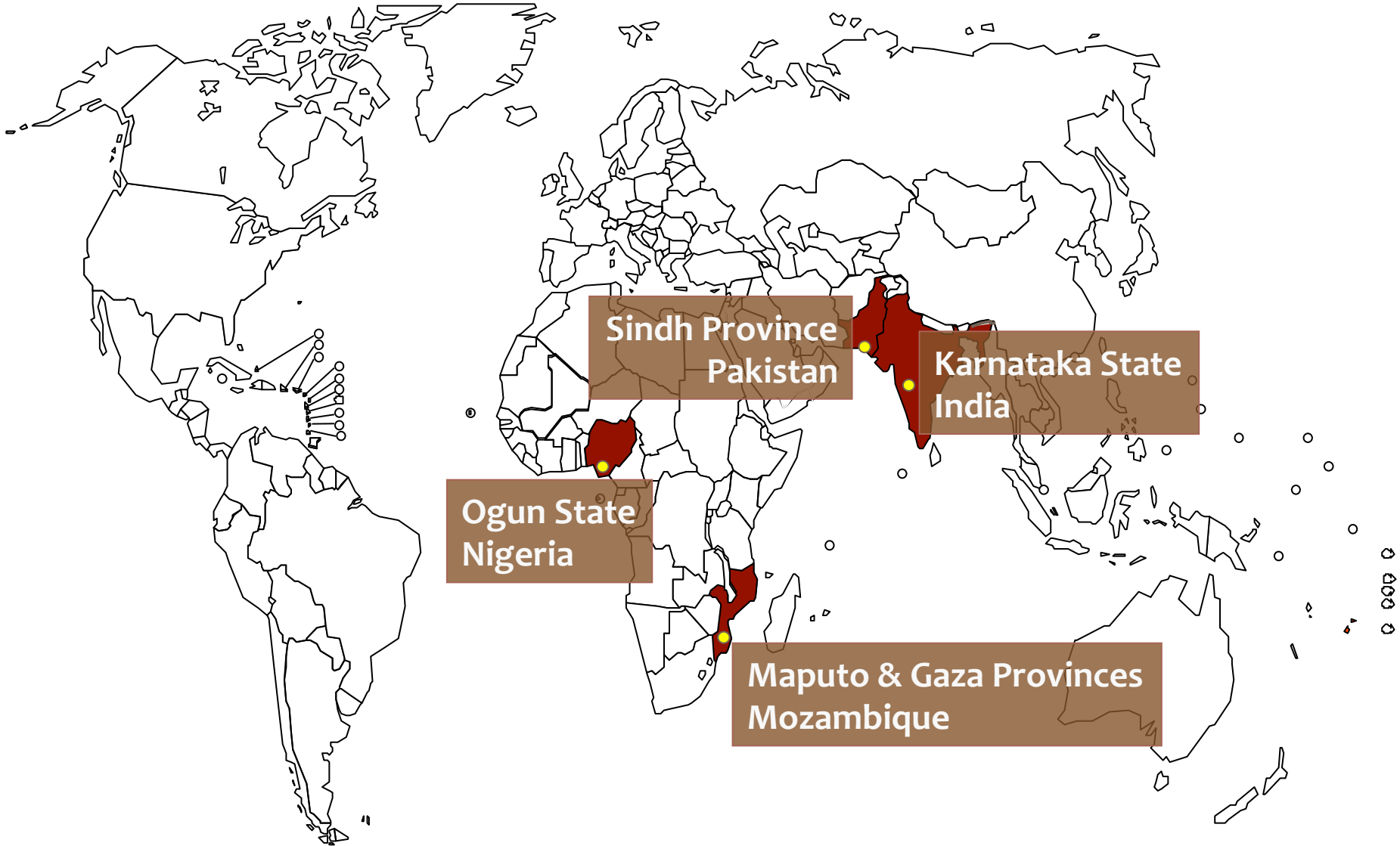
- Human resource constraints and the prospect of task-shifting (all four countries)
- Community health worker knowledge and management of pre-eclampsia (all four countries)
- The influence of relationships on maternal well-being in Mozambique
- The spatial epidemiology of maternal deaths in Gaza and Maputo provinces, Mozambique
- Personal relationships, social capital and resilience in Southern Mozambique

- **RCOG World Congress 2016**

- Estimates of pre-eclampsia, maternal and perinatal mortality: results from the Community Level Interventions for Pre-eclampsia (CLIP) baseline surveys (all four countries)

CLIP sites

≈87,000 pregnant women



App-guided CLIP triggers to initiate community interventions

Trigger	Action
miniPIERS p \geq 25%	▶ Triage/Transport/Treatment
sBP \geq 160	▶ Triage/Transport/Treatment
eclampsia	▶ Triage/Transport/Treatment
pv bleeding (presumed abruption)	▶ Triage/Transport/Treatment
++++ proteinuria	▶ Triage/Transport/Treatment
absent fetal movements \geq 12h	▶ Triage/Transport/Treatment

OVERCOMING THE 3 DELAYS

community engagement & cHCP education



home-based (\pm transfer to PHC) or PHC-based assessment & initial management

urgent transport (<4h)
(if: miniPIERS p \geq 25%, sBP \geq 160, stroke, coma, eclampsia, pv bleeding, ++++ protein, absent FM \geq 12h)

non-urgent transport (<24h)
(if: miniPIERS p <25%, sBP 140-159mmHg, <+ +++ protein)

facility capacity enhancement

CME/CPD
M&M reviews



CEmOC facility for definitive care

ongoing BP control
ongoing MgSO₄
delivery – IOL vs C/S
newborn care

App-guided CLIP package of care (\geq 1 trigger)

750mg methyldopa po	(only if sBP \geq 160; not repeated in PHC)
10g MgSO ₄ im	(if sBP \geq 160, eclampsia, miniPIERS p \geq 25%, pv bleeding + sBP \geq 140; not repeated in PHC)
urgent transport	(if sBP \geq 160, eclampsia, coma, stroke, miniPIERS p \geq 25%, pv bleeding, ++++ protein, no FM \geq 12h)

App-guided CLIP triggers to initiate community interventions

OVERCOMING THE 3 DELAYS

Triggers/Transport/Treatment

community engagement & cHCP education



facility capacity enhancement

CME/CPD
M&M reviews



CEmOC facility for definitive care

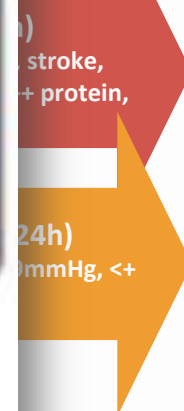
ongoing BP control
ongoing MgSO₄
delivery – IOL vs C/S
newborn care



