



May 15, 2016 1030-1215 pm

# Harm and Safety: Improvement in Women's Health

Sue Gullo RN, MS Director IHI

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*Quality Improvement Consultant / Health Foundation IHI Fellow 2006-2007* 

# Introductions

Sue Gullo



#### • Annette Bartley



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# Session overview

- Pregnancy and childbirth are a critical time in not only the woman's health, but that of her family and new-born. It is, however, only a snapshot in the lifespan of a woman.
- This session will explore the impact the social determinants of health have on health, and will provide an overview of key safety interventions to address key clinical obstetric and neonatal events that impact health and outcomes.

# Session objectives

- Describe the social determinants of health and the impact on the health of women and newborns.
- Discuss key safety interventions to address adverse pregnancy and neonatal outcomes in the United States and other countries.
- Discuss how these interventions can be introduced.

# Public Health

- Public health is a broad subject that arguably embraces all aspects of our lives from the air we breathe, the food we eat, the place we live in, work and leisure as well as our genetic, ethnic and cultural heritage.
- All these factors contribute to overall health.
- In order to create the best possible outcomes for women and babies we need to take the wider social determinants of health into consideration as we design our healthcare service.
- Health promotion plays a key factor.

#### What are social determinants of health?

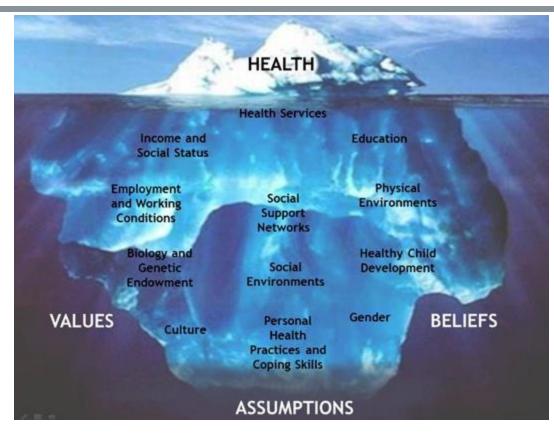
 The social determinants of health are the conditions in which people are born, grow, live, work and age. These circumstances are shaped by the distribution of money, power and resources at global, national and local levels. The social determinants of health are mostly responsible for health inequities - the unfair and avoidable differences in health status seen within and between countries.





Figure 1. The Health Map: determinants of health and well-being From Barton, H. and Grant, M. (2006). A health map for the local human habitat. The Journal for the Royal Society for the Promotion of health, 126(6), pp 252-253. ISSN 1466-4240

# Lets begin with the bigger picture



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# Public health message- Dubai



< The Public Health & Safety Department has initiated a public service campaign to warn children & pregnant women from entering cafes with creative messages hung on all the cafes' doors in Dubai. The messages will be addressed by the fetus or children & aimed towards the parents... smoking is your choice... not mine

< Door-sized posters publicising the campaign have been plastered on cafe entrances across the emirates where people go to smoke the hookah pipes

# IHI's Innovation Work

AIM:

To develop a population approach to *reduce preterm births* among Medicaid (women receiving insurance through the government supported plan) recipient women

# Methods

- Evidence scan
- 50+ expert interviews/site visits across 20 states to identify best practices
- Expert design meeting
- Validate theory of change and bundle of interventions
- Prototype test bundle of interventions with one community

# Risk factors for preterm birth

#### **Clinical risk factors**:

- A previous history of pre-term birth
- Multiple gestation
- Short interval between pregnancies
- Cervical length measured during pregnancy
- Age (<16 or >35)
- Positive fetal fibronectin
- Hypertension
- BMI (underweight or overweight)
- Renal disease
- Anti-phospholipid syndrome
- Antenatal depression
- Genital tract infections
- Preterm rupture of membranes
- Antepartum haemorrhage
- Other

#### Social/structural risk factors:

- Late care enrollment/inadequate prenatal care
- Tobaccouse
- Maternal income
- Maternal education
- Maternal stress
- Marital status
- Unstable housing
- Other

# Clinical and social interventions to reduce preterm birth

#### **Clinical interventions:**

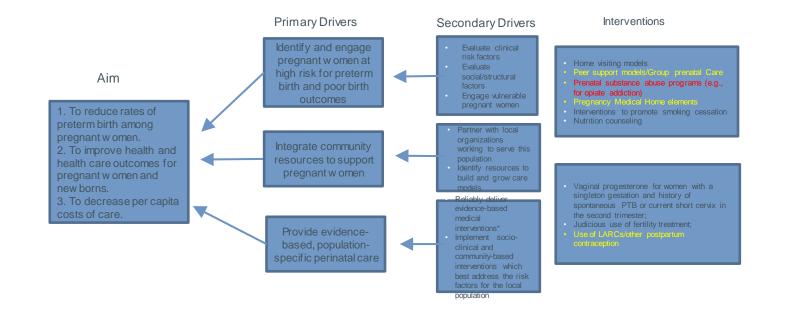
- Progesterone for women with a singleton gestation and a history of spontaneous PTB;
- Vaginal progesterone for women with a singleton gestation and current short cervix in the second trimester;
- Consideration of cerclage for women with a singleton gestation and a history of a prior spontaneous PTB and a current short cervix, particularly if the length is <15 mm;</li>
- Elimination of elective inductions before 39 weeks;
- Evidence-based management of other major risk factors (e.g., preeclampsia management, pharmacotherapy to address heavy smoking)
- Judicious use of fertility treatment
- Other

