



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

KP Washington Study Team

Research Institute



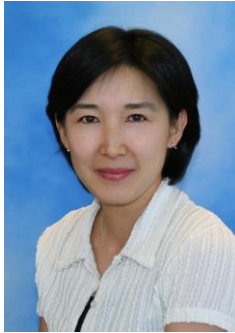
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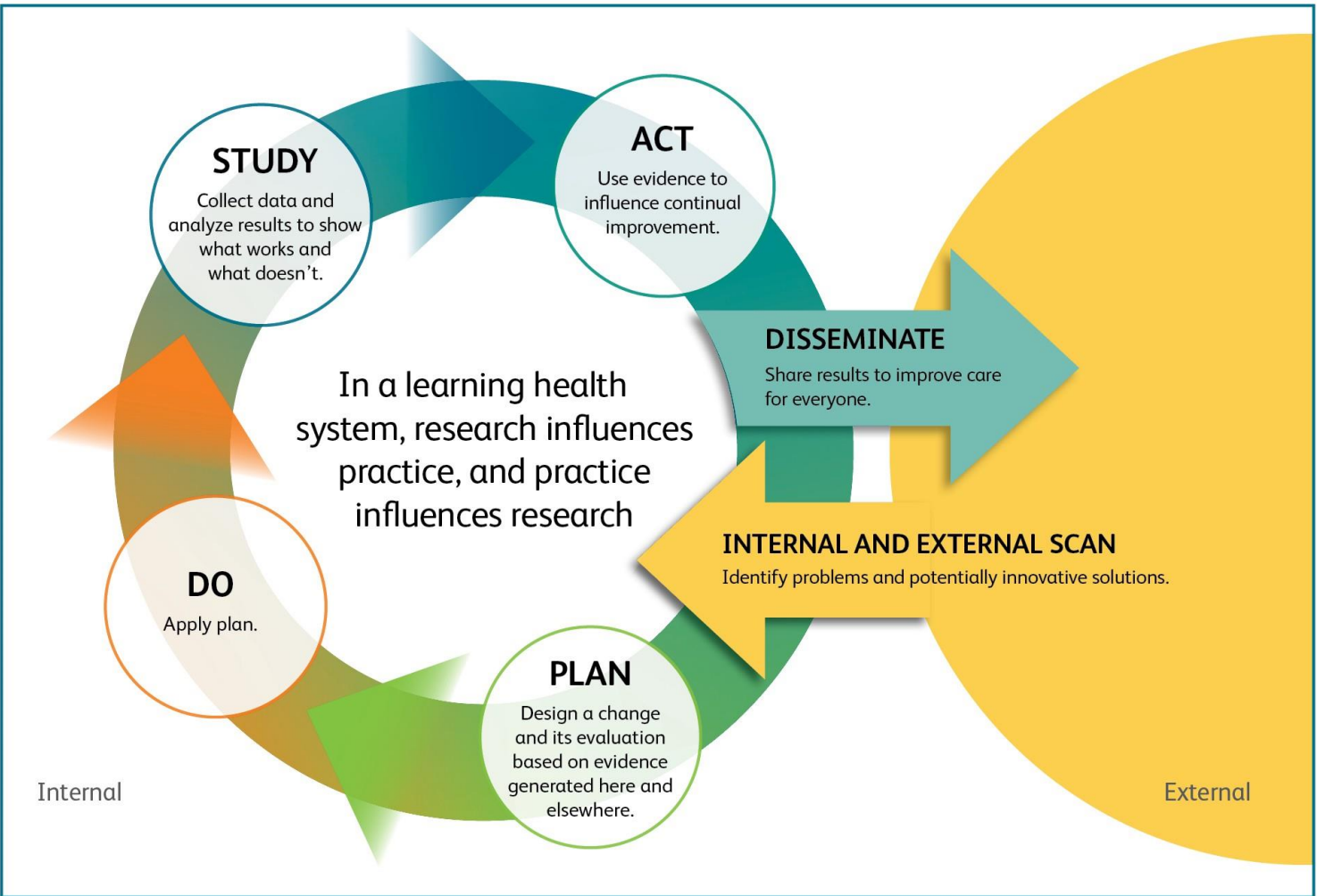


David McCulloch
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Jane Dimer
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Learning Health System