App-
initial
miniPI
sBP ≥1
eclamp
pv ble
++++ p
absent



home-based
(± transfer to PHC)
or PHC-based
assessment &
initial
management



facility capacity
enhancement
CME/CPD
M&M reviews



CEmOC facility for
definitive care
ongoing BP control
ongoing MgSO₄
delivery – IOL vs C/S
newborn care

comm
& c

App-
750mg
10g Mg
urgent



12h)

App-guided CLIP triggers to initiate community interventions

miniPIERS p \geq 25%

sBP \geq 160

eclampsia

pv bleeding (presumed abruption)

++++ proteinuria

absent fetal movements \geq 12h

OVERCOMING THE 3 DELAYS

→ Triage/Transport/Treatment

→ Triage/Transport/Treatment

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→ Triage/Transport/Treatment

facility capacity enhancement

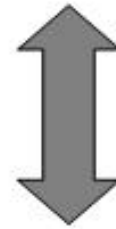
CME/CPD

M&M reviews



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newborn care



home-based
(\pm transfer to PHC)
or PHC-based
assessment &
initial
management



App-guided CLIP triggers to initiate community interventions

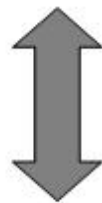
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++++ proteinuria	----->	▶ Triage/Transport/Treatment
absent fetal movements \geq 12h	----->	▶ Triage/Transport/Treatment

OVERCOMING THE 3 DELAYS

facility capacity enhancement



home-based
(\pm transfer to PHC)
or PHC-based
assessment &
initial
management



App-guided CLIP package of care (\geq 1 trigger)

- 750mg methyldopa po (only if sBP \geq 160; not repeated in PHC)
- 10g MgSO₄ im (if sBP \geq 160, eclampsia, miniPIERS p \geq 25%, pv bleeding + sBP \geq 140; not repeated in PHC)
- urgent transport (if sBP \geq 160, eclampsia, coma, stroke, miniPIERS p \geq 25%, pv bleeding, ++++ protein, no FM \geq 12h)

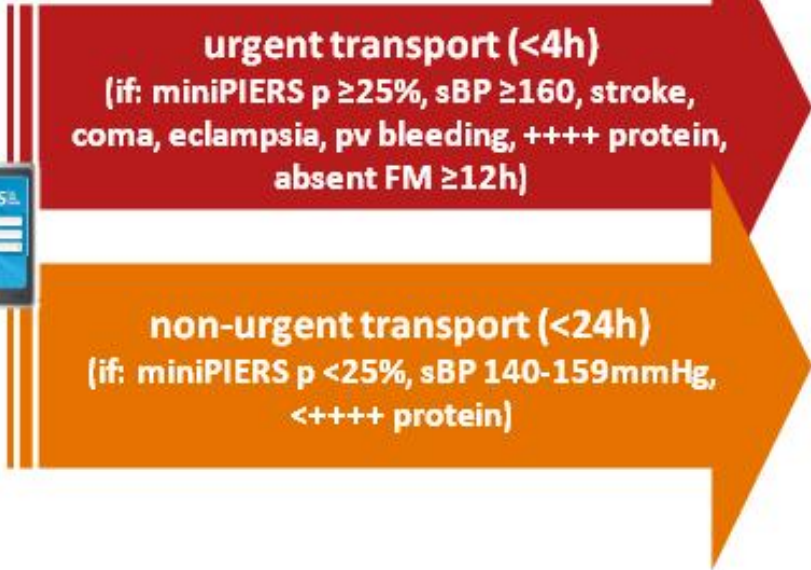
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App-guided CLIP triggers to initiate community interventions

- miniPIERS p $\geq 25\%$
- sBP ≥ 160
- eclampsia
- pv bleeding (presumed al)
- ++++ proteinuria
- absent fetal movements