#### Socio-clinical interventions:

More evidence:

- Group antenatal care
- Some home visiting models
- Psychosocial interventions to promote smoking cessation
- Midwife-led continuity models
- Nutrition counseling
- Maternity medical home model
- Other

# **Theory: A Population Approach**



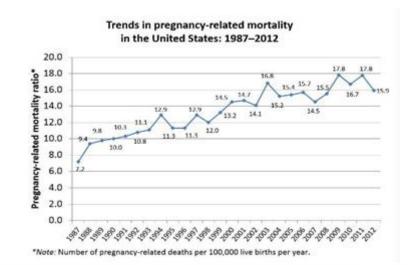
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# **Bundle of Interventions**

- Maternity medical home model
- Peer support (including group prenatal care)
- Integration of substance use treatment and perinatal care
- Shared decision making around pregnancy intention

# Testing our theory: lessons learned

- Spectrum of pregnancy intention
- Closing the disparity gap
- Maternal outcomes



# Next steps: Prototype testing

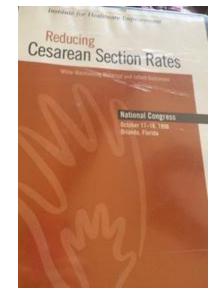
- Partnership with Detroit WIN Network and HFHS
- Co-design community intervention based on interventions
- 9-month prototype test



## A Historical Reflection 1995-2016

1995 BTS Improving Maternal and Neonatal Outcomes:

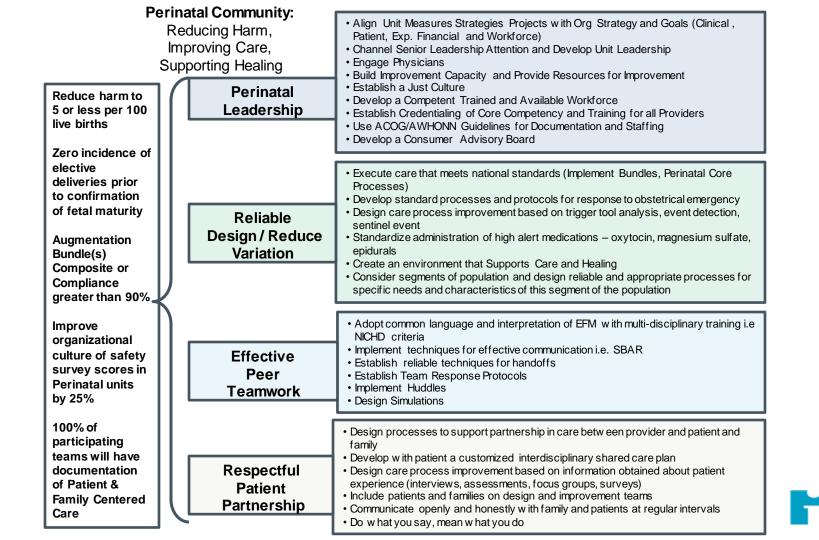
 Reducing Cesarean Section Rates National Congress



Innovation (2003-2006) Community (2009 – 2014)	IMPACT (2006 – 2009)	Perinatal Improvement			
AIM: Reduce birthtrauma and risk by innovative designand testing by February 2006.	AIM: <i>Reduction of Harm Outcome Measure-Perinatal Adverse Events</i>	AIM: Reducing Harm, Improving Care, Supporting Health International Teams joined Community (2009-2014) Expedition: Improving Perinatal Safety The Oxytocin Bundle (2010)			
Expert Meeting (2003)	White Paper (2006)	Faculty Team expanded: PIC Hospital Members (2010)			
Developed idealized Design Concept Diagram (2004)	Launch Perinatal IMPACT Community (2006) IHI Perinatal Web and Action (2006)	Innovation Workgroup Second Stage Safety (2010) Labor Deep Dive Tool (2010) Revised Driver Diagram -Leadership (2010) Advanced Bundles developed (2010) Birth Outcomes Initiative - Louisiana (2010-2012)			
Oxytocin Bundles Meeting (2004)	Catholic Healthcare West (2006)				
Phase I: Ascension Healthcare/Premier Perinatal Effort (2004)	Mayo System (2006)	International Perinatal Collaborative Guidance: (Scotland &			
	Developed Building Blocks (2007)	Denmark) (2011)			
	Developed Initial Driver Diagram (2007)	Faculty Team expanded: Patient Representative (2011) ACOG Toolkit (IHI oxytocin bundles) (2012)			
Phase II: Ascension Healthcare/Premier Perinatal Effort (2005)	Oxytocin High Alert Medication Deep Dive (2007)	IHI How to Guide: Obstetrical Adverse Events (2012) Obstetrical Sepsis Summit (2012)			
Initial Change Package for OB	VacuumBundle Developed (2008)	NCC Uses Oxytocin Bundles for Certification (2012)			
(2006)	International Perinatal Collaborative Guidance:	Deep Dive Structure Tool (2012) IHI HEN HRET (Perinatal Content) (2012)			
100,000 Lives Campaign – mentor netw ork (OB) (2006)	<ul><li>Wales 1000 Lives Campaign (2007)</li><li>Northern Ireland (2009)</li></ul>				
	IMPACT Ended (8/2009)	Maternity Action Team (2013)			
	PIC initiated (9/2009)	Retired Original Oxytocin Bundles ((2013) Expedition: Treating Maternal Sepsis (2013) Neonatal Advantage Bundle (2013) Late Preterm Infant (2013) Innovation Neonatal Workgroup (2013) Innovation Nulliparous Workgroup (2013) CMS Louisiana Performance Improvement Grant (2013) Maternity Action Playbook: Leadership Driver & Change Package (2014) Critical Incident Coaching (2014)			

