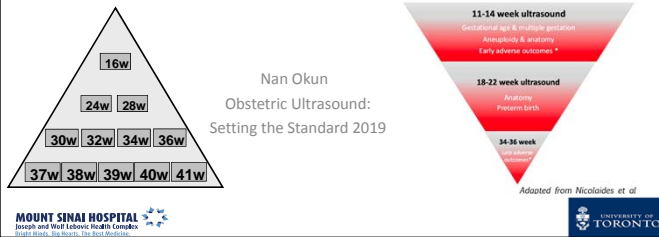


Obstetric Screening in 2019



Disclosures

- I have no conflicts of interest to declare



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Learning Objectives

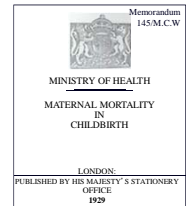
- To challenge the *current* concept of prenatal screening within an outdated model of prenatal care
- To propose modernization of prenatal screening in a more contemporary model of prenatal care
 - Build on foundation of screening for Down syndrome for Great Obstetric Syndromes
 - Preeclampsia
 - Preterm birth

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Traditional Prenatal Care

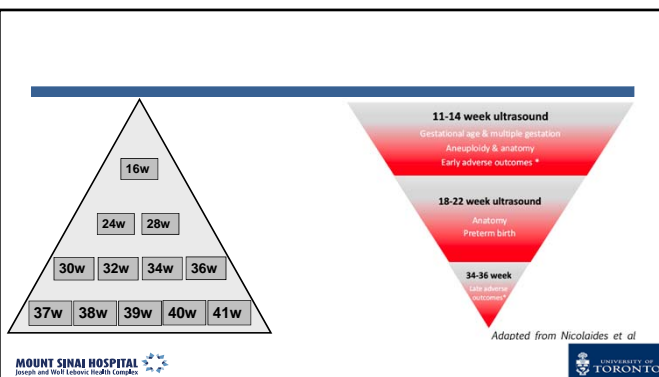
- "Antenatal care....originated from models developed in Europe in the early decades of the past century"
 - "As medical knowledge and technology have evolved, new components have been added..."
 - "There have also been shifting patterns, and power struggles between obstetricians, primary care physicians and midwives, in who delivers...antenatal care for low-risk women..."
- Cochrane Review comparing Alternative vs Standard
Packages of Antenatal care: 16 July 2015



Memorandum on Antenatal Clinics, Ministry of Health in the UK, 1929

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The first trimester of pregnancy

- Has changed from a trimester to "get through" to access expert care to an opportunity to educate, assess and triage ongoing pregnancy care

GUEST EDITORIAL

Prevention = Pre-Conception Counselling



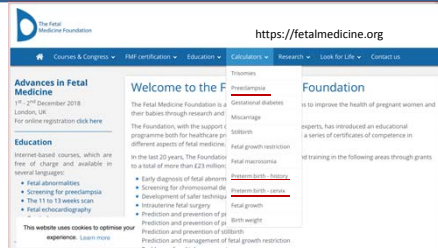
R. Douglas Wilson, MD, MSc
Department of Obstetrics and Gynecology, Cumming School of Medicine, University of Calgary, Calgary, AB

R. D. Wilson

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Population Screening for the Great Obstetrical Syndromes



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Characteristics of a Screening Test

Characteristics of a Screening Test

Condition should be important

Should be a reliable test for the condition

Facilities for diagnosis and treatment available

Should be latent or asymptomatic phase

Effective treatment

Test should be acceptable to population

Natural history should be understood

Should be agreement on who to treat

Cost effective

NO1

Wilson JM, Jungner G. The principles and practice of screening for disease. Geneva, Switzerland: World Health Organization; 1968. (Public Health Papers no. 34)

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Condition should be Important

Down syndrome

1/800 (0.1%)

Preeclampsia

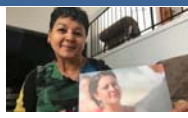
<1-8%

14-20% maternal deaths, 40% of fetal mortality (WHO)

Preterm Birth

8%

Remains most important cause of neonatal morbidity/mortality



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PREECLAMPSIA

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Is there an effective treatment?