OVERCOMING THE 3 DELAYS

community engagement & cHCP education



facility capacity enhancement
CME/CPD
M&M reviews

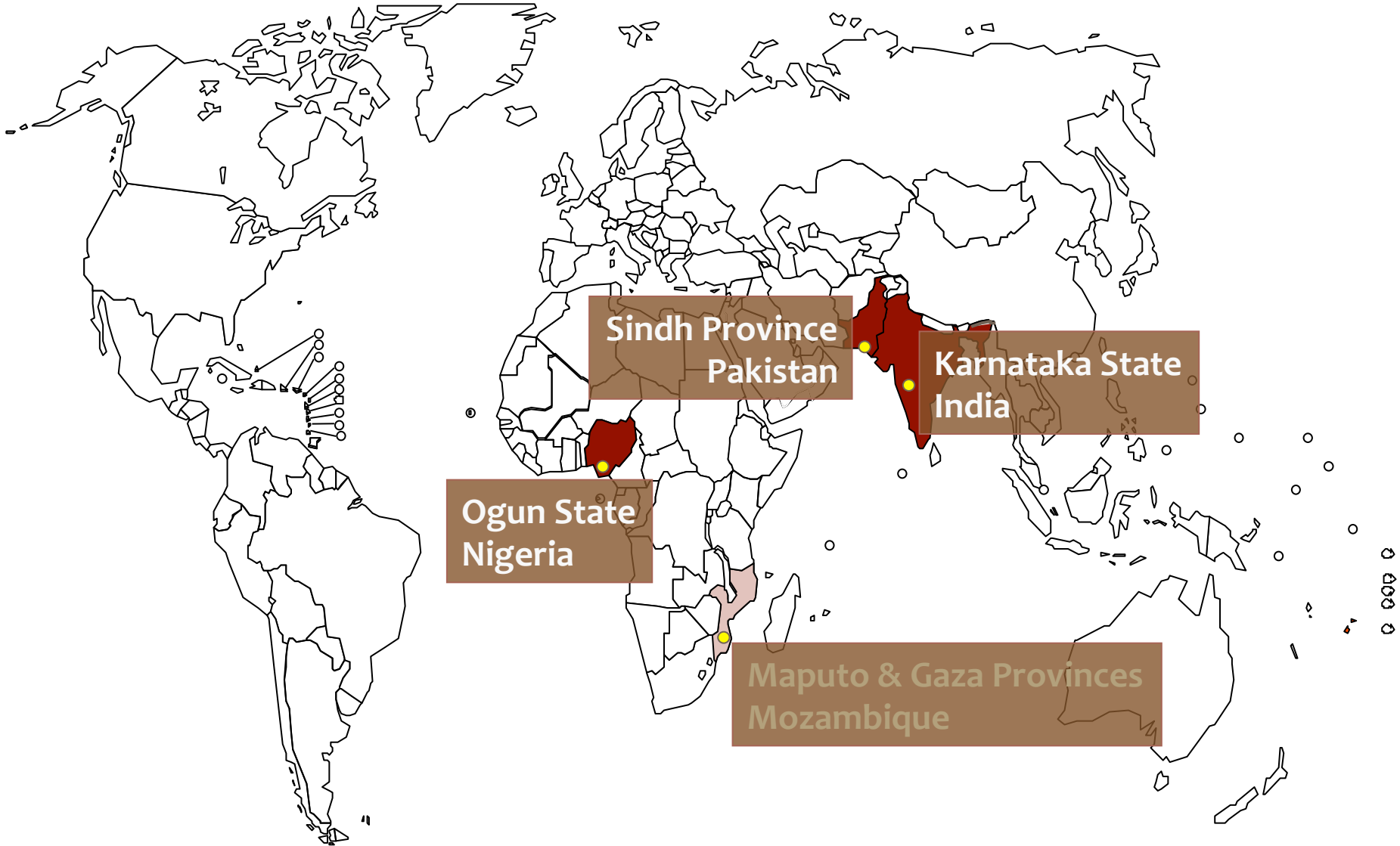


CEmOC facility for definitive care
ongoing BP control
ongoing MgSO₄
delivery – IOL vs C/S
newborn care

- App-guided CLIP pa**
- 750mg methyldopa po (c
 - 10g MgSO₄ im (i
 - urgent transport (i

CLIP sites – pilot trials

≈17,000 pregnant women



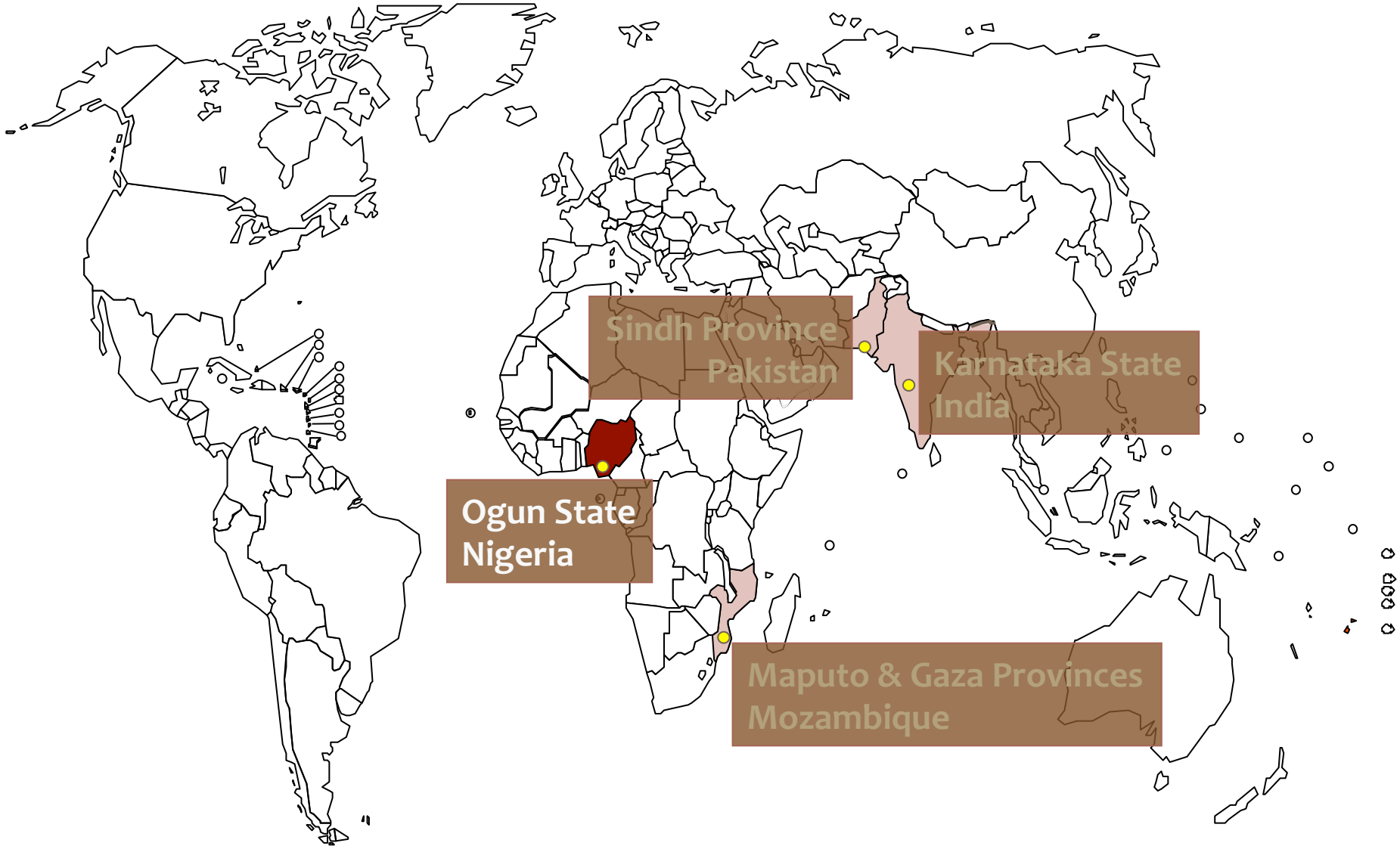
CLIP pilot trial

interim data

- **Nigeria**
 - 10,320 women enrolled
 - 3248 women visited
 - 5% incidence HDP
 - 121/163 (74%) referrals immediately accepted
- **Pakistan**
 - 4356 women enrolled
 - 1653 women visited
 - 7.7% incidence HDP
 - 82/127 (65%) referrals immediately accepted
- **India**
 - 2209 women enrolled
 - 964 women visited
 - 4.9% incidence HDP
 - 33/47 (70%) referrals immediately accepted