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)**

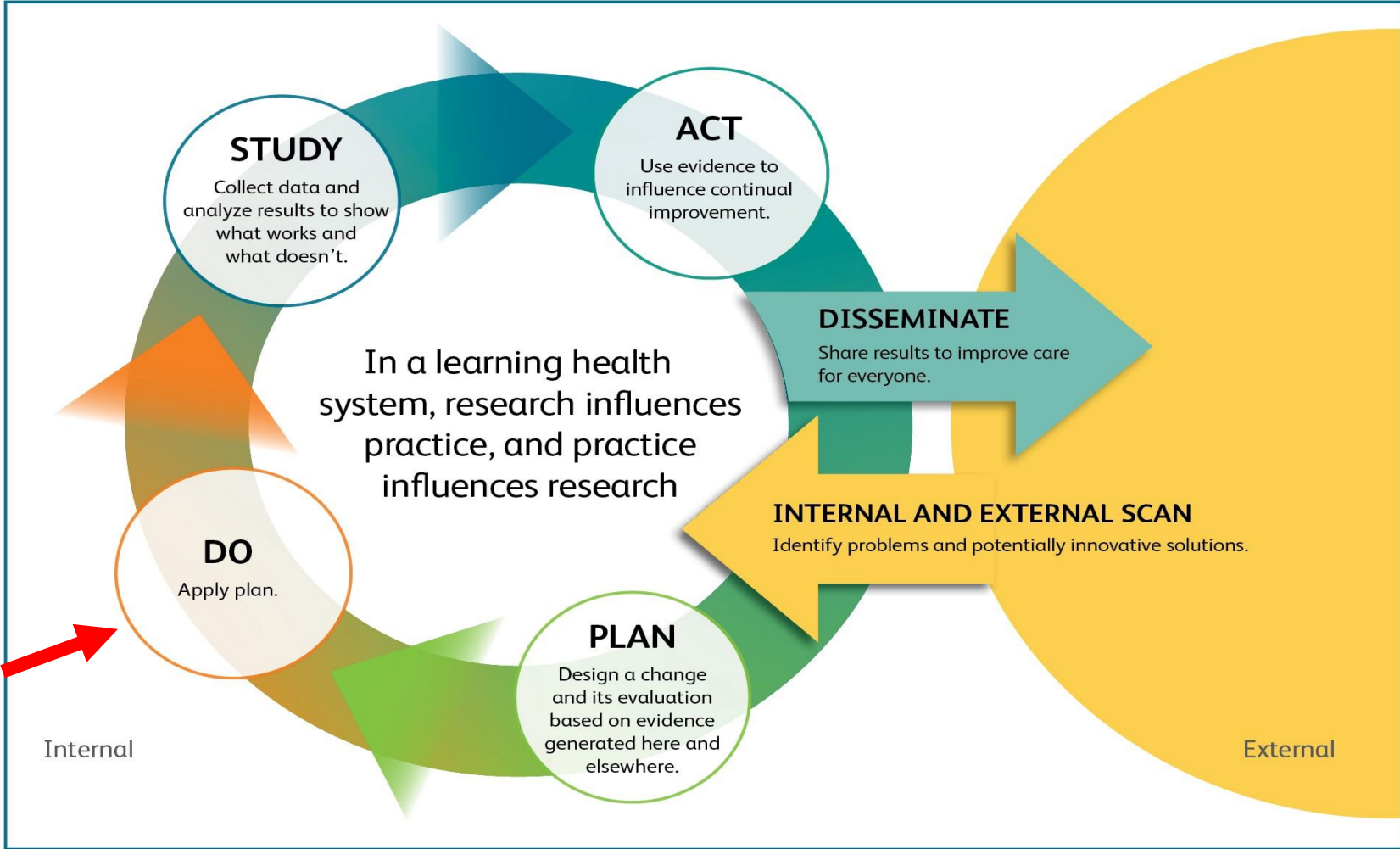
KPWA Guideline Change

- **In 2011, KPWA adopted the 1-step strategy, changing pregnancy care within the integrated group practice**

KPWA GDM Guideline Change

Group Practice	Network
<ul style="list-style-type: none">1. Testing changes<ul style="list-style-type: none">– Testing for preexisting diabetes at 9-11 weeks– 1-step screening for GDM at 24-28 weeks2. Treatment changes<ul style="list-style-type: none">– Lower threshold to start medication– Insulin 1st line	<ul style="list-style-type: none">▪ 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