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PREVENTION OF PRE-ECLAMPSIA BY EARLY ANTIPLATELET THERAPY

M. BEAUFILS
R. DONSIMONI

S. UZAN
J. C. COLAU

THE LANCET, APRIL 13, 1985

RCT 102 patient at high risk for PE randomized to Group A (300 mg dipyridamol/150 mg ASA) or group B (no treatment)

TABLE II—OUTCOME OF PREGNANCY

	Group A (n=48)	Group B (n=45)	p
Normal pregnancy	29	12	<0.005
Hypertension (isolated)	19	22	NS
Pre-eclampsia	0	6	<0.01
Fetal and neonatal loss	0	5	<0.02
Severe IUGR (live births)	0	4	<0.05

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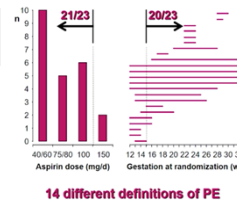
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Antiplatelet agents for prevention of pre-eclampsia: a meta-analysis of individual patient data Lancet 2007

- 32,217 women in 31 RCT's (ASA 23)
- RR for PE: 0.90 (95% CI 0.84-0.97)
 - RR < 34 w: 0.90 (95% CI 0.83-0.98)

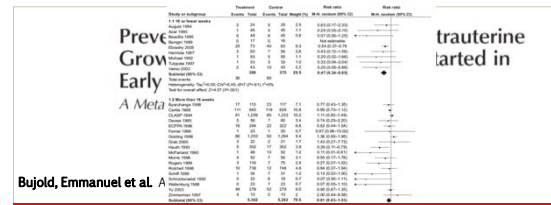
Interpretation

Antiplatelet agents during pregnancy are associated with moderate but consistent reductions in the RR of PE, PTB <34 w and serious adverse outcome



Lisa M Askie, Lelia Duley, David J Henderson-Smart, Lesley A Stewart, on behalf of the PARIS Collaborative Group*

Prevention of preeclampsia



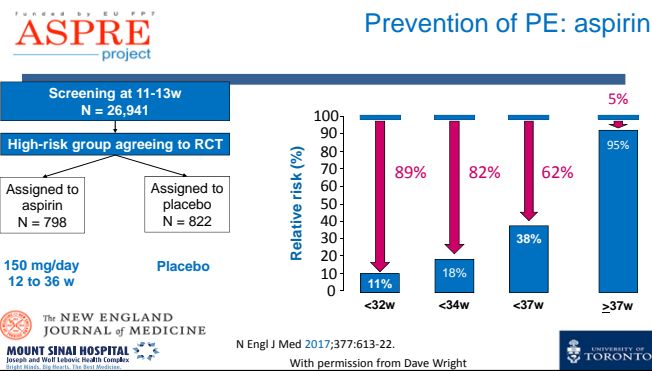
Bujold, Emmanuel et al. A

Low-dose aspirin started at 16 weeks or earlier was associated with a significant reduction in preeclampsia (relative risk [RR] 0.47, 95% CI 0.34–0.65)

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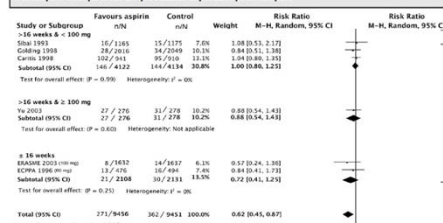
Prevention of PE: aspirin



Aspirin for the prevention of preterm and term preeclampsia: systematic review and metaanalysis

Stephanie Robarge, PhD; Emmanuel Bujold, MD, MSc; Kypros H. Nicolaides, MD

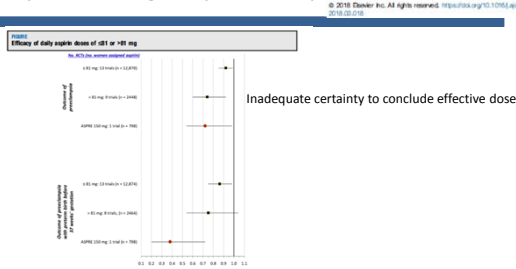
FIGURE 4
Forest plot on aspirin for the prevention of preterm preeclampsia