CLIP site – CRADLE device

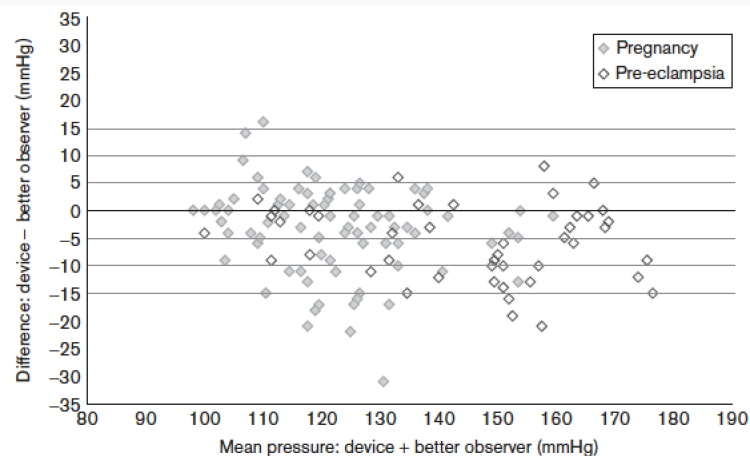
≈87,000 pregnant women



Additional diagnostic performance

Nigeria

- **Microlife**
 - **CRADLE BP device**



Nathan et al. *Blood Press Monit* 2015

App-guided CLIP triggers to initiate community interventions

- miniPIERS p $\geq 25\%$ -----> Triage/Transport/Treatment
- sBP ≥ 160 -----> Triage/Transport/Treatment
- dBP ≥ 110 -----> Triage/Transport/Treatment
- SI ≥ 1.7 -----> Triage/Transport/Treatment
- eclampsia -----> Triage/Transport/Treatment
- pv bleeding (presumed abruption) -----> Triage/Transport/Treatment
- ++++ proteinuria -----> Triage/Transport/Treatment
- absent fetal movements $\geq 12h$ -----> Triage/Transport/Treatment

OVERCOMING THE 3 DELAYS

community engagement & cHCP education

home-based (\pm transfer to PHC) or PHC-based assessment & initial management

urgent transport (<4h)
(if: miniPIERS p $\geq 25\%$, sBP ≥ 160 , dBP ≥ 110 , SI ≥ 1.7 , stroke, coma, eclampsia, pv bleeding, ++++ protein, absent FM $\geq 12h$)

non-urgent transport (<24h)
(if: miniPIERS p $< 25\%$, sBP 140-159mmHg, <+ +++ protein)

facility capacity enhancement

CME/CPD
M&M reviews



CEmOC facility for definitive care

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newborn care

App-guided CLIP package of care (≥ 1 trigger)

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- urgent transport (if sBP ≥ 160 , dBP ≥ 110 , SI ≥ 1.7 , eclampsia, coma, stroke, miniPIERS p $\geq 25\%$, pv bleeding, ++++ protein, no FM $\geq 12h$)

Additional diagnostic performance

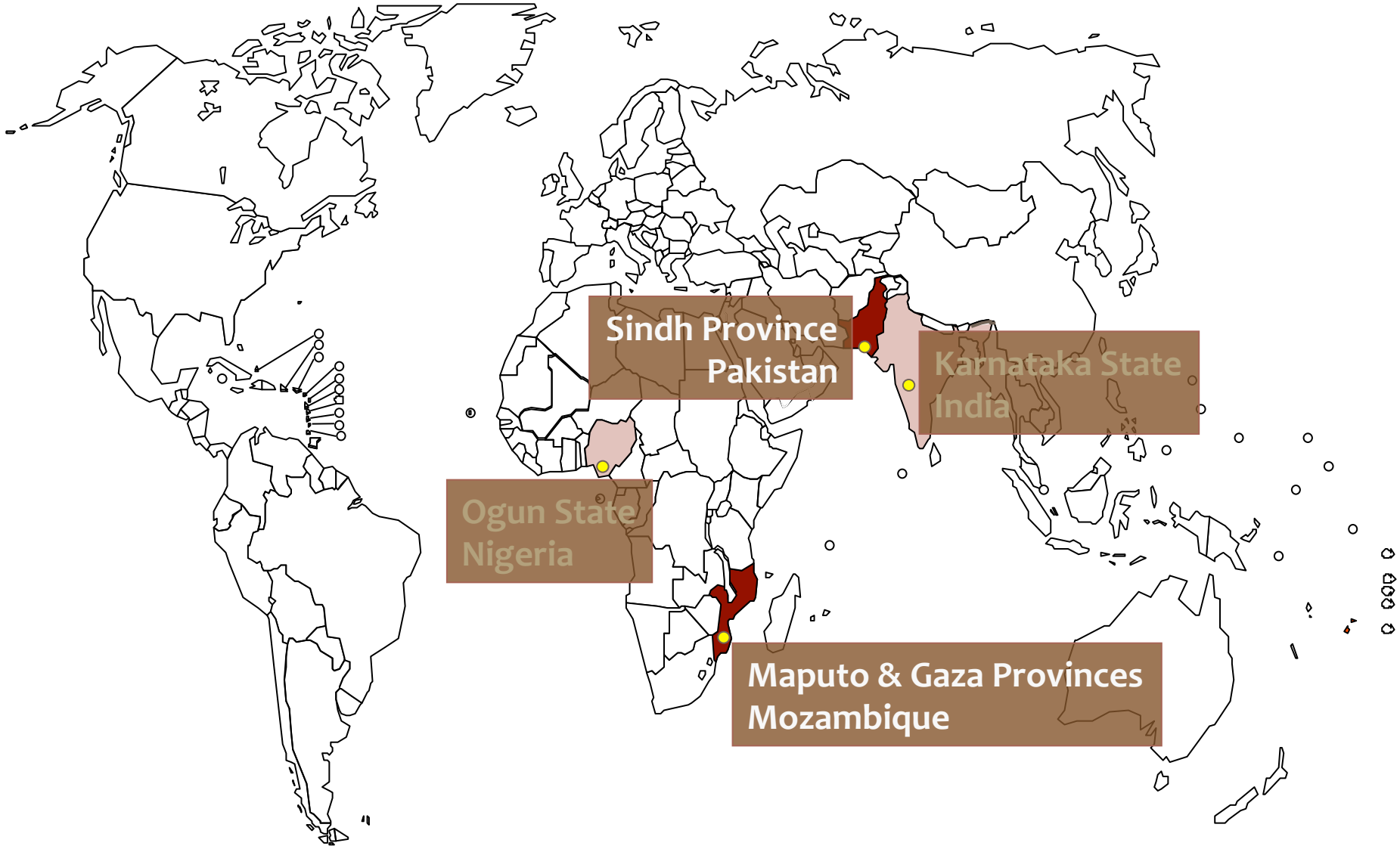
Mozambique & Pakistan

- **LionsGate Technologies**
 - Phone oximeter[®] through AudioOx[®] port
 - Adds SpO₂ to miniPIERS
 - Crowd-funded through the Sensor Project (<http://www.thesensorproject.org/>)



