This Continuing Professional Education Program is generously supported by the March of Dimes in partnership with Johnson & Johnson.
Paul Jarris, MD, MBA *(Moderator)*  
Chief Medical Officer, Sr. Vice President Mission Impact, March of Dimes Foundation

Lisa Waddell, MD, MPH *(Moderator)*  
Sr. Vice President Maternal Child Health & NICU Innovation, Deputy Medical Director, March of Dimes Foundation
What is your background?

1. Academia or research
2. Clinical and public health
3. Pharmacist
4. Policy
5. Community based organization
6. Affected family or other
Today’s Speakers

Charlie Lockwood, MD, MHCM
Dean of the Morsani College of Medicine and Senior Vice President, University of South Florida Health, Professor, Obstetrics and Gynecology

Jodi Abbott, MD, MS
Assistant Dean of Patient Safety & Quality Improvement Education, Associate Professor Boston University School of Medicine Department of Ob/Gyn Boston Medical Center
Preeclampsia: Definitions, Epidemiology, Etiology and Prevention with LDA

Charles J. Lockwood, MD
Professor of Obstetrics & Gynecology and Public Health
Dean, Morsani College of Medicine and SVP USF Health
University of South Florida
Disclosures

The content of my presentation in this activity will include discussion of use of generic low dose aspirin in pregnancy.
Learning Objectives

• To understand the prevalence of preeclampsia
• To appreciate risk factors for the disorder
• To know the optimal gestational age at initiation and dosage of low dose aspirin for the prevention of preeclampsia
Definitions

• **Preeclampsia** is defined as the new onset hypertension and proteinuria or hypertension and end-organ dysfunction ± proteinuria after 20 weeks in a previously normotensive woman (ACOG 2013)

• **Chronic hypertension (CHTN)** antedates pregnancy or presents before 20 weeks or persists longer than 12 weeks postpartum.
Definitions

• **Superimposed preeclampsia** is the new onset of proteinuria, end-organ dysfunction, or worsening or resistant hypertension after 20 weeks in a woman with CHTN.

• **Eclampsia** is the development of seizures in a woman with preeclampsia, in the absence of other relevant neurologic conditions.

• **Gestational hypertension** is hypertension without proteinuria or other signs/symptoms of preeclampsia after 20 weeks, resolving by 12 weeks postpartum.
Epidemiology of Preeclampsia

• Complicates 3.4% of pregnancies with 2-fold higher prevalence in 1st pregnancy.
• Accounts for 9% of U.S. maternal deaths.
• Risk factor for future cardiovascular disease and metabolic disease in women.
• Associated with stillbirth, IUGR and oligohydramnios in fetus.

(Anath et al BMJ. 2013;347:f6564)
Epidemiology of Preeclampsia

Risk Factors include:
1) Prior PE (RR 8.4; 95% CI: 7.1-9.9); if severe recurrence rate is 25 to 65%; if not severe, 5 to 7%.
2) Nulliparity (RR 2.1; 95% CI: 1.9-2.4)
3) Family Hx (RR 2.9; 95% CI: 1.7-4.9)
4) Multiple gestation (RR 2.9, RR 2.6-3.1)
5) Preexistent conditions:
   a) Type 1 DM (RR 3.7, 95% CI 3.1-4.3)
   b) CHTN (RR 5.1, 95% CI 4.0-6.5)*
   c) BMI > 30 (RR 5.1, 95% CI 4.0-6.5)*
   d) CRD (RR 1.8, 95% CI 1.5-2.1)

(Bartsch E, et al. BMJ. 2016;353:i1753. PMID: 27094586)
Etiology of Preeclampsia

1) Decidual inflammation and vasculopathy, increased activated macrophages, decreased uNK cells (e.g., SLE, CHTN, obesity, DM, nulliparity).

2) Shallow extravillous trophoblast invasion.

3) Failure of uterine spiral artery remodeling

4) Progressive relative placental hypoxia.

5) Release of placental anti-angiogenic substances (sFlt-1 and endoglin).

Etiology of Preeclampsia

6) Systemic endothelial cell damage, decrease PGI2/TXA2, vasospasm, increased platelet aggregation and turnover and:

7) Hypertension ±

8) Renal glomeruloendotheliosis/proteinuria ±

9) End-organ damage (liver function abnormalities, ARDS, seizures, ARF, cardiomyopathy) ±

10) Fetal death, IUGR, oligohydramnios

Prevention

Low dose aspirin (LDA) reduces frequency of PE, as well as preterm birth, and IUGR by 10-20% in moderate to high risk women.

Rationale:
1) PE associated with increased platelet turnover, decreased Pgl2/TXA2.
2) PE is associated with systemic and/or decidual inflammation which is attenuated by PE (anti-NFkB effects).

