A Learning Health System Story: Perinatal Outcomes Associated with a Major Change in Gestational Diabetes Screening

Kaiser Permanente Washington Health Research Institute
KP Washington Study Team

Research Institute

- Sascha Dublin: PI
- Gaia Pocabelli: Co-I
- Katherine Newton: Co-I
- Onchee Yu: Biostatistician

Delivery System

- Susan Warwick
- David McCulloch
- Jane Dimer

Funder: Partnership for Innovation
Learning Health System

In a learning health system, research influences practice, and practice influences research.

**STUDY**
Collect data and analyze results to show what works and what doesn’t.

**ACT**
Use evidence to influence continual improvement.

**DO**
Apply plan.

**PLAN**
Design a change and its evaluation based on evidence generated here and elsewhere.

**DISSEMINATE**
Share results to improve care for everyone.

**INTERNAL AND EXTERNAL SCAN**
Identify problems and potentially innovative solutions.
Outline

- Introduction and background
- Methods
- Results
- Discussion
Introduction

- Gestational diabetes (GDM) is defined as onset or first recognition of abnormal glucose tolerance during pregnancy

- GDM is common and important
  - Prevalence 4-18% depending on population and testing strategy
  - Increases risks to mother and infant including stillbirth, very large infant, cesarean delivery, infant birth injury
Impact on the Patient

- Stigma or impact on sense of self
- Home monitoring: check blood sugar 6x a day (requires pricking finger)
- May need to start medications, often insulin
  - Injection
  - Risk of hypoglycemia
- Increased antenatal monitoring (e.g., nonstress tests)
- Early induction of labor may be recommended
Introduction

- Widely accepted that we need to screen for and treat GDM to avoid adverse outcomes for women and babies
- Not clear which screening approach is best
- Different organizations and professional societies have endorsed different approaches
Traditional Approach to Screening

- **2-step approach**: screening and if positive, receive diagnostic test (3 hr glucose tolerance test)

- Endorsed by American College of Obstetricians & Gynecologists
Context

- HAPO Study (2008)
  - Worse outcomes seen in women with elevated blood glucose not meeting criteria for GDM
    - ↑ cesarean delivery, ↑ large-for-gestational age infants
  - Are we underdiagnosing GDM?
- New approach proposed: all pregnant women should receive a more in-depth and sensitive test for GDM
New Approach

- **Traditional 2-step approach**: screening and if positive, receive diagnostic test (3 hr glucose tolerance test)

- **New proposed 1-step approach**: all pregnant women receive a diagnostic test (75 g, 2 hr glucose tolerance test)
  - Also lowered the threshold (i.e., glucose levels) to qualify as GDM
  - Expected to increase the prevalence of GDM 2-fold
Impact on Healthcare System

- Need for increased resources
- Spend more time talking with patients about blood sugar
- Nursing staff need time to counsel women about diet, home blood sugar monitoring, reviewing home values
- Prescribing medications
- Increased antenatal monitoring such as ultrasounds, nonstress testing
- Early induction of labor
Kaiser Permanente Washington

- One of 8 Kaiser Permanente regions
- Integrated healthcare delivery system in Northwest US
  - Provides both healthcare and insurance coverage
  - About 710,000 members and 7000 deliveries per year
  - 2/3 of members receive care within the KPWA delivery system (integrated group practice)
KPW Health Research Institute

- Public interest, multidisciplinary research institute
- Emphasis on practical research
- Most funding is external (NIH, CDC, FDA, foundations)
In 2011, KPWA adopted the 1-step strategy, changing pregnancy care within the integrated group practice.
## KPWA GDM Guideline Change

### Group Practice

1. Testing changes
   - Testing for preexisting diabetes at 9-11 weeks
   - 1-step screening for GDM at 24-28 weeks

2. Treatment changes
   - Lower threshold to start medication
   - Insulin 1st line

### Network

- No changes
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Implementation of Guideline Change

- Epic “Smart Set” made ordering the right screening test automatic
- Leaders visited clinics promoting new guidelines
- Clinical staff had some concerns including about resources needed and burden on teams
- No formal plan to study outcomes
- Resources, personnel initially not in place or aligned to make a rigorous evaluation feasible
Proposal and Funding

- Women’s Health leaders had strong desire for data about the clinical outcomes
- A different project brought Drs. Dublin and Warwick together
- Together we sought funding from the Partnership for Innovation
- Rapid review and funding
  - Applied in October 2015, funded January 2016
Objective

To compare maternal and neonatal outcomes among deliveries in the Group Practice before and after the GDM guideline change

Deliveries in the contracted network during the study period served as a control group
In a learning health system, research influences practice, and practice influences research.
Methods