CLIP sites - oximetry

≈87,000 pregnant women



App-guided CLIP triggers to initiate community interventions

- miniPIERS p $\geq 25\%$ -----> Triage/Transport/Treatment
- sBP ≥ 160 -----> Triage/Transport/Treatment
- SpO₂ <93%** -----> **Triage/Transport/Treatment**
- eclampsia -----> Triage/Transport/Treatment
- pv bleeding (presumed abruption) -----> Triage/Transport/Treatment
- ++++ proteinuria -----> Triage/Transport/Treatment
- absent fetal movements $\geq 12h$ -----> Triage/Transport/Treatment

OVERCOMING THE 3 DELAYS

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non-urgent transport (<24h)
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facility capacity enhancement

CME/CPD
M&M reviews



CEmOC facility for definitive care

ongoing BP control
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App-guided CLIP package of care (≥ 1 trigger)

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- urgent transport (if sBP ≥ 160 , **SpO₂ <93%**, eclampsia, coma, stroke, miniPIERS p $\geq 25\%$, pv bleeding, ++++ protein, no FM $\geq 12h$)

- **Maternal death (“maternal death rate”)**
 - deaths during pregnancy or ≤ 42 d of pregnancy (or last contact day if contact not maintained to 42d) /1,000 identified pregnancies
- **Maternal morbidity**
 - one/more life-threatening complications of pregnancy during pregnancy or ≤ 42 d of pregnancy (or last contact day if contact not maintained to 42d) /1,000 identified pregnancies
- **Perinatal & late neonatal death (“perinatal death rate”)**
 - IUFD [$\geq 20^{+0}$ and/or ≥ 500 g], early neonatal mortality [d0-6 of postnatal life] and late neonatal mortality [d7-28 of postnatal life]/1,000 identified pregnancies
- **Neonatal morbidity**
 - non-lethal events of seizure and coma during d0-28 of postnatal life /1,000 identified pregnancies

CLIP definitive trial

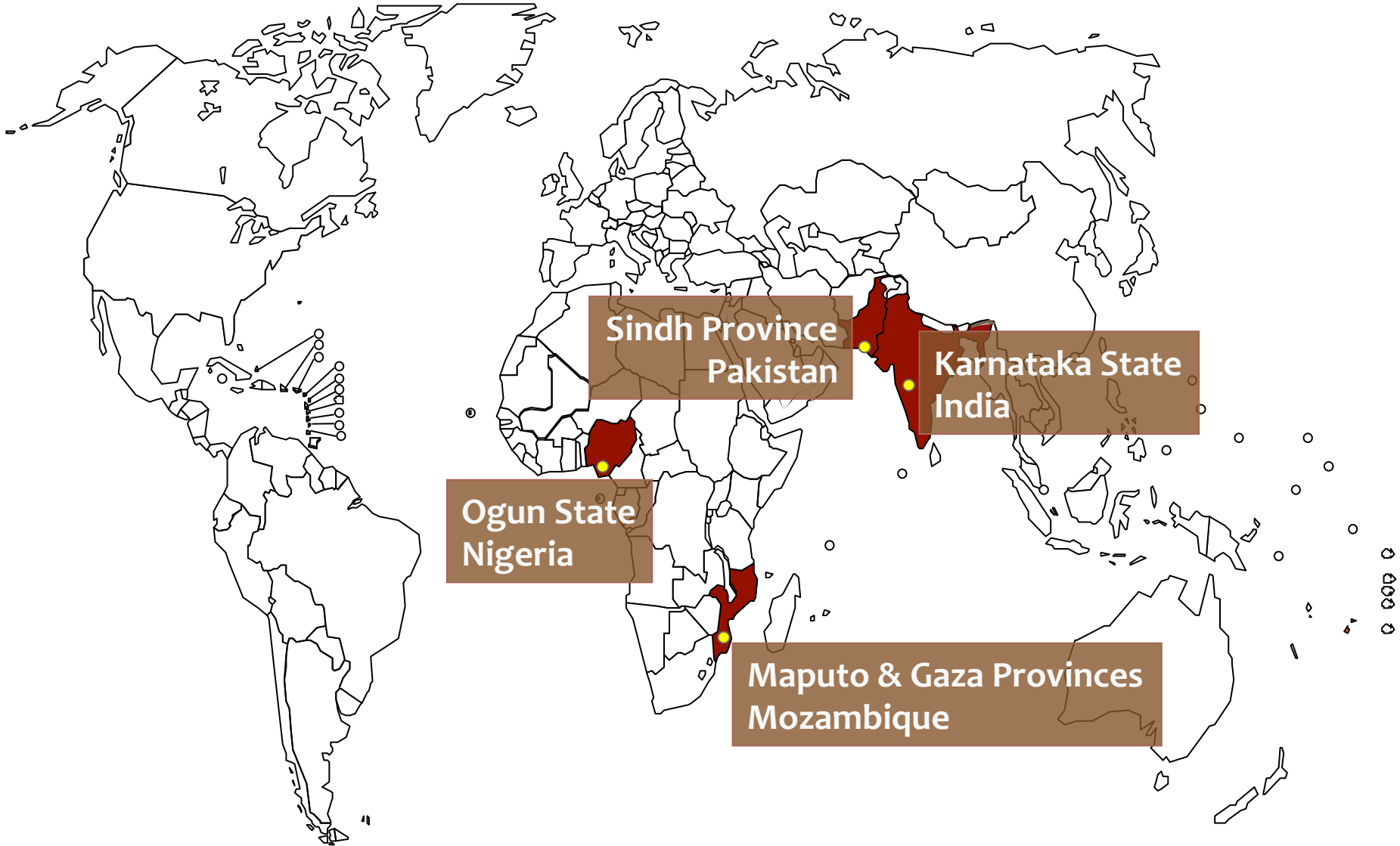
updates



- **Nigeria**
 - Start date: 15 March 2015
- **Mozambique**
 - Start date: 1 April 2015 (pending MgSO_4 sourcing)
- **Pakistan**
 - Start date: 18 January 2015
- **India**
 - Start date: 1 November 2014