(Cadavid AP. Front Immunol. 017;8:261. PMID 28360907)
## Prevention

**Key Studies: large RCTs**

<table>
<thead>
<tr>
<th>Study</th>
<th>Type of Study</th>
<th>Rate of PE in LDA vs. placebo</th>
<th>Stat.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lancet. 1993;341(8842):396</td>
<td>RCT in moderate to high risk Italian women (age extremes, CHTN, CKD, prior PE/IUGR, twins); LDA 50 mg</td>
<td>15.2% vs 19.3% (no difference in other APA)</td>
<td>NS</td>
</tr>
<tr>
<td>N Engl J Med. 1993; 329: 1213-8</td>
<td>RCT by NICHD MFMU in nulliparas; LDA 60 mg</td>
<td>4.6% vs. 6.3% (best in pts with increased sBP 5.6% vs. 11.9%)</td>
<td>0.05 0.01</td>
</tr>
<tr>
<td>Lancet. 1994;343(8898):619</td>
<td>RCT Prophylaxis for PE, IUGR (85%) or Tx PE or IUGR (15%); LDA 60 mg</td>
<td>6.7% vs. 7.6% (PTB 19.7 vs. 22.2%)</td>
<td>NS P &lt;.003</td>
</tr>
<tr>
<td>N Engl J Med. 1998; 338: 701-5</td>
<td>RCT by NICHD MFMU in moderate to high risk women (IDDM, CHTN, twins, prior PE); LDA 81 mg</td>
<td>18% vs. 20% (no difference in other APA)</td>
<td>NS</td>
</tr>
</tbody>
</table>
## Prevention

### Key Studies: large RCTs and meta-analyses

<table>
<thead>
<tr>
<th>Study</th>
<th>Type of Study</th>
<th>Rate of PE in LDA vs. placebo</th>
<th>Stat.</th>
</tr>
</thead>
<tbody>
<tr>
<td>BJOB. 2003; 110(5):475-84</td>
<td>RCT nulliparas; LDA 100 mg</td>
<td>1.7% vs. 1.6% (higher IUGR &lt; 3%ile in LDA group, no other difference in other APA)</td>
<td>NS</td>
</tr>
<tr>
<td>N Engl J Med. 2017;377(7): 613-22</td>
<td>RCT High risk based on: Uterine artery Dopplers, PAPP-A, PlGF, Ob/Med hx, BMI and MAP; LDA 150 mg</td>
<td>Preterm PE: 1.6% vs. 4.3% Any PE: 0.4 vs. 1.8% (no difference in other APA)</td>
<td>0.004 NS</td>
</tr>
<tr>
<td>Lancet. 2007; 369:1791-8</td>
<td>Meta-analysis of 32,217 pts; Antiplatelet agents</td>
<td>RR PE: 0.90 (0.84-0.97); RR sPE: 0.90 (0.83-0.98)</td>
<td></td>
</tr>
<tr>
<td>Ann Intern Med. 2014; 160:695-703</td>
<td>USPSTF Systematic review of 23 “good quality” studies</td>
<td>RR PE: 0.76 (0.62 to 0.95) RR IUGR: 0.80 (0.65-0.99) RR PTB: 0.86 (0.76-98) (no significant harms)</td>
<td></td>
</tr>
</tbody>
</table>
Optimal Dose and EGA at Initiation

Roberge et al. systematic review and meta-analysis of RCTs comparing LDA to placebo or no Tx; 45 trials with 20,909 women randomized to 50 to 150 mg daily. Results stratified by GA at initiation ≤16 or >16 weeks.

Findings:
1. LDA ≤16 weeks markedly reduced PE (RR 0.57; 0.43-0.75), sPE (RR of 0.47; 0.26-0.83) and IUGR (RR of 0.56; 0.44-0.70) with dose-response effect up to 150 mg.
2. LDA initiated after 16 weeks had less beneficial for PE (RR 0.81; 95%CI: 0.66-0.99) and no effects for sPE or IUGR and no dose response effect.

Optimal Dose and EGA at Initiation

Mehere et al, examined individual participant data on 32,217 women recruited in 31 RCTs comparing LDA or other antiplatelet agents vs. either placebo or no Tx. Results stratified by GA at initiation of therapy < 16 weeks versus \(\geq16\) weeks.

**Findings:** No significant difference among women randomized before vs. \(\geq16\) weeks for PE (RR 0.90; 0.79-1.03 vs. 0.90; 95%CI: 0.83-0.98, respectively).

U.S. Preventive Services Task Force.

Recommends LDA (81 mg) as a preventive medication after 12 weeks gestation in women who had $\geq 1$ high risk factor(s) and consideration of such treatment in patients with “several” moderate-risk factors.