	IHI Perinatal Communit	y Care Bundle S	Sequencing		
Elective Induction Bundle	Augmentation Bundle	Augmentation Bundle		IHI Oxytocin Bundles (2004)	
(Initial-Oxytocin)	(Initial-Oxytocin)	(Initial-Oxytocin)			
• GA>39 weeks	<ul> <li>EFW documented</li> </ul>	EFW documented		Basic Oxytocin Bundles Defined as patient who receive	
<ul> <li>Pelvic Assessment</li> </ul>	<ul> <li>Pelvic Assessment</li> </ul>	Pelvic Assessment		Oxytocin for elective induction or a ugmentation. Focus	
<ul> <li>Recognition and managemen</li> </ul>	t of • Recognition and manage	<ul> <li>Recognition and management of</li> </ul>		eliminating elective delivery prior to 39 weeks, adoptic	
ta ch ys ystole	ta ch ys ystole	ta chysystole data a chysystole data chysystole data chysystole data a chysystole da		of team definition and reliable execution of componen	
<ul> <li>Recognition and managemen</li> </ul>		<ul> <li>Recognition and management of FHR</li> </ul>		indicators.	
Status (Category I-normal)	Status (Exclusion of Cates	Status (Exclusion of Category III)			
more than 8 in the nullinarous in	cept 39 weeks as minimal GA for elect atient, the probability of vaginal delive	anv after labor i	nduction is similar	Additional Bundles developed and supported by faculty and Innovati	
to spontaneous labor.Focus mov on (just) Oxytocin. Evidence Base	es to pharmacologic or mechanical ini	itiation of labor	- no longer focused	Workgroups	
Advanced Non-Medically					
Indicated Bundle	Advanced Indicated Induction Bundle	Advanced Aug	mentation Bundle	Vacuum Bundle (2008)	
Defined: Patient without a	Defined: Patient with a medical	Defined:		Alternative labor strategies	
medical indication for delivery.	indication for induction			<ul> <li>Prepared patient</li> </ul>	
		EFW docu	mented	High probability of success	
<ul> <li>Confirmation of term</li> </ul>	Acceptable medical indication for	Pelvic Asse	essment	Maximum application time and	
gestation.	labor induction documented	U	n and managemen		
Pelvic Assessment Favorable	(locally defined)	oftachysy		Exitstrategyavailable	
Bishop Score *(locally	Pelvic Assessment	-	n and managemen	t	
defined)	Recognition and management of		tus (Category I -	Neonatal Advantage Bundle (2013)	
<ul> <li>Recognition and</li> </ul>	complications of induction method	,	of Coto convilui)	<ul> <li>NRP appropriate (vigorous infait</li> </ul>	
management of	(including tachysystole)	- (Exclusion	of Category III)	-41+ w eeks gestation	
complications of induction	Recognition and management of			<ul> <li>Identification of risk of</li> </ul>	
method (including	FHR Status		amniotomy, nipple cupuncture, and	in ection/sepsis	
tachysystole)	Exclusion of Category III FHR	,	cupulicture, allo	Delayed cord clamping	
<ul> <li>Recognition and management of FHR Status (Category I-</li> </ul>	4	Oxytocin)		<ul> <li>Breastfeeding Initiation</li> <li>Delayed bath- (for first hour of li</li> </ul>	
	1			Delayed bath- (101 mist hour of h	
normal)					

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# Perinatal Improvement Community Measurement Strategy