- **Design**: before-after cohort study
- **Data sources**: KPWA electronic health records and linked state birth certificates
- **Study population**:
  - Singleton deliveries, 2009-2014, with infant records (N = 30,332)
  - Excluded if age <15 years, inadequate enrollment, preexisting diabetes, or no linked birth certificate
  - N = 23,257 remained
Methods

- Comparison:

  All deliveries after (2012-2014) vs. before (2009-2010) guideline change, among two groups:

  1. Group practice – exposed to guideline change

  2. Network – not exposed to the guideline change
Methods

- Outcomes:
  - Uptake of GDM guideline
    - E.g., type of screening test received; use of diabetes medication and type of medication used
  - Maternal and neonatal outcomes
    - E.g., GDM diagnoses, induction of labor, primary cesarean delivery, macrosomia, neonatal intensive care unit (NICU) admission
## Methods

### Analysis:

- Modified Poisson regression using Generalized Estimating Equations (because women might have more than one pregnancy)
- Adjusted for various factors (e.g. maternal age, race/ethnicity, education, smoking, prepregnancy body mass index, parity)
- Difference-in-difference method

Results
### Number of deliveries before and after the guideline change

<table>
<thead>
<tr>
<th></th>
<th>Group Practice</th>
<th>Network</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>11,314</td>
<td>7,840</td>
</tr>
<tr>
<td><strong>Before (2009-2010)</strong></td>
<td>4,977</td>
<td>3,386</td>
</tr>
<tr>
<td><strong>After (2012-2014)</strong></td>
<td>6,337</td>
<td>4,454</td>
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</table>
# Characteristics of deliveries

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td></td>
<td>n = 11,314</td>
<td>n = 7,840</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maternal age ≥ 35 years</td>
<td>24%</td>
<td>19%</td>
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<tr>
<td>Race/ethnicity, non-white</td>
<td>30%</td>
<td>21%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education: ≥ high school</td>
<td>82%</td>
<td>80%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoked during pregnancy</td>
<td>4%</td>
<td>4%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prepregnancy obesity</td>
<td>21%</td>
<td>23%</td>
<td></td>
<td></td>
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<tr>
<td>Nulliparous</td>
<td>49%</td>
<td>42%</td>
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</tbody>
</table>

Obesity was defined as BMI ≥30 kg/m²
Receipt of 1-step testing for GDM

<table>
<thead>
<tr>
<th>Incidence (% of deliveries)</th>
<th>Before</th>
<th>After</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group Practice</td>
<td>&lt;1%</td>
<td>87%</td>
</tr>
<tr>
<td>Network</td>
<td>&lt;1%</td>
<td>4%</td>
</tr>
</tbody>
</table>
Receipt of 1-step testing for GDM
Use of insulin during pregnancy

<table>
<thead>
<tr>
<th>Incidence (% of deliveries)</th>
<th>Group Practice</th>
<th>Network</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>1.2%</td>
<td>1.3%</td>
</tr>
<tr>
<td>After</td>
<td>3.7%</td>
<td>1.2%</td>
</tr>
</tbody>
</table>
Gestational diabetes diagnoses

RR = 1.65
RR = 1.17

\[
RR_{DD} = \frac{1.65}{1.17} = 1.41 \text{ (95% CI: 1.17-1.69)}
\]
Primary cesarean delivery

\[ RR = 0.92 \]

\[ RR = 0.93 \]

\[ RR_{DD} = 0.99 \ (0.87-1.12) \]
Induction of labor

RR = 1.13
RR = 0.94

RR_{DD} = 1.20 (1.09-1.32)
Macrosomia (birthweight ≥ 4,500 g)

RR = 0.84

RR = 0.99

RR_{DD} = 0.84 (0.55-1.30)
Neonatal hypoglycemia

RR = 1.13
RR = 0.94

RR_{DD} = 1.77 (1.14-2.75)
Association between guideline and primary outcomes

**Increased risk**
- GDM diagnoses: ↑ 41%
- Induction of labor: ↑ 20%
- Neonatal hypoglycemia diagnoses: ↑ 77%

**No association**
- Primary cesarean
- Macrosomia (≥4,500 g)
- Large-for-gestational age
- Small-for-gestational age
- NICU admission
### Association between guideline and secondary outcomes

<table>
<thead>
<tr>
<th>Increased risk</th>
<th>No association</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Outpatient nonstress testing: ↑ 12%</td>
<td>- Vaginal delivery after cesarean</td>
</tr>
<tr>
<td></td>
<td>- Operative vaginal delivery</td>
</tr>
<tr>
<td></td>
<td>- Neonatal jaundice</td>
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<tr>
<td></td>
<td>- Birth injury</td>
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<tr>
<td></td>
<td>- Other NICU</td>
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<tr>
<td></td>
<td>- Gestational hypertension</td>
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<td></td>
<td>- Preeclampsia</td>
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<td></td>
<td>- Ultrasound in 3rd trimester</td>
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<tr>
<td></td>
<td>- Preterm birth</td>
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<tr>
<td></td>
<td>- Perineal tear</td>
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</table>
Discussion
### Summary