## U.S. Preventive Services Task Force.

<table>
<thead>
<tr>
<th>High Risk Group</th>
<th>Moderate Risk Group</th>
<th>Low Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of prior PE, particularly if associated with adverse pregnancy outcome (e.g., IUGR, preterm birth, stillbirth)</td>
<td>Adverse Obstetrical history (IUGR, low birthweight infant, other prior adverse outcome or inter-pregnancy interval &gt;10 yrs)</td>
<td>Prior uncomplicated pregnancy and term delivery</td>
</tr>
<tr>
<td>Type 1 or 2 diabetes</td>
<td>Obesity (BMI &gt; 30 kg/m²)</td>
<td></td>
</tr>
<tr>
<td>CHTN</td>
<td>Nulliparity</td>
<td></td>
</tr>
<tr>
<td>Autoimmune disease (SLE, APPA syndrome)</td>
<td>Sociodemographic factors (AA race, low SES)</td>
<td></td>
</tr>
<tr>
<td>Multifetal pregnancy</td>
<td>Age ≥ 35 years</td>
<td></td>
</tr>
<tr>
<td>Renal disease</td>
<td>Family history of PE in first degree relative)</td>
<td></td>
</tr>
</tbody>
</table>
ACOG Practice Advisory (July 2016)

• Women are considered to be at high-risk for preeclampsia if one or more of the following risk factors are present:
  – History of preeclampsia, especially if accompanied by an adverse outcome
  – Multifetal gestation
  – Chronic hypertension
  – Diabetes (Type 1 or Type 2)
  – Renal disease
  – Autoimmune disease (such as systematic lupus erythematosus, antiphospholipid syndrome)

• Initiate aspirin (81mg) between 12-28 weeks
My Recommendations

Tx women with any of the USPSTF high risk factors or women with 2 or more of the USPSTF moderate risk factors with LDA either 81 mg or 122 mg (a tablet and a half) once a day starting at 12 to 14 weeks.
Saving Lives: Developing an Aspirin Intervention to Reduce Negative Maternal and Fetal Outcomes in at Risk Women

Jodi F. Abbott MD MHCM
jabbott@bu.edu
Asst. Dean for Patient Safety and Quality Improvement
Learning Objectives
At the Completion of this talk attendees will:

1) Understand barriers to the implementation of medical knowledge into clinical practice, and those specific to implementing aspirin in pregnancy
2) Discuss prevention of medically indicated preterm birth nationally and locally as one opportunity to reduce racial disparities in preterm birth
3) Utilize the tools of quality improvement to develop strategies to implement aspirin broadly and locally
My Aspirin Project is supported by a grant

Financial disclosures
OECD International Infant Mortality Rates

Organization for Economic Cooperation and Development 2017 Data oecd.org
OECD International Infant Mortality Rates

Organization for Economic Cooperation and Development 2017 Data oecd.org
OECD International Infant Mortality Rates

Organization for Economic Cooperation and Development 2017 Data oecd.org
US Preterm Birth Rate Rises for the 2nd year in a row

2017 March of Dimes Premature Birth Report Card shows moms and babies face higher risk of preterm birth based on race and zip code

White Plains, NY | Wednesday, November 1, 2017
W. Edwards Deming
Gandhi of Quality Improvement

“Without data you’re just another person with an opinion.”

- W. Edwards Deming, Data Scientist
Epidemiology

**International**

- 4.6% and 1.4% deliveries for preeclampsia and eclampsia
- 10 to 15% of maternal deaths are associated with preeclampsia and eclampsia

**National**

- Preeclampsia in 2-5% of all pregnancies in the U.S.
- Leading cause of maternal morbidity and up to 19% maternal mortality
- Rates of hypertension in pregnancy are increasing

**BMC**

- Approximately 30% of pregnancies complicated by pre-eclampsia, Gestational HTN and/or IUGR
- Approximately 40% of preterm births are due to preeclampsia, Gestational HTN and/or IUGR
- Rates of hypertension in pregnancy are increasing

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New England’s Largest Safety Net hospital
50% Families have an income <$20,000 (Federal Poverty Level)
30% non English Speaking
68% Speak language other than English at home
68% of our patients identify as Hispanic/Black or Black
We deliver 70% of Black and Latina women in the City of Boston
Racial Differences in Prevalence

African American women are more likely to have preeclampsia/hypertensive disease in pregnancy

Racial Disparities in Comorbidities, Complications, and Maternal and Fetal Outcomes in Women with Preeclampsia/Eclampsia

- A retrospective cohort analysis using data from the National Inpatient Sample (NIS) from 2004 to 2012
- They identified 1,175,046 weighted patient discharges with preeclampsia/eclampsia. The incidence of preeclampsia was 6.04% in African American women, compared to 2.58% in Hispanic women and 3.75% among white women (p <0.0001)

The USPSTF recommends the use of aspirin (81mg) as preventive medication after 12 weeks of gestation in women who are at high (>8%) risk for preeclampsia.