IPD meta-analysis

≈87,000 pregnant women



Treatment

the Gynuity Health Projects Oral Antihypertensive trial

PI: Hillary Bracken



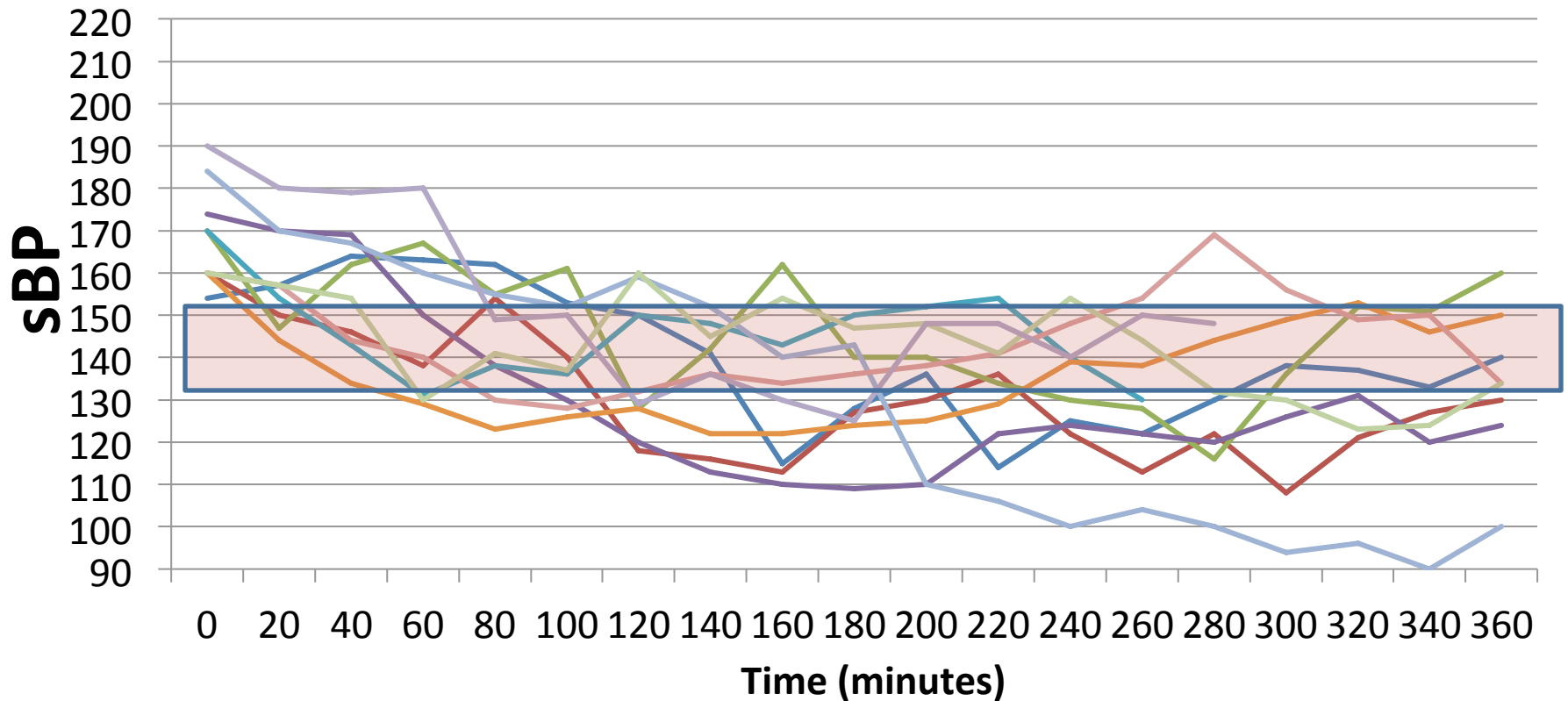
Gynuity HP oral antihypertensive trial



- **Site**
 - Nagpur, India
- **Individual patient open-label RCT for women with severe pregnancy hypertension**
- **Pilot phase (dose finding) & Definitive phase**
 - **Comparing:**
 - Oral nifedipine (10mg)
 - Oral labetalol (200mg)
 - Oral methyldopa (1000mg)
- **1^o outcome**
 - BP within the target range at 6h without an adverse outcome

Nifedipine (sBP)

Case 1 Case 2 Case 3 Case 4 Case 5
Case 16 Case 17 Case 18 Case 19 Case 20

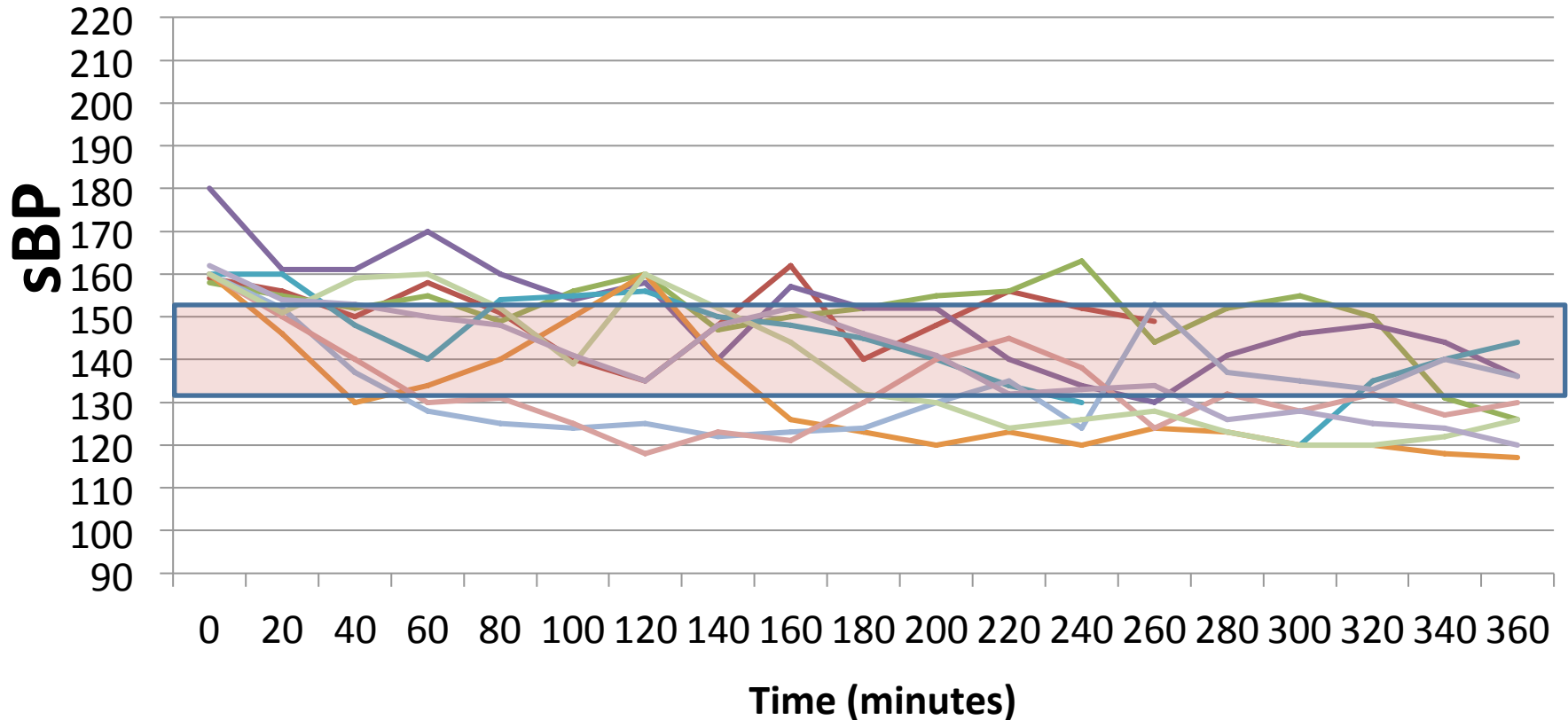


*Note: Case 2 received a second additional antihypertensive

Treatment goal (130-150 mmHg systolic)