- **Guideline adopted**
  - 2-step → 1-step approach
  - ↑ use of insulin during pregnancy

- **Increased risk**
  - GDM diagnoses
  - Labor induction
  - Outpatient nonstress testing
  - Neonatal hypoglycemia diagnoses

- **No association**
  - Other adverse maternal and neonatal outcomes
  - The hoped-for benefits did not materialize
Evidence from Prior Studies

- Randomized trials
  - A few small studies; some quality issues (e.g., not intention to treat)
  - Reported feasibility, GDM prevalence, costs
  - Not powered for maternal and neonatal outcomes

- Observational studies – small number, mixed results
Prior Studies

- **Observational studies**
  
  - 3 studies (Spain, Taiwan) suggested benefits, e.g. ↓ cesarean, ↓ NICU
  
  - 2 US studies showed no benefit, and possibly an increase in cesarean delivery (Feldman 2016, Palatnik 2017)
  
  - Our study is the 3\textsuperscript{rd} US study and again shows no benefit
Discussion: Limitations

- > 1 change with guideline: testing & treatment
- Not randomized
- Had to study entire population of pregnant women
  - Could not identify the women most affected, those who would test positive only with the 1-step approach
  - This could dilute an effect and make it harder to detect
Discussion: Strengths

- Large sample size
- Rich data on population characteristics and covariates
- Could study both processes and outcomes of care
- Control group unexposed to guideline change
  - Accounts for background time trends
Summary of Findings

- Adoption of 1-step approach at KPWA associated with increases in:
  - GDM diagnoses
  - Labor induction
  - Neonatal hypoglycemia diagnoses
  - Outpatient nonstress testing

- No benefit for other maternal and neonatal outcomes

Overall, no evidence of a benefit to adoption of the 1-step approach to GDM screening and diagnosis.
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What happened next?

- Presented our findings to delivery system leaders
- Shared findings with local clinic chiefs
  - Heard support for going back to previous approach
- KPWA convened a workgroup to review and revise the GDM guideline (December 2017)
May 2018: Return to 2-step testing

May 10, 2018

Guideline Updates

- Gestational Diabetes: Two-step screening test, new glucose targets, third-trimester ultrasound
- Prenatal Care: Initial-visit ultrasound, more frequent depression screening

Gestational Diabetes: Two-step screening test, new glucose targets, third-trimester ultrasound for women on insulin
Dissemination

- Presented results at the Society for Maternal-Fetal Medicine national meeting in January 2018
- Manuscript published August 2018
One-Step Approach to Identifying Gestational Diabetes Mellitus: Association With Perinatal Outcomes

Pocobelli, Gaia, PhD; Yu, Onchee, MS; Fuller, Sharon; Fraser, James R.; Wartko, Paige D, MPH; Chen, Lu, PhD; Newton, Katherine M., PhD; Dimer, Jane, MD; McCulloch, David K., MD; Warwick, Susan, MD; Dublin, Sascha, MD, PhD

Obstetrics & Gynecology: August 17, 2018 - Volume Publish Ahead of Print - Issue - p
doi: 10.1097/AOG.0000000000002780
Original Research: PDF Only
Challenges

- Evaluation was not built into original plan for practice change
  - Initially, no obvious alignment of personnel and resources to support evaluation

- Access to data may be challenging
  - Pregnancy data have some unique features, e.g. need for mom-baby linkage and birth certificates

- Leadership transitions within healthcare system

- Obtaining funding for evaluations can be difficult and may take a long time
Why did findings lead to practice change?

- Research question came from clinical leaders
- Ongoing engagement between research team and clinical leaders
  - Focus on actionable results
- Leaders had the ability to disseminate findings and drive practice change
- Rapid action to convene guideline group to revisit recommendations
  - Research team participated in guideline review group
Learnings

- With major practice change, plan for evaluation from the beginning
- Healthcare systems should nurture relationships and invest in data to create infrastructure and human capital
- Rapid internal funding can have a huge impact on ability to evaluate internal initiatives
- This work can lead to improvements in patient care, staff satisfaction, and more effective use of resources
### KPWA Study Team

- **Onchee Yu, MS** (Biostatistician)
- **Sharon Fuller** (Programmer)
- **James R. Fraser** (PM)
- **Lu Chen, PhD** (Postdoctoral Fellow)
- **Paige Wartko, MPH** (Doctoral Student)
- **Katherine Newton, PhD** (Investigator, Emeritus)
- **Susan Warwick, MD** (KPWA, Obstetrics/gynecology)
- **Jane Dimer, MD** (Swedish, Obstetrics/gynecology)
- **David McCulloch, MD** (KPWA, Medical Director, Clinical Improvement)
Questions?