The answer is 17 years, what is the question: understanding time lags in translational research

Zoë Slote Morris, Steven Wooding, and Jonathan Grant

See editorial "Knowledge, lost in translation" in volume 104 on page 487.

This article has been cited by other articles in PMC.
Framework for Analyzing the Adoption of Innovations

Health Belief Model of Self Efficacy

- Perceived susceptibility to the problem
- Perceived consequences of the problem
- Perceived Benefits of the action
- Perceived Barriers to the action

Perceived threat

Self Efficacy

Expectation of Intervention’s effectiveness

Developed in the 1950s by social psychologists Hochbaum, Rosenstock and Kegels working in the U.S. Public Health Services
Health Belief Model
Applied to Aspirin

Perceived risk of HTN/PTD

Perceived dangers of HTN/PTD

Self Determination Regarding Aspirin for HTN/PTD risk reduction

Expectation of Aspirin’s effectiveness

Perceived Benefits of Aspirin for risk reduction

Perceived Barriers to Aspirin

GOAL

To reduce the rates of iatrogenic preterm birth and IUGR due to hypertensive disease in pregnancy

AIM

To increase PNA prescription to 90% of high risk women by September 30, 2107
**AIM**

To increase PNA prescription to 90% and use to 70% for all at-risk women at BMC within 6 months of implementation to ultimately reduce IUGR and iatrogenic preterm births due to hypertensive disorders in pregnancy.

**Primary Drivers**

- Screen
- Prescribe
- Take
- Maintenance

**Secondary Drivers**

- Pt. presents in 1st trimester
  - Providers screen appropriately
- Provider identifies risk factors
  - EPIC allows script to be written
- Pt. goes to pharmacy
  - Pharmacy releases meds
  - Pt is aware of benefits
  - Family supports taking meds
- Providers need to check in
  - Pt believes it will help
  - Other providers won’t discontinue

**MEASURES:**
1. % Screened Appropriately
2. % Providers prescribing
3. % ASA picked up
4. % ASA taken
5. Decreased Preterm, IUGR, Preeclampsia
Pt. presents in 1st trimester
Providers screen appropriately

Provider identifies risk factors
EPIC allows script to be written

Pt. goes to pharmacy
Pharmacy releases meds
Pt. is aware of benefits
Family supports taking meds

Providers need to check in
Pt. believes it will help
Other providers won’t discontinue

- Pt knows she is pregnant and calls for prenatal care
- BMC needs available slots for appointment
- Pt has access to care to see provider in 1st trimester

- Educating providers 1:1 on importance of screening
- Students working with providers in Intake and Centering to screen patients
- Creating educational video and materials for providers
- Screening tool created for providers on EPIC
- Research team email reminder 1x/month regarding initiative to providers
- Provider documents results of screen on EPIC

- Provider is educated on USPSTF guideline of risk factors
- Provider remembers and asks patient about risk factors
- Provider lists patient RF’s or # of RF’s
- Provider prescribes script for patients who qualify for PNA
- Provider overrides EPIC message on Aspirin contraindication in pregnancy

- EPIC message about Aspirin C/I removed

- Provider tells pt to go to pharmacy to pick up med
- Pt believes PNA is important for her to take requires adequate pt education

- Pharmacy surveyed about preconceptions on Aspirin prescription in pregnancy
- Pharmacy educated on initiative of PNA for HTN in pregnancy
- Pharmacy believes in PNA safety in pregnancy
- Pharmacy filling prescription of Aspirin even though it is offered OTC

- Pharmacy and Provider educate pt on PNA benefits, when/how to take PNA
- Remove pharmacy stickers about Aspirin contraindication in pregnancy

- Gather family thoughts on Aspirin use in pregnancy
- Develop patient/family education material (flier and videos) to educate on PNA use and continuing in pregnancy

- Follow up phone call with patient within 48-72 hours of screening for PNA
- Confirm with pharmacy prescription filled
- Early and frequent education throughout pregnancy via education materials and from pharmacy, providers, research assistants
- Postpartum pt education in women with HTN about prevention in future pregnancies
- Check in at each clinic visit to confirm pt continuing PNA
- Educating providers not to continue PNA (through delivery?)
Classification of Professional interventions

- DISTRIBUTION OF EDUCATIONAL MATERIALS
- EDUCATIONAL MEETINGS
- LOCAL CONSENSUS PROSESSES
- LOCAL OPINION LEADERS
- PATIENT MEDIATED INTERVENTIONS; NEW INFORMATION FROM PATIENT COLLECTED INFORMATION
- AUDIT AND FEEDBACK
- REMINDERS (PROMPTS)
- MARKETING
- MASS MEDIA

EPOC TAXONOMY: Cochrane Effective Practice and Organization of Care
Classification of Professional interventions