Labetalol (sBP)

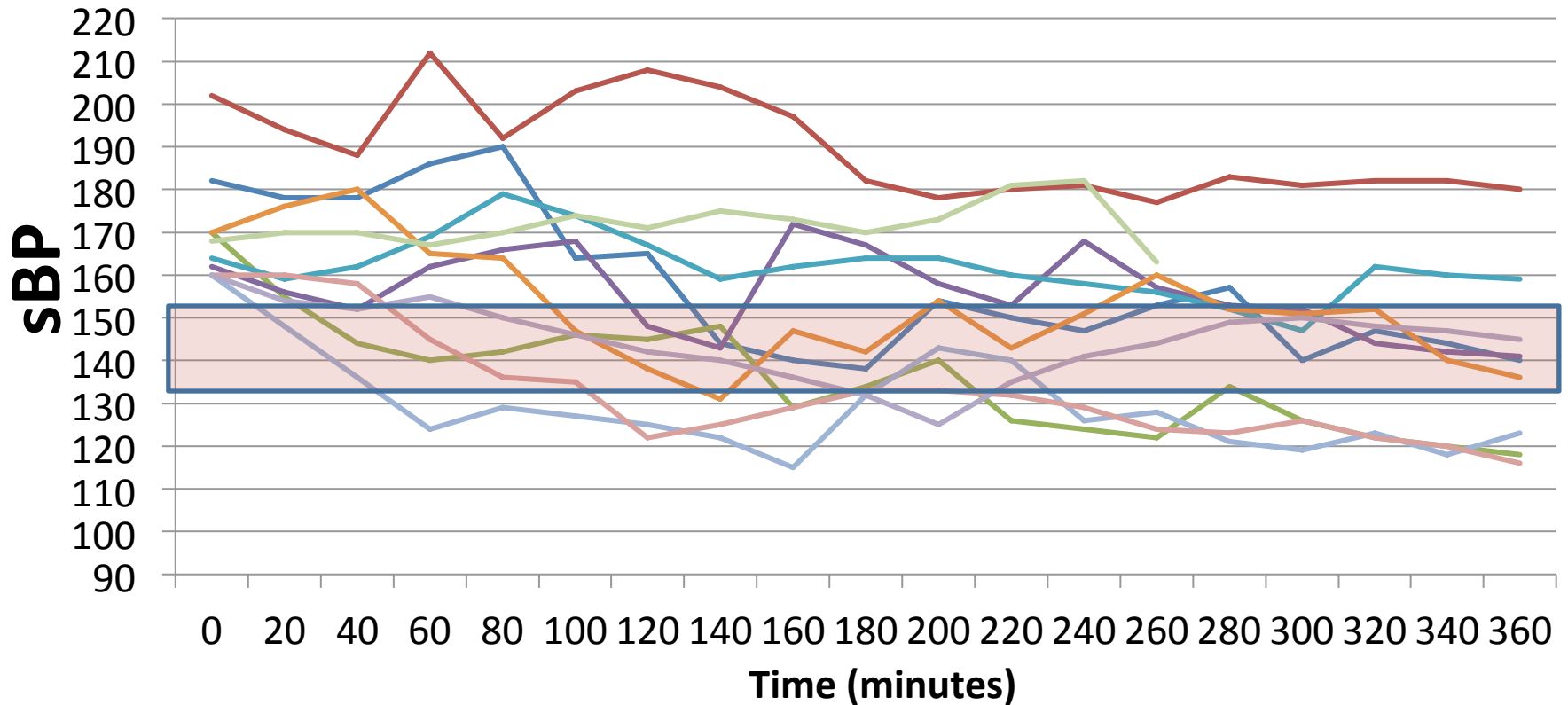
Case 6 Case 7 Case 8 Case 9 Case 10
Case 21 Case 22 Case 23 Case 24 Case 25



Treatment goal (130-150 mmHg systolic)

Methyldopa (sBP)

Case 11 Case 12 Case 13 Case 14 Case 15
Case 26 Case 27 Case 28 Case 29 Case 30



*Note: 5 cases (# 12, 14, 15, 29, 26) received a second additional antihypertensive



Treatment goal (130-150 mmHg systolic)

Gynuity HP oral antihypertensive trial



- **Definitive trial – approvals granted in January 2015**
 - Drug Controller General of India
 - ICMR
- **Recruitment to start this month**
- **Target recruitment: 671 women**
 - nifedipine: 298 women
 - labetalol: 298 women
 - methyldopa: 75 women
- **1^o outcome**
 - **Successful outcome will be considered blood pressure that reaches the target (defined as sBP 130-150mmHg and dBP 80-100 mmHg) at 6h without an adverse outcome**
 - **Adverse outcomes include:**
 - Hypotension (sBP <120mmHg and/or dBP <70mmHg and fetal compromise)
 - Caesarean section for fetal distress
 - Severe headache
 - Severe headache requiring discontinuation of drug
 - Eclampsia