Perinatal Care Measurement Strategy							
	<b>Optional Measures</b>						
Annual / Bi-annual Structure Assessments	Monthly Outcome & Structure Measures	Initial Weekly or Monthly Process Measures	Advanced Weekly or Monthly Outcome and Process Measures	Outcome, Balance or Process Measures			
<u>Oxytocin Deep Dive</u> *	<u>Perinatal</u> <u>Harm</u> *	Augmentation Bundle <u>Composite</u> and <u>Compliance</u> * (Oxytocin)	Vacuum Bundle <u>Composite/Compliance</u> *	Transfer to Higher Level of Care (A) (B)			
	Time Between Elective Deliveries	Elective Induction Bundle <u>Composite</u> and	Advanced Augmentation	Patient and Family Satisfaction			
<u>Culture of</u> <u>Safety Survey</u>	39 wks	<u>Compliance</u> * (Oxytocin)	Bundle <u>Composite</u> / <u>Compliance</u> *	Documentation Reliability ( <u>Infant/Mother</u> )*			
	Elective Delivery Rate prior to 39 completed weeks	Augmentation Induction Monthly Bundle	Advanced Elective Induction Bundle	Time Between (Decision - Incision)			
	gestation (TJC PC.01)	Compliance (Oxytocin)	<u>Composite</u> / <u>Compliance</u> *	Prophylactic Antibiotic in C-section			
Labor Deep Dive*	Cesarean rate for low-risk first birth women			Birth trauma rate measures (NQF)			
	(TJC PC.02)	Elective Induction Monthly Bundle Compliance (Oxytocin)	Advanced Indicated Induction Bundle <u>Composite</u>	Incidence of episiotomy (NQF)			
	Patient and Family Centered Care		/ <u>Compliance</u> *	Gestational Age Reliability (Test Measure)			

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#### **IHI to National Movements**



The American College of Obstetricians and Gynecologists WOMEN'S HEALTH CARE PHYSICIANS



Division of Reproductive Health



Society for Maternal-Fetal Medicine (SMFM)



Maternal Child Health Branch (MCH-B)

#### National Maternal Health Initiative: Strategies to Improve Maternal Health And Safety May 5<sup>th</sup> 2013 New Orleans, LA

# USA, Council on Patient Safety



http://www.safehealthcareforeverywoman.org/secure/home#

### Maternity Safety Bundles: "What every birthing facility should have..."

- Obstetric Hemorrhage Safety Bundle
- VTE Prevention Safety Bundle
- Severe Hypertension Safety Bundle
- Maternal Early Warning Criteria (triggers)
- Safe Reduction of Primary Cesarean Births Bundle
- Patient, Family and Staff Support Bundle

# Use of Current Bundles in the Field

#### Welcome! Cuban Hospital celebrates its 1,000th baby



Tribune News Network

Doha

THE Cuban Hospital (TCH) a member of Hamad Medical Corporation (HMC) has



- Conclusion: The study findings revealed that maternal complications such as gestational diabetes, gestational hypertension, ante-partum hemorrhage, and maternal anemia were significantly higher in older pregnant women.
   Similarly, neonatal complications were higher in the newborns of older women.
- Gestational hypertension was the leading maternal complication observed in Arab women.

**Focus on Severe Hypertension Bundle** 

http://www.jfcmonline.com/temp/JFamCommunityMed20127-7551969\_205839.pdf

# Hypertensive Disorders in Pregnancy What Was Learned

#### The Good

 Excellent prenatal care with close observation for worsening disease and timely intervention can decrease poor outcomes

# Hypertensive Disorders in Pregnancy What Was Learned

#### The Bad

- Preventable severe morbidity or mortality related to poor clinical application of new knowledge regarding:
  - Dynamic nature of preeclampsia
  - Multi-systemic nature of preeclampsia
  - Possibility of post partum worsening or initial presentation of preeclampsia often outside of obstetric care
- The overcommitment to previously taught rigid diagnostic "triad" criteria for preeclampsia

# Hypertensive Disorders in Pregnancy What Was Learned

Recommended changes:

- Classification
- Diagnostic criteria
- Management

# Hypertensive Disorders in Pregnancy Changes in Classification

• PIH	GONE
<ul> <li>Severity of proteinuria</li> </ul>	GONE
<ul> <li>Presence of fetal IUGR</li> </ul>	GONE
<ul> <li>The term "mild" preeclampsia</li> </ul>	GONE

## Hypertensive Emergencies- Management

### Quickly identify and manage

- >160 systolic OR >110 diastolic is considered an hypertensive emergency in pregnancy
  - This should be confirmed within 15 minutes and therapy initiated in order to decrease blood pressure
  - Standardized protocols should be used for treatment, provider notification, fetal and maternal surveillance

## Timing of delivery- management

- Patients with Chronic hypertension without maternal or fetal complications should not be delivered before 38 completed weeks
- Patients with uncomplicated preeclampsia should be delivered at 37 completed weeks

Report of the American College of Obstetricians and Gynecologists' Task Force on Hypertension in Pregnancy: Executive Summary. Obstetrics & Gynecology. 122(5):1122-1131, November 2013.