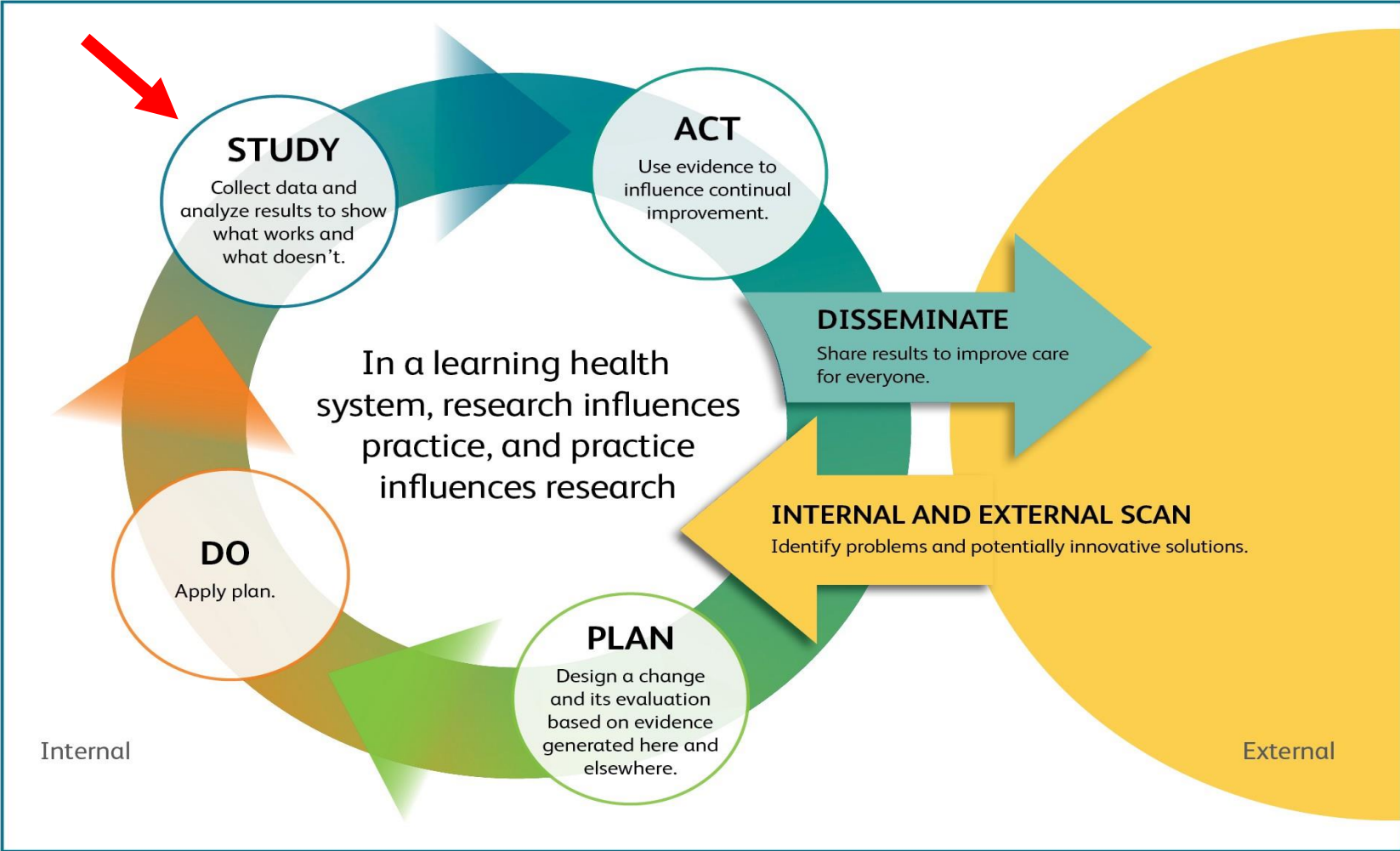
- **Women's Health leaders had strong desire for data about the clinical outcomes**
- **A different project brought Drs. Dublin and Warwick together**
- **Together we sought funding from the Partnership for Innovation**
- **Rapid review and funding**
 - **Applied in October 2015, funded January 2016**

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

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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**
 - Dimick JB et al. JAMA 2014; 312 (22):2401-2.