» DISTRIBUTION OF EDUCATIONAL MATERIALS
» EDUCATIONAL MEETINGS
» LOCAL CONSENSUS PROCESSES
» LOCAL OPINION LEADERS
» PATIENT MEDIATED INTERVENTIONS; NEW INFORMATION
» AUDIT AND FEEDBACK
» REMINDERS (PROMPTS)
» MARKETING
» MASS MEDIA

Most Effective:

HARD STOPS IN THE EHR
AUDIT AND FEEDBACK

EPOC TAXONOMY: Cochrane Effective Practice and Organization of Care
GOAL

To reduce the rates of iatrogenic preterm birth and IUGR due to hypertensive disease in pregnancy

AIM

To increase PNA prescription to 90% of high risk women by September 30, 2017
% pts by race with gHTN, preeclampsia, IUGR

<table>
<thead>
<tr>
<th>Race</th>
<th>gHTN/Preeclampsia</th>
<th>IUGR</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>African American/Black</td>
<td>38</td>
<td>50</td>
<td>88</td>
</tr>
<tr>
<td>Hispanic</td>
<td>31</td>
<td>21</td>
<td>52</td>
</tr>
<tr>
<td>Caucasian</td>
<td>20</td>
<td>17</td>
<td>37</td>
</tr>
<tr>
<td>Other</td>
<td>11</td>
<td>13</td>
<td>24</td>
</tr>
<tr>
<td>Total</td>
<td>61</td>
<td>24</td>
<td>85</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Race</th>
<th>gHTN/Preeclampsia</th>
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<tr>
<td>Caucasian</td>
<td>20</td>
<td>17</td>
<td>37</td>
</tr>
<tr>
<td>Other</td>
<td>11</td>
<td>13</td>
<td>24</td>
</tr>
<tr>
<td>% of Total Pts</td>
<td>23</td>
<td>9</td>
<td>33</td>
</tr>
</tbody>
</table>
Preeclampsia, gHTN, and/or IUGR in current pregnancy

- 83 cases of the following:
  - 24 cases of preeclampsia
  - 37 cases of gHTN
  - 24 cases of IUGR

- 79 of these patients qualified for PNA

60% patients had potentially preventable complications if on prenatal aspirin

71% of qualified pts with IUGR and/or preeclampsia or gHTN were not on Prenatal Aspirin
Patient Survey Data
% of surveyed about aspirin safety in pregnancy?

<table>
<thead>
<tr>
<th>Language</th>
<th>Safe</th>
<th>Not Safe</th>
<th>Not Sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>English</td>
<td>9</td>
<td>29</td>
<td>12</td>
</tr>
<tr>
<td>Spanish</td>
<td>2</td>
<td>17</td>
<td>0</td>
</tr>
<tr>
<td>Grand Total</td>
<td>11</td>
<td>46</td>
<td>12</td>
</tr>
</tbody>
</table>
Causes of “aspirin in pregnancy-is-unsafe” preconceived notions

- Midwife
- Family/Cultural
- Physician
- Own Research

Aspirin is NOT safe to use in pregnancy
Pharmacist Survey Data
Low Dose Aspirin is safe in pregnancy...

Low Dose Aspirin can prevent hypertensive disease in pregnancy...

% people

(Strongly) Disagree  (Strongly) Agree
27 45 27

(Strongly) Disagree  Neutral  (Strongly) Agree
32 36 32
Hesitations in filling prescription?

- < 30% report feeling (very) comfortable filling a prescription of aspirin for a patient who is pregnant

- Self-reported hesitations
  - Bleeding, harm to fetus, risk vs. benefit, lack of knowledge

% aware of USPSTF guidelines for Aspirin in pregnancy to prevent hypertensive disorders of pregnancy?

- 73 No
- 27 Yes
If a pregnant patient came to my pharmacy with a prescription for aspirin (81mg), I would feel comfortable dispensing her prescription.
Stakeholder Directed Implementations

- Educational materials
- Newsletters
- Pharmacist Algorithms
- Continuing Education lectures
- CVS health

- Educational materials
- Surveys
- Focus groups
- Educational Video
- In hospital counseling

- Healthy Start
- Boston Community Action Network
- Google
- Focus groups

- Emails
- Lectures
- Distributed materials
- Newsletters
- Focus groups
Aspirin for Evidence-Based Preeclampsia Prevention trial: influence of compliance on beneficial effect of aspirin in prevention of preterm preeclampsia

**FIGURE 2**
Aspirin effect on preterm preeclampsia in compliance subgroups

<table>
<thead>
<tr>
<th>Compliance</th>
<th>Aspirin n/N vs Placebo n/N (OR; 95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥90%</td>
<td>5/556 vs. 22/588 (0.24; 0.09 to 0.65)</td>
</tr>
<tr>
<td>&lt;90%</td>
<td>8/243 vs. 13/234 (0.59; 0.23 to 1.53)</td>
</tr>
<tr>
<td>All</td>
<td>13/796 vs. 35/822 (0.38; 0.20 to 0.74)</td>
</tr>
</tbody>
</table>

Odds ratio (OR) for preterm preeclampsia in aspirin group with 95% confidence intervals (CI) in total population and subgroups with compliance of <90% and ≥90%.