# Hypertensive Disorders in Pregnancy Conclusions

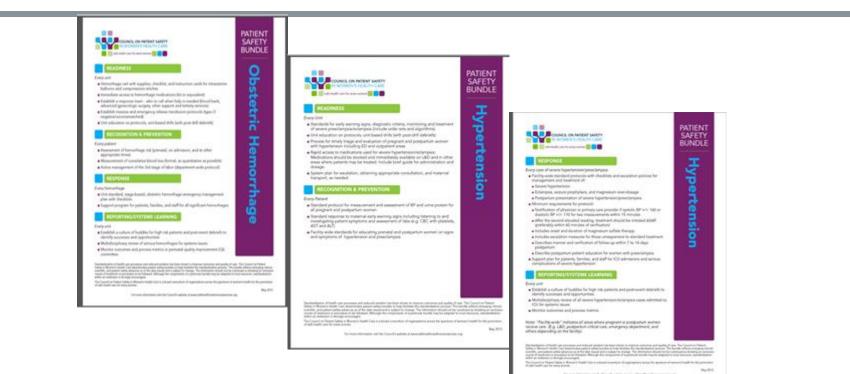
- Preeclampsia is a dynamic disease
- Preeclampsia is a Multi-Systemic disease
- Preeclampsia can initially present or worsen post partum, often outside of obstetric care
- Changes in classification, diagnosis and management are needed to more closely reflect current knowledge of HDP

## Learning in Louisiana - Our AIM together

By September 23, 2016, we will reduce obstetric adverse events by 40% in the following categories:

- 1. Obstetric Hemorrhage Events
- 2. Preeclampsia and Severe Hypertension
- 3. Maintain or further decrease non-medically indicated inductions prior to 39 weeks

## **Pre-work**



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## **Major Resources**

A California Toolkit to Transform Maternity Care

Improving Health Care Response to Obstetric Hemorrhage Version 2.0 A California Quality Improvement Toolkit

March 24, 2015

THIS COLLABORATIVE PROJECT WAS DEVELOPED BY: THE OBSTETRIC HEMORPHAGE TASK FORCE THE CALIFORNIA MATERNAL QUALITY CARE COLLABORATIVE MATERNAL, CHILD AND ADOLESCENT HEALTH DIVISION; CENTER FOR FAMILY HEALTH

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH





CMQCC

CMQCC PREECLAMPSIA TOOLXIT PREECLAMPSIA CARE GUIDELINES CDPH-MCAH Approved 12(2013)

ERRATA 5.13.14 A California Toolkit to Transform Maternity Care

Improving Health Care Response to Preeclampsia: A California Quality Improvement Toolkit

THIS COLLABORATIVE PROJECT WAS DEVELOPED BY: THE PREECLAMPSIA TASK FORCE CALIFORNIA MATERINAL QUALITY CARE COLLABORATIVE MATERINAL CHILD AND ADDLESCENT HEALTH DWINKINK CENTER FOR FAMILY HEALTH

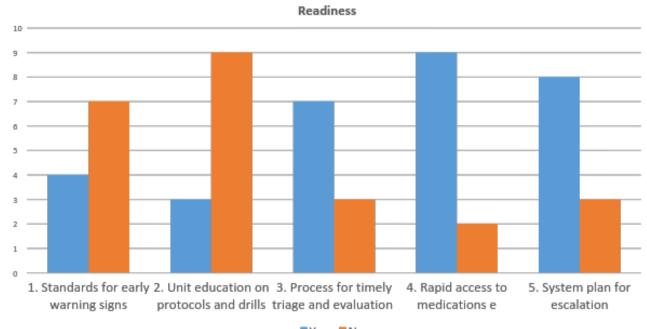


CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

## **Results So Far**

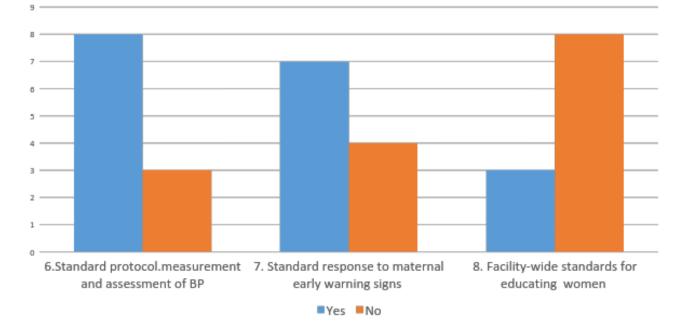
Designing the work for the Louisiana Sites



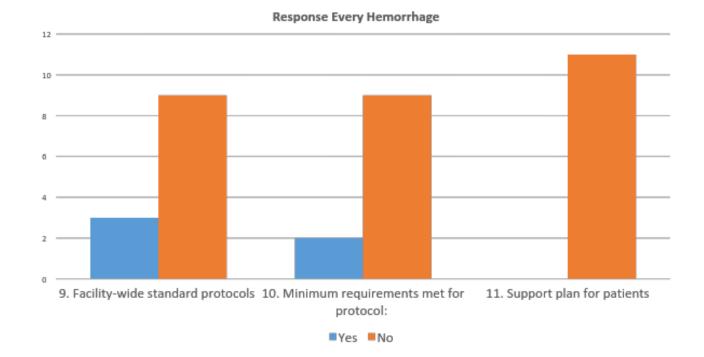


■Yes ■No

Recognition and Prevention (every patient)