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Optimal aspirin dosing for preeclampsia prevention



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Associations between the timing and dosing of aspirin prophylaxis and term and preterm pre-eclampsia

- Bujold review is insufficient evidence to restrict ASA to <16 weeks, or to increase dosage to >100 mg.
- ASPREE trial "welcome addition" but only compared one dose and one start time
- RCT's directly comparing timing and dosing are needed

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Lisa Askie, Lelia Duley
10.1136/bmjebm-2018-110931

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Reliable Test for Condition: Current Screening Guidelines

NICE (2010) ¹⁸	WHO (2011) ²⁰	ACOG (2013) ¹⁴
Previous hypertensive disease during a pregnancy*	Previous preeclampsia	Previous preeclampsia
Chronic kidney disease	Renal disease	Chronic renal disease
Autoimmune disease (including SLE/APS)	Autoimmune disease	SLE
Type 1 or type 2 diabetes	Preexisting diabetes mellitus	Preexisting diabetes mellitus
Chronic hypertension	Chronic hypertension	Chronic hypertension
Multiple pregnancy	Multiple pregnancy	Multiple pregnancy
Nulliparity		Primiparity
Age 40 years or older		Age 40 years or older
Pregnancy interval of more than 10 years		
Body mass index of ≥ 35 kg/m ² at booking		Obesity
Family history of preeclampsia		Family history of preeclampsia

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How do NICE guidelines perform?

- Screening Program for Preeclampsia Study (SPREE)
- Comparison of screen by NICE guidelines to screen by “mini combined test” of FMF (maternal factors, MAP, PAPP-A) for any preeclampsia holding PR constant for both
- Women on ASA (4.5% of 16747) per NICE or other reasons accounted for in statistics

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Ultrasound Obstet Gynecol 2018; 51: 743–750.

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How do NICE guidelines perform?

	NICE (%DR for 10% PR)	FMF Mini Test (maternal factors, MAP, PAPP-A) (%DR for 10% PR)
Any PE	30	42.5
Preterm PE	40.8	53.5

- Add PLGF and UtA-PI: DR 82.4%

23% NICE pos women took ASA

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Ultrasound Obstet Gynecol 2018; 51: 743–750.

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How many women appropriately receive low dose ASA?

Table. Rates of ASA prophylaxis for preeclampsia in the current and other published observational studies

First author/reference	Setting, era	Study design	Participants assessed or surveyed	Number of participants included	Rate of ASA prophylaxis (%)
Wide-Svensson ²	Sweden, 1992	Questionnaire	Obstetricians surveyed about ASA use in women with mild hypertension	79	8
			Obstetricians surveyed about ASA use in women with severe hypertension	79	20
Khedun ³	South Africa, 1996–1997	Questionnaire	Obstetricians surveyed about ASA use in women with chronic hypertension	425	58
Hellmann ⁴	717 childbirth clinics in Germany, era not reported	Questionnaire	Obstetricians surveyed about ASA use in women with moderate or severe hypertension	717	38.1
Chappell ⁵	25 hospitals in the UK, 2003–2005	Analysis of a database from randomized clinical trial	Pregnant women at high risk for preeclampsia	2399	24
Current study	Single hospital, Toronto, 2012–2015	Retrospective cohort study	All consecutive pregnant women Subset of pregnant women at high risk for preeclampsia	8672 1727	3.0 7.6

ASA, aspirin.