Wright et al. Aspirin treatment compliance determines efficacy in preeclampsia reduction.

**FIGURE 3**
Effect of maternal factors on compliance of ≥90%

<table>
<thead>
<tr>
<th>Racial origin</th>
<th>Odds Ratio with 95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caucasian (reference)</td>
<td></td>
</tr>
<tr>
<td>Afro Caribbean</td>
<td></td>
</tr>
<tr>
<td>South Asian</td>
<td></td>
</tr>
<tr>
<td>East Asian</td>
<td></td>
</tr>
<tr>
<td>Mixed</td>
<td></td>
</tr>
</tbody>
</table>

Odds ratio with 95% confidence interval for obstetric and medical history on compliance of ≥90%.
Patient-mediated knowledge translation (PKT) interventions for clinical encounters: a systematic review

Anna R. Gagliardi, France Légaré, Melissa C. Brouwers, Fiona Webster, Elizabeth Badley and Sharon Straus

Received: 28 November 2015 | Accepted: 23 February 2016 | Published: 29 February 2016

694 studies of which 16 were eligible

Interventions
  ▶ Print material
  ▶ Electronic material
  ▶ Counseling
  ▶ Offered in addition to physician consultation
    ▶ Before During or After
  ▶ All studies were focused on knowledge activation
  ▶ All studies showed positive benefit
    ▶ Knowledge
    ▶ Decision Making
    ▶ Communication
    ▶ Behavior
Index Pregnancy Interventions at Boston Medical Center

- Standardized Patient Counseling of Hospitalized Patients at Delivery with Gestational or Chronic Hypertension or Fetal Growth Restriction
- Standardized Electronic Health Record documentation
- Focus on Normalizing Conversations about aspirin as pregnancy risk reduction
# Sample of Education Materials

## What You Need To Know: Aspirin in Pregnancy

- It’s also known as low-dose, baby, prenatal, or 81mg aspirin
- For 30 years research has shown that prenatal aspirin has many benefits.
  - It does not harm mom or baby.¹

<table>
<thead>
<tr>
<th>Benefits of prenatal aspirin:</th>
<th>Side effects or risks of prenatal aspirin:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• It is <strong>safe</strong> to use in pregnancy</td>
<td>• Will <strong>not</strong> cause you to have increased bleeding</td>
</tr>
<tr>
<td>• Works within the placenta</td>
<td>• Does <strong>not</strong> reach the baby’s blood, <strong>has not</strong> been shown</td>
</tr>
<tr>
<td>• Helpful for both you and your baby</td>
<td>• to have negative effects on the baby’s initial development</td>
</tr>
<tr>
<td>• Lowers your chance of a premature baby</td>
<td>• Does <strong>not</strong> increase risk of miscarriage</td>
</tr>
<tr>
<td>• Lowers your chance of a low birth-weight baby</td>
<td>• Does <strong>not</strong> need to be stopped before delivery</td>
</tr>
</tbody>
</table>

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Prenatal Aspirin* in Pregnancy: Process Map

- Background literature review; Determine aim, measures, budget, driver diagram, cause/effect
- Apply for funding
- Support from local/national organizations

Baseline Data Gathering:
- Jan. & May 2017 birth log chart reviews/analysis
- Pharmacy survey and data analysis

Develop Education Materials:
- Patient and provider flyers
- Screening cards
- Office room posters
- Patient video
- Provider paraphernalia
- Provider and pharmacy process maps

Email providers about pilot implementation

Podiing Sessions at BMC:
- Group intake
- Individual intakes
- Antenatal testing unit

Midwife/ObGyn/Nurse/FamMed Meetings
- Present work
- Provider material feedback
- Workflow input

Distribute Final Materials:
- Process maps
- Flyers, posters, screening cards
- Patient video
- Paraphernalia

Implementation:
- EPIC dot phrase
- Providers to follow process map

Medical Students:
- Follow up phone call to at-risk pts and pharmacies
- Document & begin run charts

Intake Providers Involved:
- Review patient screening
- Prescribe PNA
- Fill PNA

Local Change:
- Increased PNA prescription
- Decreased preeclampsia
- Decreased IUGR and preterm births

Spread:
- Local: community health centers
- Local: academic centers
- National: academic and community centers

PDSA Cycles
- Cont. current prenatal and retrospective birth log chart reviews
- Cont. follow up patient phone calls
- Run charts every other week
- Adjustments/reminders

IT involved
- EPIC screening part of intake dot phrase
- Prompt PNA prescription for at-risk patients
- Remove “Aspirin C/I in pregnancy” message