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#### Structure

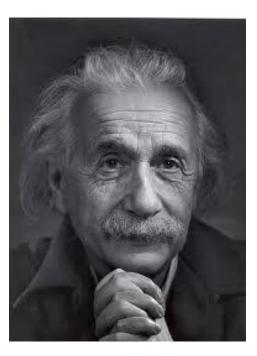
Reporting/Systems Learning (every unit)	YES	NO
S1. Establish a culture of huddles for high risk patients and post- event debriefs to identify successes and opportunities	5	6
S2. Multidisciplinary review or all severe hypertensive/eclampsia cases admitted to ICU for systems issues	5	6
S3. Monitor outcomes and process metrics	7	4

## Designing for reliability

- Every system is perfectly designed to get the results it gets *Batalden*
- Is your system designed to achieve best possible outcomes for women and children?
- How do we begin to transform and improve our systems and processes in order to achieve best outcomes?

## Einstein

#### Doing the same over and over again and expecting different results



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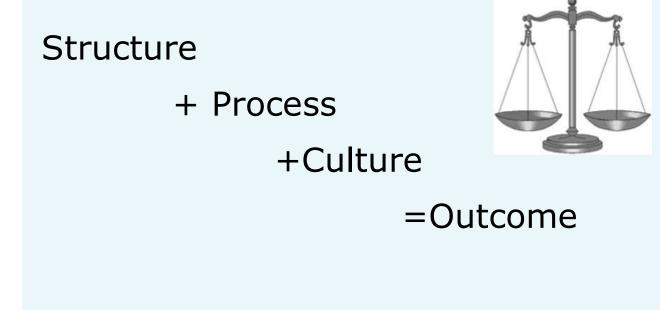
## Keep it simple!

'That's been one of my mantras" focus and simplify. Simple can be harder than complexity: you have to work hard to get your thinking clean to make it simple. But it's worth it in the end because once you get there you can move mountains' Steve Jobs

Steve Jobs 1955-2011



# We need a framework for improvement



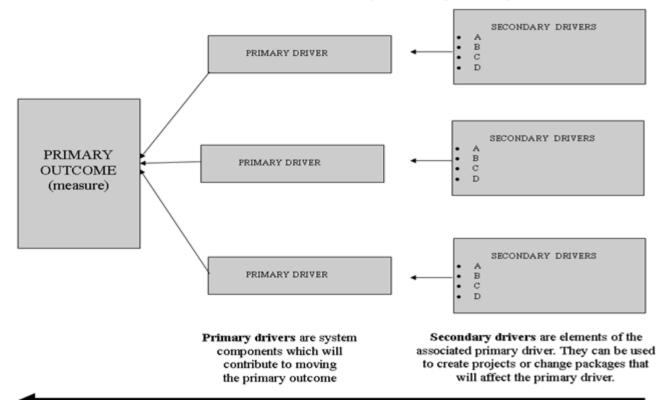
\*Added to Donabedian's original formulation by R. Lloyd and R. Scoville.

Driver diagram template

Institute for Healthcare

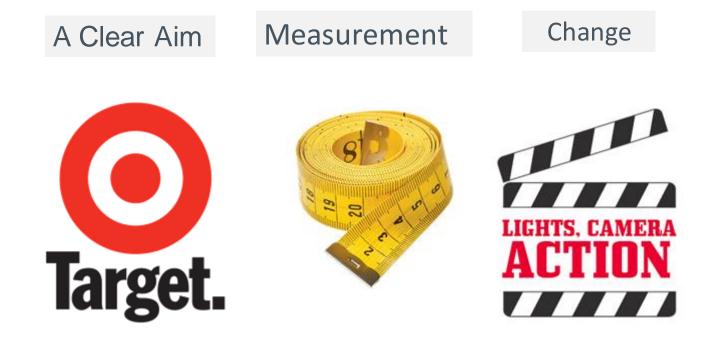
Improvement

**Definition**: A driver diagram is used to conceptualize an issue and determine its system components which will then create a pathway to get to the goal





### Improvement requires...



## Scotland- Social and lifestyle

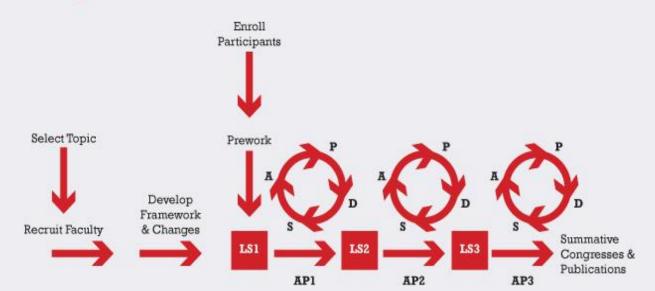
- factors 2009 ISD data
  - 14741-25% babies born into areas of highest deprivation in Scotland
  - **18.1%** of pregnant women reported smoking at booking



## The Scottish Patient Safety Maternity Programme

Dr Patricia O'Connor Dr Pauline Lynch

#### **Breakthrough Series Collaborative Model**



#### Key

LS1 Learning Session AP Action Period P-D-S-A Plan-Do-Study-Act

#### Supports

Email Visits Phone Conferences Monthly Team Reports Assessments

Reference: Institute for Healthcare Improvement, Boston, MA, USA (www.ihi.org)

## Scotland- Using the data to improve

Mortality in child birth

- 20% of women who died were either first booked for antenatal care after 20 weeks gestation.
- Had missed over four routine antenatal appointments,
- Or
- Did not seek care at all
- CMACE Saving Mothers Lives 2007



## Maternity care collaborative

The overall aims of the Maternity Care strand are to:

 Increase the percentage of women satisfied with their experience of maternity care to > 95% by 2015, and reduce the incidence of avoidable harm in women and babies by 30% by 2015.