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J Obstet Gynaecol Can 2017;39(7):722–723

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Screening for Down Syndrome: Bayes Theorem

Posterior \propto Prior
 \times Likelihood

Reverend Thomas
Bayes: 1702–1761

Maternal history: *a priori* risk

+

Biophysical markers

+

Biochemical markers

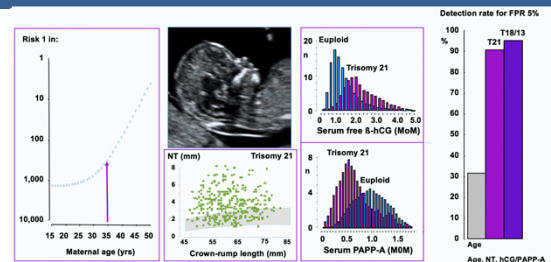
Adjusted risk

Nicolaides et al

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Screening for aneuploidies: The first trimester combined test (FTS)

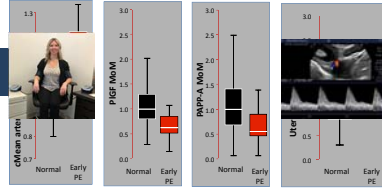


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T1 Combined Marker Screen for Preeclampsia

- Mat Demographic Factors
- History



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Poon et al. 2009



How well does T1 multiple marker screen for PE work?

- 3 independent cohort studies with blinding to results, no intervention
- Combined cohort size: n = 61,174

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With permission from Dave Wright



Performance of screening: DR for a 10% screen positive rate

TABLE 2
Performance of screening, with 95% confidence interval, for early-PE, preterm-PE, and all-PE by the triple test in the 3 data sets

Method of screening	Discrimination		Calibration	
	AUROC curve	DR for 10% SPR	Slope	Intercept
Early-PE				
Training set	0.95 (0.93, 0.97)	87 (80, 92)	0.92 (0.84, 1.01)	0.05 (-0.14, 0.23)
SQS	0.97 (0.95, 0.99)	93 (76, 99)	0.98 (0.80, 1.17)	0.05 (-0.38, 0.48)
SPREE	0.96 (0.93, 0.98)	90 (78, 96)	0.92 (0.79, 1.04)	0.45 (0.16, 0.73)
Preterm-PE				
Training set	0.91 (0.89, 0.93)	75 (70, 80)	0.95 (0.89, 1.02)	-0.19 (-0.32, -0.07)
SQS	0.93 (0.89, 0.96)	75 (62, 85)	1.00 (0.85, 1.15)	-0.19 (-0.47, 0.09)
SPREE	0.93 (0.92, 0.95)	83 (76, 89)	1.05 (0.95, 1.15)	0.17 (-0.01, 0.35)
All-PE				
Training set	0.83 (0.81, 0.84)	52 (49, 55)	1.07 (1.02, 1.12)	-0.57 (-0.64, -0.50)
SQS	0.82 (0.80, 0.85)	49 (43, 56)	1.06 (0.94, 1.17)	-0.44 (-0.58, -0.29)
SPREE	0.85 (0.83, 0.87)	53 (49, 58)	1.17 (1.08, 1.26)	-0.41 (-0.52, -0.31)

AUROC, area under the receiver operating characteristic; DR, detection rate; SQS, systematic lupus erythematosus; SPREE, Superior Prenatal Risk-Stratification and Early Detection of Preeclampsia; SQS, screening quality study.

Wright et al. Competing risks model in screening for preeclampsia. Am J Obstet Gynecol 2019.

Maternal factors+
MAP
Uta-PI,
PAPP-A



The PREDICTION Study

First-trimester prediction of preeclampsia and other placenta-mediated pregnancy complications

Bujold E, Audibert F, Johnson J, Okun N, Forest JC, Chaillet N, Giguere Y, Masse B

Primary Objective:

To validate the 11-13 week FMF*screening test for preterm preeclampsia

Fetal Medicine Foundation UK

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What about "high risk" women who screen negative on FMF algorithm?