Medical Students:
- Follow up phone call to at-risk pts and pharmacies

Local Change:
- Increased PNA prescription
- Decreased preeclampsia
- Decreased IUGR and preterm births

Prenatal aspirin infused into prenatal vitamins

Continued support
- March of Dimes
- Boston Public Health Commission
- Present at CAN meeting

Share Knowledge:
- Present at conferences
- Publish work

National Change:
- Decreased preeclampsia
- Decreased IUGR and preterm births

Spread
- Local: community health centers
- Local: academic centers
- National: academic and community centers
Prenatal Aspirin in Pregnancy: Providers

low-dose, 81mg, baby aspirin

Patient is here for first prenatal visit or is < 28 weeks gestation not on prenatal aspirin

Yes

Screen* patient for risk factors for hypertensive disease in pregnancy

Dot phrase: .bmcobprenatalaspirin To Document risk factors

Screen positive?

Yes

Review and Provide Patient Education material

Patient < 12 weeks gestation?

Prescribe prenatal aspirin today
- Educate patient to start taking prenatal aspirin nightly beginning 12 weeks
- Not required to discontinue prior to delivery

Patient 12-28 weeks gestation?

Prescribe prenatal aspirin today
- Educate patient to start taking prenatal aspirin nightly starting today
- Not required to discontinue prior to delivery

*Screening Criteria

<table>
<thead>
<tr>
<th>Any of the following high-risk factors:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ History of preeclampsia</td>
</tr>
<tr>
<td>□ Multifetal gestation</td>
</tr>
<tr>
<td>□ Chronic hypertension</td>
</tr>
<tr>
<td>□ Diabetes</td>
</tr>
<tr>
<td>□ Renal disease</td>
</tr>
<tr>
<td>□ Autoimmune disease</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Several of the following moderate-risk factors:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Nulliparity</td>
</tr>
<tr>
<td>□ BMI &gt;30</td>
</tr>
<tr>
<td>□ Family history of preeclampsia</td>
</tr>
<tr>
<td>□ African American or Black</td>
</tr>
<tr>
<td>□ Public health insurance</td>
</tr>
<tr>
<td>□ Age ≥35 years</td>
</tr>
<tr>
<td>□ History of IUGR</td>
</tr>
<tr>
<td>□ Previous adverse pregnancy outcome (i.e. miscarriage)</td>
</tr>
<tr>
<td>□ &gt;10-year pregnancy interval</td>
</tr>
</tbody>
</table>

Link PNA prescription to "pregnancy" diagnosis on problem list
Aspirin

Caution: Pregnant women should not enter.
Why “Prenatal Aspirin”?

▶ We want to associate the use of Aspirin with Prenatal Care
▶ We want Patients, Providers & Pharmacists on the same page that it is prescribed specifically for risk reduction in pregnant women
▶ We want to reinforce the use of aspirin for risk reduction in pregnancy for our patients and their families
▶ Initial research in European studies suggests that higher doses than 81mg may be ideal, especially for women with higher BMI’s (recommended dosage may change over time)
High Risk Factors

- Median
- Goal

Therapy Percentage:

- Aspirin

Events:

- Medical Students attended intake clinics
- Provider Focus group
- Email sent to Providers
- Presentation at QI Quarterly

Weeks in 2017:

High Risk Based on 2 or more moderate risk factors

Percent Prescribed Aspirin

- Goal
- Median
- Presentation at QI Quarterly
- Medical Students Attended Intake Clinics
- Provider Focus Group
- Email sent to providers

Weeks in 2017
“Better is possible. It does not take genius. It takes diligence. It takes moral clarity. It takes ingenuity. And above all, it takes a willingness to try.”

Atul Gawande
Bibliography

Building a movement
Invitation to participate in Prematurity Campaign Collaborative

Purpose: To engage a wide array of organizations, drawing on their collective expertise to identify issues and new ideas, as well as opportunities for outreach, alignment, and implementation.

You are invited to do the following as a Collaborative participant:

✔ Join quarterly virtual meetings of full Collaborative
✔ Suggest ideas or topics for consideration by the Steering Committees or workgroups
✔ Sign up for a workgroup and participate in their virtual meetings – each workgroup meets once every two months.

Use one of two ways to sign up for a workgroup:

1. Complete the sign-up form on marchofdimes.org/collaborative
2. Email collaborative@marchofdimes.org

Website: marchofdimes.org/collaborative
SAVE THE DATE
Prematurity Campaign Collaborative Summit
May 21-22, 2018
Washington, DC Metropolitan Area

The summit will convene thought leaders to advance policy and practice, mobilize community leadership, share and spread emerging ideas and promising practices, and energize stakeholders to achieve equity and reduce preterm birth.

More details to come.
For some pregnant women, taking low-dose aspirin may help reduce your risk for serious problems for you and your baby, like preeclampsia and premature birth.