Avoidable harm is defined by the further sub aims to:

- reduce stillbirths and neonatal mortality by 15%
- reduce severe post-partum haemorrhage (PPH) by 30%
- reduce the incidence of non-medically indicated elective deliveries prior to 39 weeks gestation by 30%
- offer all women carbon monoxide (CO) monitoring at the booking for antenatal care appointment
- refer 90% of women who have raised CO levels or who are smokers to smoking cessation services, and
- provide a tailored package of antenatal care to all women who continue to smoke during pregnancy.

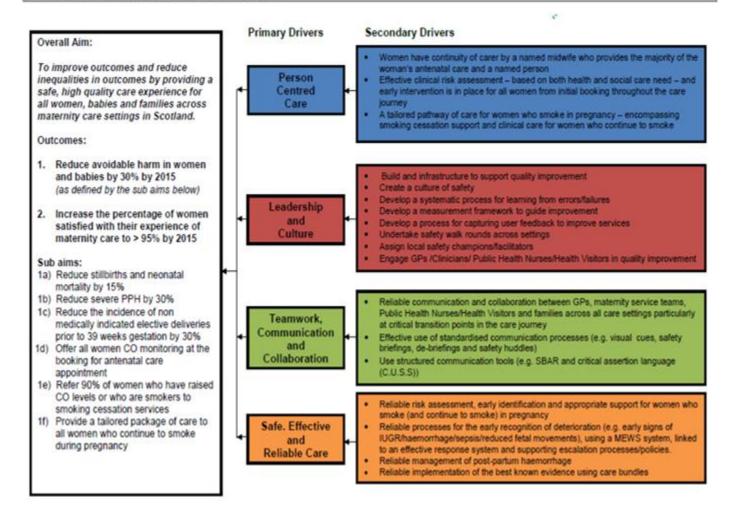
## Avoidable harm is defined

- reduce stillbirths and neonatal mortality by 15%
- reduce severe post-partum haemorrhage (PPH) by 30%
- reduce the incidence of non-medically indicated elective deliveries prior to 39 weeks gestation by 30%
- offer all women carbon monoxide (CO) monitoring at the booking for antenatal care appointment
- refer 90% of women who have raised CO levels or who are smokers to smoking cessation services,
- provide a tailored package of antenatal care to all women who continue to smoke during pregnancy.





#### Appendix 1: Maternity Workstream Driver Diagram



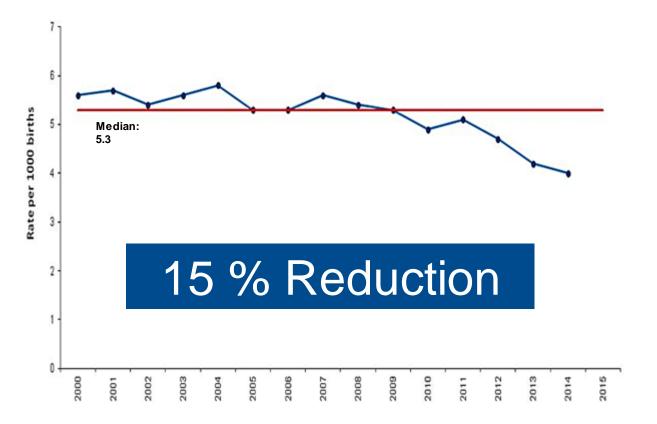
## Scottish Patient Safety Programme

**Overarching Driver Diagram** 

#### Safe and Effective Care

file:///C:/Users/Annette/Desktop/MEF%202016/Maternity%20Care%20-%20Safe%20Effective%20Reliable%20Care%20Driver%20Diagram.pdf

#### Run chart showing annual Scottish stillbirth rate (per 1000 births) 2000 to 2014, NRS





# Reliability does not happen by accident, it happens by design.

## **Definition of** *Reliability* for Health Care:

# Failure free operation over time

David Garvin Harvard Business School



The probability that a system, structure, component, process or person will successfully provide the intended functions

you can't describe what you are as a process, you don't know you're doing - W. Edwards Dem

A process is the action point for reliability. When an effective process become highly reliable, the outcomes will follow as long as they are connected to science.