Global Pregnancy Collaboration

PI: Jim Roberts

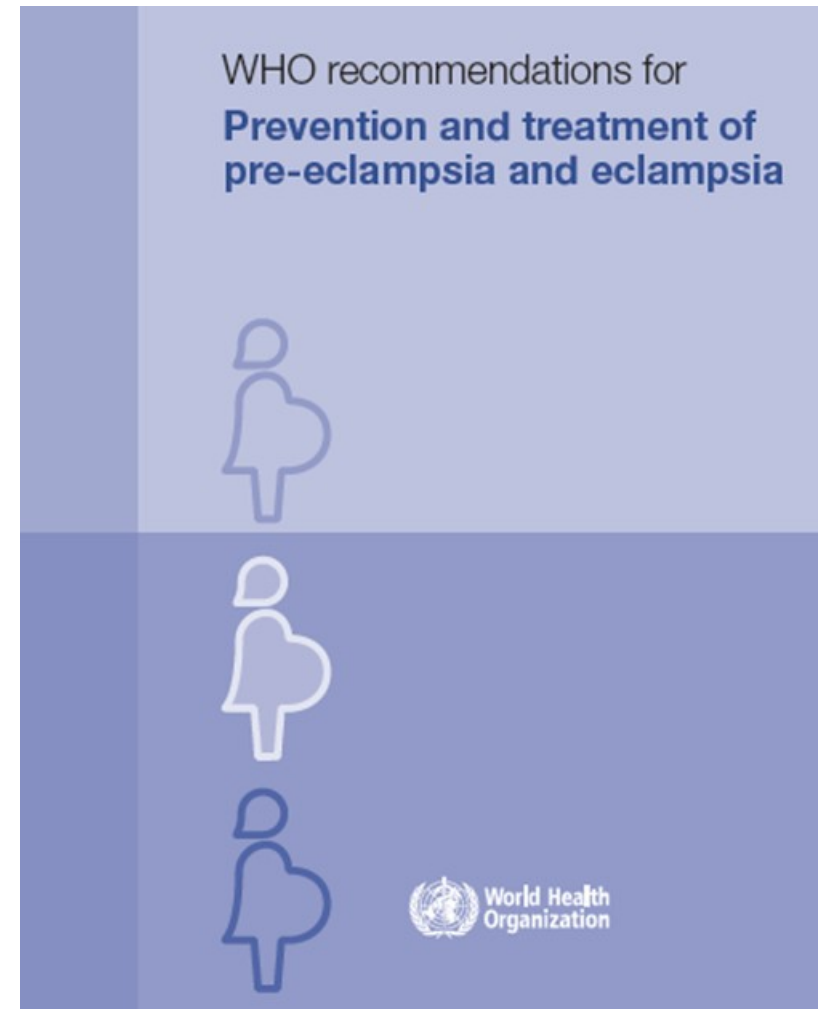


- **A consortium of 35 academic groups to advance the understanding and to improve care of pre-eclampsia and other adverse pregnancy outcomes**
 - Risk assessment
 - Prevention
 - Inform appropriate research strategies
- **Approach used extensively in cancer and cardiovascular research**
 - Bring together groups with data and biological samples
 - Pool resources
 - Allows questions to be answered that could be done in no other way
- **More from Jim later ...**

Knowledge translation

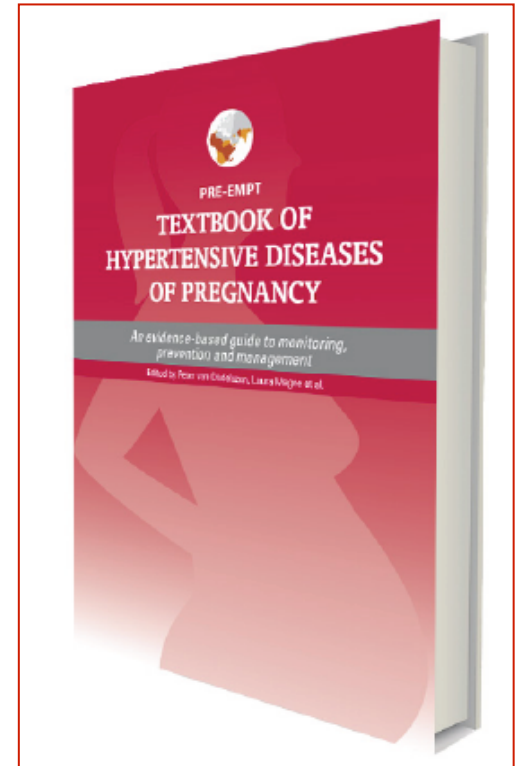
PI: Matthews Mathai

- **WHO recommendations**
 - Published 2011
- **Preeclampsia Foundation**
 - CEO, Eleni Tsigas
 - Support the Foundation's mandate, particularly outreach to women, families and clinicians in LMICs



GLOWM – HDP textbook

- **Use 2014 SOGC HDP guidelines as basis for GLOWM textbook**
 - Adapted from PPH textbook approach
 - Broaden recommendations for LMICs
 - Add content to increase LMIC relevance
 - Use CLIP set of images
 - CLIP wallchart will be produced by Sapiens/GLOWM – and modified for the textbook if found useful
 - Include material from other recent evidence-based guidelines
 - WHO, NICE, ACOG, NVOG
 - Free to purchasers in LMICs

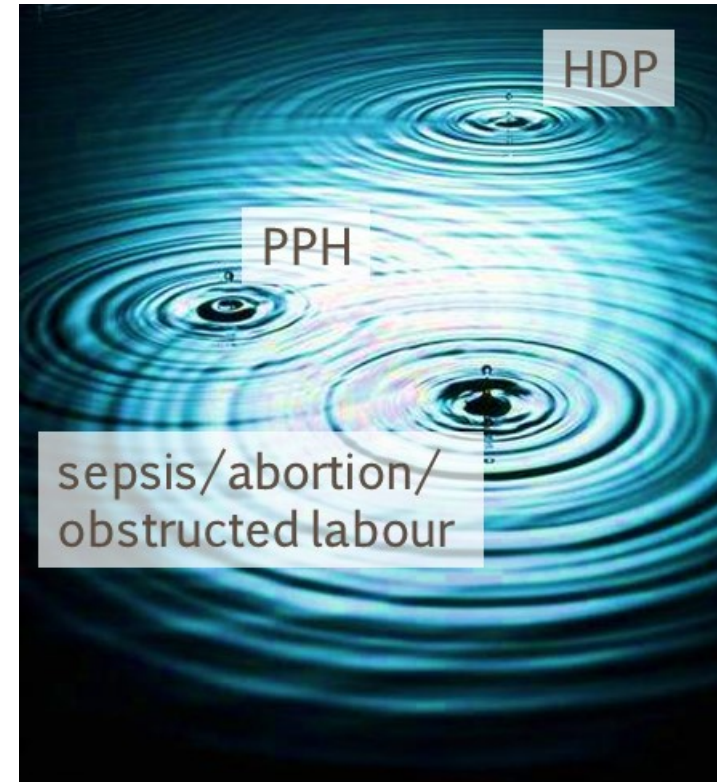


Long-term goals

That the component studies of the PRE-EMPT initiative, and their follow-up activities, prove effective, and reduce the burden of

- Life-ending
- Life-altering (e.g., stroke)
- Life-threatening (e.g., sepsis)

complications that make the HDP, and the hypotensive disorders of pregnancy, so important



Acknowledgements



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Organization**



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Thanks

Weebale Nnyo

Obrigado

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Gracias

مہربانی

Kani Mambo

Vinaka vaka levu