Preeclampsia is when you have high blood pressure and signs that some of your organs, like your kidneys and liver, are not working right. If not treated, it can cause serious problems for you and your baby. It also increases your risk for premature birth (before 37 weeks of pregnancy). Babies born early may have more health problems than babies born on time.

If you’re at risk for preeclampsia, your provider may recommend you take low-dose aspirin.

What you can do:

☑ Talk to your provider about your risk for preeclampsia. Read the list of risk factors and check off any that you have.

☑ If your provider says it’s OK, take low-dose aspirin each day. You can buy it over-the-counter, or your provider can give you a prescription for it. It’s also called baby aspirin or 81 mg aspirin.

☑ Take the aspirin exactly as your provider tells you to. Don’t take more or take it more often than your provider says.

☑ Go to all your prenatal care checkups, even if you’re feeling fine. You can have preeclampsia and not know it.

☑ If you have signs or symptoms of preeclampsia (like severe headaches, blurred vision or swelling in the hands or face) during or after pregnancy, call your provider right away.

Are you at risk?
Check off any of the risks you have and share this sheet with your provider. If you have even one risk, ask your provider about low-dose aspirin:

You’re at highest risk for preeclampsia if:
- You’ve had preeclampsia before.
- You’re pregnant with multiples.
- You have high blood pressure, diabetes, kidney disease or an autoimmune disease like lupus.

Other risk factors for preeclampsia:
- You’ve never had a baby before, or it’s been more than 10 years since you had a baby.
- You’re obese.
- Your family members have had preeclampsia.
- You had complications in a previous pregnancy, like your baby had low birthweight.
- You had fertility treatment called in vitro fertilization.
- You’re 35 or older.
- You’re African-American. African-American women are more likely than others to have preeclampsia.
- You have little education or income.

Watch videos about preeclampsia at: marchofdimes.org/preeclampsia
Dosis baja de aspirina para prevenir la preeclampsia y el nacimiento prematuro

Para algunas embarazadas, tomar aspirina en dosis baja podría ayudar a reducir el riesgo de tener graves problemas, como preeclampsia y nacimiento prematuro.

Preeclampsia es cuando tiene alta presión arterial y señales de que algunos de sus órganos, como sus riñones e hígado, no están funcionando bien. Si no es tratada, puede causar graves problemas para usted y su bebé. También aumenta su riesgo de nacimiento prematuro (antes de las 37 semanas). Los bebés nacidos antes de tiempo pueden tener más problemas de salud que los bebés que nacen a tiempo.

Si corre riesgo de preeclampsia, su profesional puede recomendárselo que tome aspirina en dosis baja.

¿Corre riesgo?
Marque cualquier de los riesgos que tenga y comparta esta hoja con su profesional. Aunque solo tenga un riesgo, pregúntele a su profesional sobre la aspirina en dosis baja:

Usted corre un riesgo mayor de preeclampsia si:
- 
- 
- 
- 

Otros factores de riesgo de preeclampsia:
- 
- 
- 
- 

Qué puede hacer:
- Hable con su profesional sobre su riesgo de preeclampsia. Lea la lista de factores de riesgo y marque cualquiera que tenga.
- Con la aprobación de su profesional, tome a diario una aspirina en dosis baja. Usted puede comprarla sin receta, o su profesional le puede dar una receta. También se llama aspirina de 81 mg.
- Tome la aspirina exactamente como se lo indique su profesional. No tome más ni la tome con más frecuencia de lo que dice su profesional.
- Vaya a todas sus visitas prenatales aunque se sienta bien. Usted puede tener preeclampsia sin saberlo.
- Si tiene señales o síntomas de preeclampsia (como dolores de cabeza fuertes, visión borrosa o hinchazón en las manos o cara) durante o después del embarazo, llame a su profesional de inmediato.

Mire un video sobre la preeclampsia en: nacersano.org/preeclampsia
Low-dose aspirin helps reduce a woman’s risk for preeclampsia and premature birth.

**Recommend** low-dose aspirin if the woman has 
≥1 of these *high risk* factors for preeclampsia:

- History of preeclampsia, especially when accompanied by an adverse outcome
- Multifetal gestation
- Chronic hypertension
- Type 1 or 2 diabetes
- Renal disease
- Autoimmune disease (systemic lupus erythematosus, antiphospholipid syndrome)

**Consider** low-dose aspirin if the woman has several of these *moderate risk* factors for preeclampsia:

- Nulliparity
- Obesity (BMI >30 kg/m²)
- Family history of preeclampsia (mother or sister)
- Sociodemographic characteristics (African-American race, low socioeconomic status)
- Age ≥35 years
- Personal history factors (LBW or SGA, previous adverse pregnancy outcome, >10-year pregnancy interval)

For information or to order: email: aspirinbanner@marchofdimes.org

USPSTF, 2014
Thank You