## Framework for Reliable Design

- Process reliability is linked to outcomes by science
- Initial focus needs to be on reliability of process not outcomes
- > What are the key steps in your process?
- Identify potential defects
- Articulate this process clearly to all
- Assign roles and responsibilities
- Measure process compliance and feedback progress
- > All or none



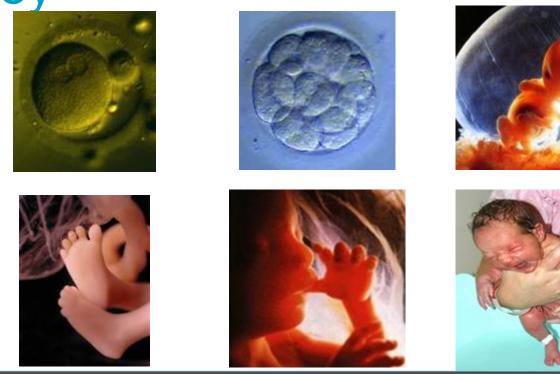




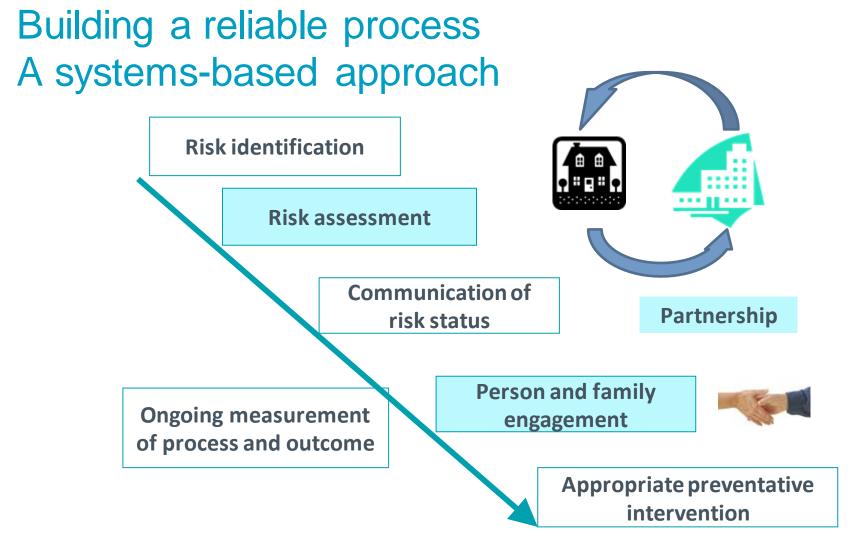
 "When applied to clinical processes consider the viewpoint of the patient by invoking the <u>all or</u> <u>none</u> measure."

**IHI Innovation Team** 

# Segmentation of the iourney



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## Real Time Data for Improvement –

#### RISK ASSESSMENT AND SSKIN CARE BUNDLE COMPLIANCE

Compliance	•	Non-compliance	••
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WARD:1 DATE: 01.1.11 TIME: 14.00

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Total %
Risk Assessment	V	V	V	V	х	80%

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Total %
Surface	~	1	V	1	х	80%
Skin Inspection	1	1	V	V	х	80%
Keep Moving	~	1	V	~	х	80%
Incontinence	~	1	V	~	х	80%
Nutrition	1	х	х	1	х	40%
Compliance / Non-Compliance	$\mathbf{C}$			$\mathbf{\odot}$	-	
Total %	100%	0%	0%	100%	0%	40%

## Reliable risk assessment of mother

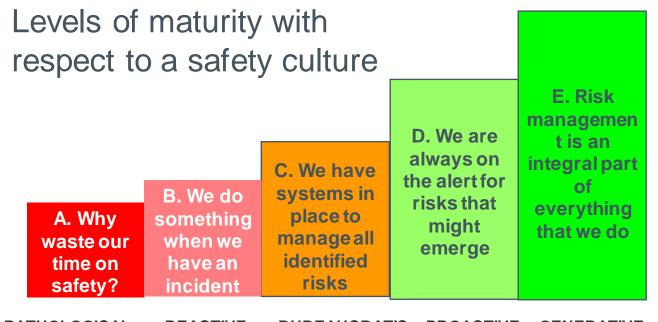
Components	1	2	3	4	5	Total compliance
1. First antenatal appointment no later than weeks						
2. Risk assessment for high risk (smoking, obesity, pre-existing conditions, asthma, bleeding/diabetes)						
3. Effective communication of risk status						
4. Preventative strategies in place to minimise risk						
5. Alert /escalation process						
Individual component compliance						

## Vive la Difference!



- No matter how well designed you think your care processes are the fact is that 'to err is human'
- Human factors will always prevail
- Hence you need to design into the process a safety net/ back up system that will ensure that should there be a human error, the system will be able identify the issue and intervene to avoid harm/error

## Manchester Patient Safety Framework



PATHOLOGICAL REACTIVE BUREAUCRATIC PROACTIVE GENERATIVE

THE MOST RELIABLE WAY TO PREDICT THE FUTURE IS TO CREATE IT.

**ABRAHAM LINCO** 

## In summary, we discussed

- The social determinants of health and the impact on the health of women and newborns.
- Key safety interventions to address adverse pregnancy and neonatal outcomes in the United States and other countries.
- How these interventions can be introduced.

## Questions?





## **Thank You!**

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