ASPRE trial: incidence of preterm pre-eclampsia in patients fulfilling ACOG and NICE criteria according to risk by FMF algorithm

- Secondary analysis of ASPRE participants to determine the rates of preeclampsia among pregnancies high risk by NICE/ACOG but negative by FMF test

Ultrasound Obstet Gynecol 2018; 51: 738-742

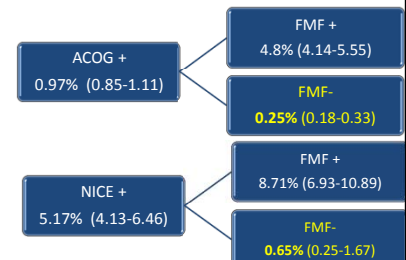
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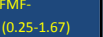
ASPRE trial: incidence of preterm pre-eclampsia in patients fulfilling ACOG and NICE criteria according to risk by FMF algorithm

Ultrasound Obstet Gynecol 2018; 51: 738-742

- Preterm PE: 0.7%



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Characteristics of a Screening Test

Characteristics of a Screening Test	Preeclampsia screening
Condition should be important	✓
Should be a reliable test for the condition	✓
Facilities for diagnosis and treatment available	?
Should be latent or asymptomatic phase	✓
Effective treatment	✓
Test should be acceptable to population	?
Natural history should be understood	✓
Should be agreement on who to treat	✓
Cost effective	?



“Don’t forget to start”

- “Prediction and Prevention of early Preeclampsia in Ontario: An Implementation Study”

PRETERM BIRTH



Is PTB a disorder warranting population screening?

Characteristics of a Screening Test

Condition should be important
Should be a reliable test for the condition
Facilities for diagnosis and treatment available
Should be latent or asymptomatic phase
Effective treatment
Test should be acceptable to population
Natural history should be understood
Should be agreement on who to treat
Cost effective

Preterm Birth

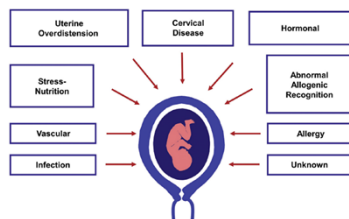
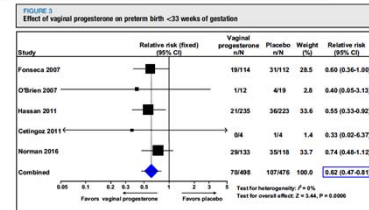


Fig. 4. Pathological processes implicated in the preterm parturition syndrome. Reproduced with permission from Romero et al. [10].

Vaginal progesterone for preventing preterm birth and adverse perinatal outcomes in singleton gestations with a short cervix: a meta-analysis of individual patient data

Roberto Romero, MD, DMedSci, Agustín Conde-Agudelo, MD, MPH, PhD, Eduardo Da Fonseca, MD, John M. O'Brien, MD, Elcin Cetinkoz, MD, George W. Creasy, MD, Sonia S. Hassan, MD, Kypros H. Nicolaides, MD



Effectiveness of progesterone, cerclage and pessary for preventing preterm birth in singleton pregnancies: a systematic review and network meta-analysis

A Jarde,^a O Lutsiv,^a CK Park,^b J Beyene,^b JM Dodd,^c J Barrett,^d PS Shah,^e JL Cook,^{f,g} S Saito,^h AB Biringer,ⁱ L Sabatino,^j L Giglia,^k Z Han,^l K Staub,^m W Mundle,ⁿ J Chamberlain,^o SD McDonald^a

- Compared 3 strategies for prevention of PTB (and other outcomes)
 - Progesterone: 0.44 (0.22-0.79) NNT 9 (6-26)
 - Cerclage: 0.53 (0.19-1.26)
 - Pessary: 0.62 (0.21-2.07)

Tweetable extract:

- “Progesterone was better than cerclage and pessary to prevent preterm birth, neonatal death and more in network meta-analysis”

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BJOG. 2017 Jul;124(8):1176-1189



Risk factor based screening

1. Previous history of preterm birth
2. Short Cervix length

What Interventions Are Being Used to Prevent Preterm Birth and When?

Yu Yang Feng, BHS¹; Alexander Jarde, PhD²; Ye Rin Seo, BHS¹; Anne Powell, MD³; Nwachukwu Nwibebe, MD⁴; Sarah D. McDonald, MD, MSc^{2,5,6} NIH ID: 1000000000000000

- Retrospective cohort study of 1024 women to identify 31 with previous PTB and/or short cervix
- 42% received prevention (Progesterone or cerclage)

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Screening Techniques

- What about routine screening by transvaginal ultrasound?

Recommendation

4. Because of poor positive predictive values and sensitivities and lack of proven effective interventions, routine transvaginal cervical length assessment is not recommended in women at low risk (II-2E).

Davies et al 2008:
Sensitivity 52%,
Specificity 82% PPV 4.5%
for PTB <35 wks

Davies G, Omoshuf C, Woodman M, et al. Cervix length and relation to predictors of preterm birth. J Obstet Gynaecol Can 2008;30(1):124-31.

J Obstet Gynaecol Can 2018;40(2):e151-e164

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Society for Maternal Fetal Medicine statement of universal cervical length screening

- Universal TVS for CL screening of singleton gestations without prior PTB for the prevention of PTB remains an object of debate
- CL screening in singleton gestations without prior PTB cannot yet be universally mandated
- It can be viewed as reasonable, and can be considered by individual practitioners.
- **Practitioners who decide to implement universal CL screening should follow strict guidelines (GRADE 2B)**

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SMFM Consult Series: AJOG Sept 2016



OBSTETRICS

Universal maternal cervical length screening during the second trimester: pros and cons of a strategy to identify women at risk of spontaneous preterm delivery

Samuel Parry, MD; Hyagriv Simhan, MD; Michal Elovitz, MD; Jay Iams, MD

TABLE 2
Studies/interventions needed to prevent 1 preterm delivery

Trial	No. of US studies to prevent 1 PTB	No. of women treated with P to prevent 1 PTB
Fonseca et al ¹¹	10,000/25 ^a = 400	170/25 ^a = 7
Hassan et al ¹²	10,000/17 ^b = 588	228/17 ^b = 13.4

Number of ultrasound examinations that will need to be performed and number of women with short cervical lengths who will need to be treated with progesterone to prevent 1 preterm birth in hypothetical cohort of 10,000 women undergoing cervical length screening, based on rates observed in randomized trials.^{11,12}

P, progesterone; PTB, preterm birth.
^a In hypothetical cohort of 10,000 women, 25 preterm births <34 wk will be prevented by universal cervical length screening and treatment with daily progesterone according to trial performed by Fonseca et al¹¹; ^b in hypothetical cohort of 10,000 women, 17 preterm births <32 wk will be prevented by universal cervical length screening and treatment with daily progesterone according to trial performed by Hassan et al¹².

Parry. Universal cervical length screening. Am J Obstet Gynecol 2012.

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On the other hand...

Characteristics of a Screening Test	Preterm Birth
Condition should be important	PTB associated with 1 million neonatal deaths worldwide
Should be a reliable test for the condition	TVS is reliable, validated test
Facilities for diagnosis and treatment available	All pregnant women offered routine ultrasound and can be offered TVS
Should be latent or asymptomatic phase	Short cervix early predictor for PTB
Effective treatment	Vaginal progesterone (several RCT and metaanalyses)
Test should be acceptable to population	>75% acceptance by pregnant women (AJOG 214(4) 2016)
Natural history should be understood	Short cervix precedes digital changes in cervix
Should be agreement on who to treat	TVS cervical length ≤20 mm at <24 weeks
Cost effective	Studies have supported cost effectiveness

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Khalil. Universal CL screening for the prediction and prevention of PTB. Am J Obstet Gynecol 2016.



Cervical length and obstetric history predict spontaneous preterm birth: development and validation of a model to provide individualized risk assessment

E. CELIK*, M. TO*, K. GAJEWSKA*, G. C. S. SMITH† and K. H. NICOLAIDES* on behalf of The Fetal Medicine Foundation Second Trimester Screening Group

- Examined the predictive value of routine TVS exam, and the incremental predictive value of adding obstetrical risk factors
- Outcome: Preterm birth
 - <28 weeks
 - 28 to 30 weeks
 - 31 to 3 weeks3
 - 34-36 weeks
- Obstetrical Risk:
 - Nulliparous or losses <16 weeks
 - Previous PTB with history defined by earliest delivery
 - 16 to 23 weeks
 - 24 to 33 weeks
 - 34 to 36 weeks
 - Previous term births

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Ultrasound Obstet Gynecol 2008; 31: 540-554

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Cervical length and obstetric history predict spontaneous preterm birth: development and validation of a model to provide individualized risk assessment

E. CELIK*, M. TO*, K. GAJEWSKA*, G. C. S. SMITH† and K. H. NICOLAIDES* on behalf of The Fetal Medicine Foundation Second Trimester Screening Group

Table 3 Detection rate comparing different modeling approaches in the prediction of spontaneous preterm birth, when applied to validation sample

Method of screening	GA at birth (weeks)	Detection rate (%) for fixed screen positive rates of:			
		1%	5%	10%	15%
Cervical length	<28	53.0	66.0	75.7	77.3
	28-30	20.1	40.1	57.0	64.7
	31-33	17.2	32.6	46.8	53.0
	34-36	4.1	12.7	24.2	26.6
Obstetric history and maternal characteristics	<28	7.3	15.9	22.5	26.1
	28-30	8.1	20.8	34.6	41.8
	31-33	7.4	24.0	32.2	37.2
	34-36	3.4	12.4	23.2	30.0
Cervical length and obstetric history	<28	53.0	72.4	80.6	85.4
	28-30	19.3	44.7	58.5	67.7
	31-33	15.4	38.2	53.0	59.8
	34-36	4.7	15.4	28.4	33.4
Cervical length, obstetric history and maternal characteristics	<28	52.0	69.2	82.2	83.2
	28-30	19.1	46.2	61.6	69.3
	31-33	17.2	40.0	55.3	62.9
	34-36	4.6	16.0	29.3	34.7

GA, gestational age.

- Better prediction for more severe forms of PTB
- Better prediction with more factors

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Reducing preterm birth by a statewide multifaceted program: an implementation study

John P. Newnham, MD; Scott W. White, MBBS; Suzanne Meharry, MBBS; Han-Shin Lee, MBBS; Michelle K. Pedretti, MAppSc; Catherine A. Arrese, PhD; Jeffrey A. Keelan, PhD; Matthew W. Kemp, PhD; Jan E. Dickinson, MD; Dorota A. Doherty, PhD

- Population based bundle of care with:
 - Statewide outreach of new clinical guidelines
 - Routine CL measurement at anatomy scan, with reflex TVS if CL <35 mm, or routine TVS
 - Vaginal progesterone for short CL at 16 to 24 weeks, or for previous PTB
 - Cervix length <10 mm, offer cerclage, progesterone or both
 - No delivery <38 weeks unless indicated
 - Offer smoking reduction program

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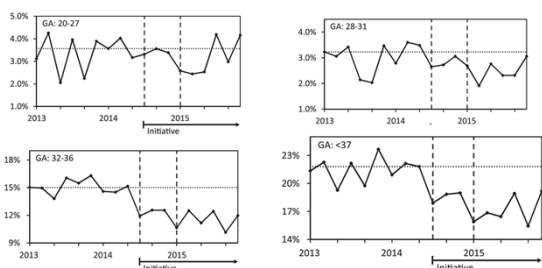
- Public health campaign to pregnant population
- Establishment of new Preterm Birth Prevention Clinic for referral

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Rates of Preterm Birth 2013 -2015



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What is next step?



- Both previous history of preterm birth and TVS cervical length predictive for PTB
- Multiple marker algorithm seems to have better performance, not as well validated (single marker screen)
- Progesterone reduces PTB with a short cervix
- Focused implementation studies

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Summary Statements

- Excellent data on preventive strategies for preeclampsia and preterm birth
- For preeclampsia:
 - Excellent data on a validated robust multiple marker screening test for preeclampsia and RCT data on effectiveness of prediction and prevention
- For preterm birth:
 - Excellent data on predictive value of shortened cervix and previous history for PTB
 - Implementation Studies needed