Results

Number of deliveries before and after the guideline change

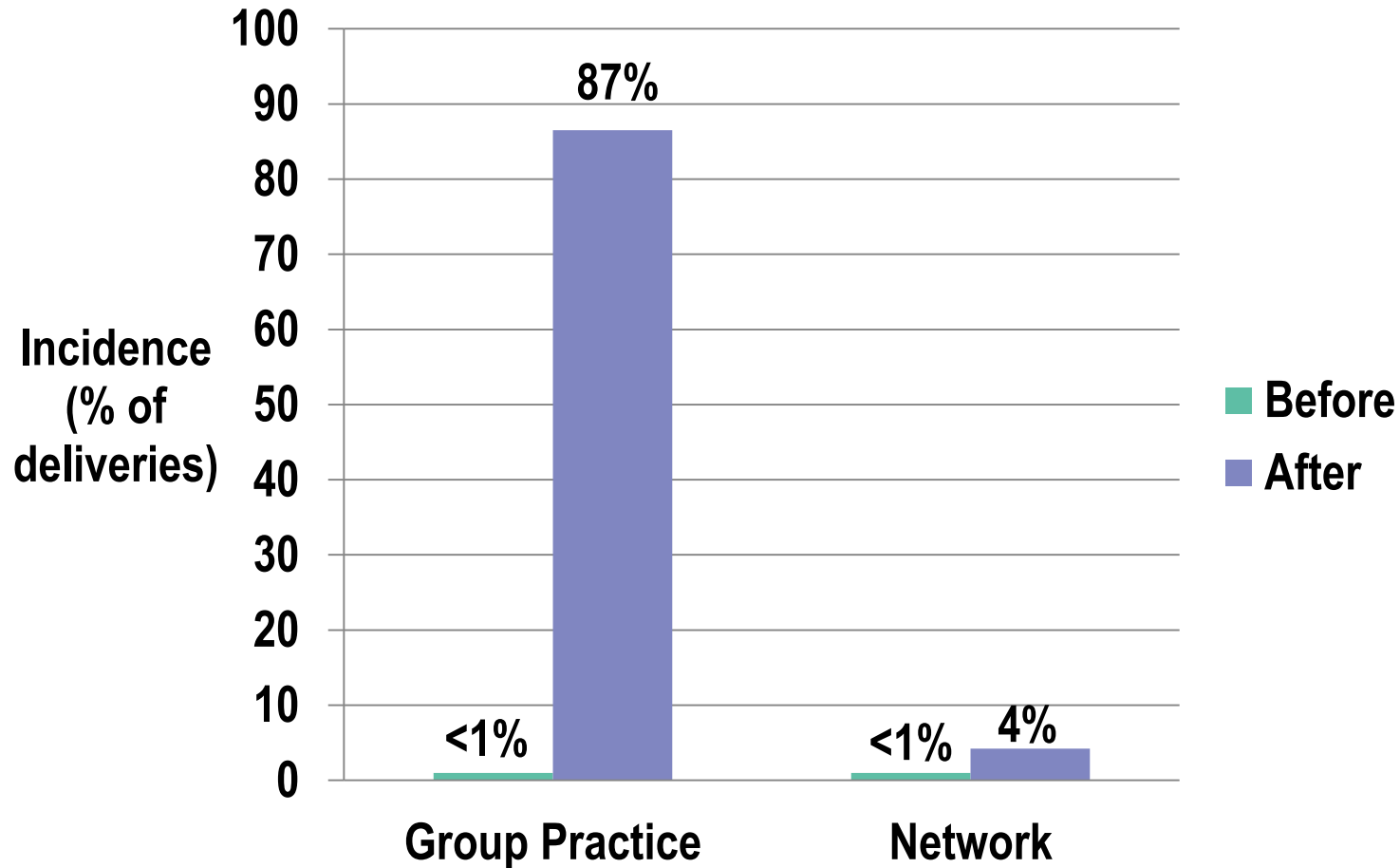
	Group Practice	Network
Total	11,314	7,840
Before (2009-2010)	4,977	3,386
After (2012-2014)	6,337	4,454

Characteristics of deliveries

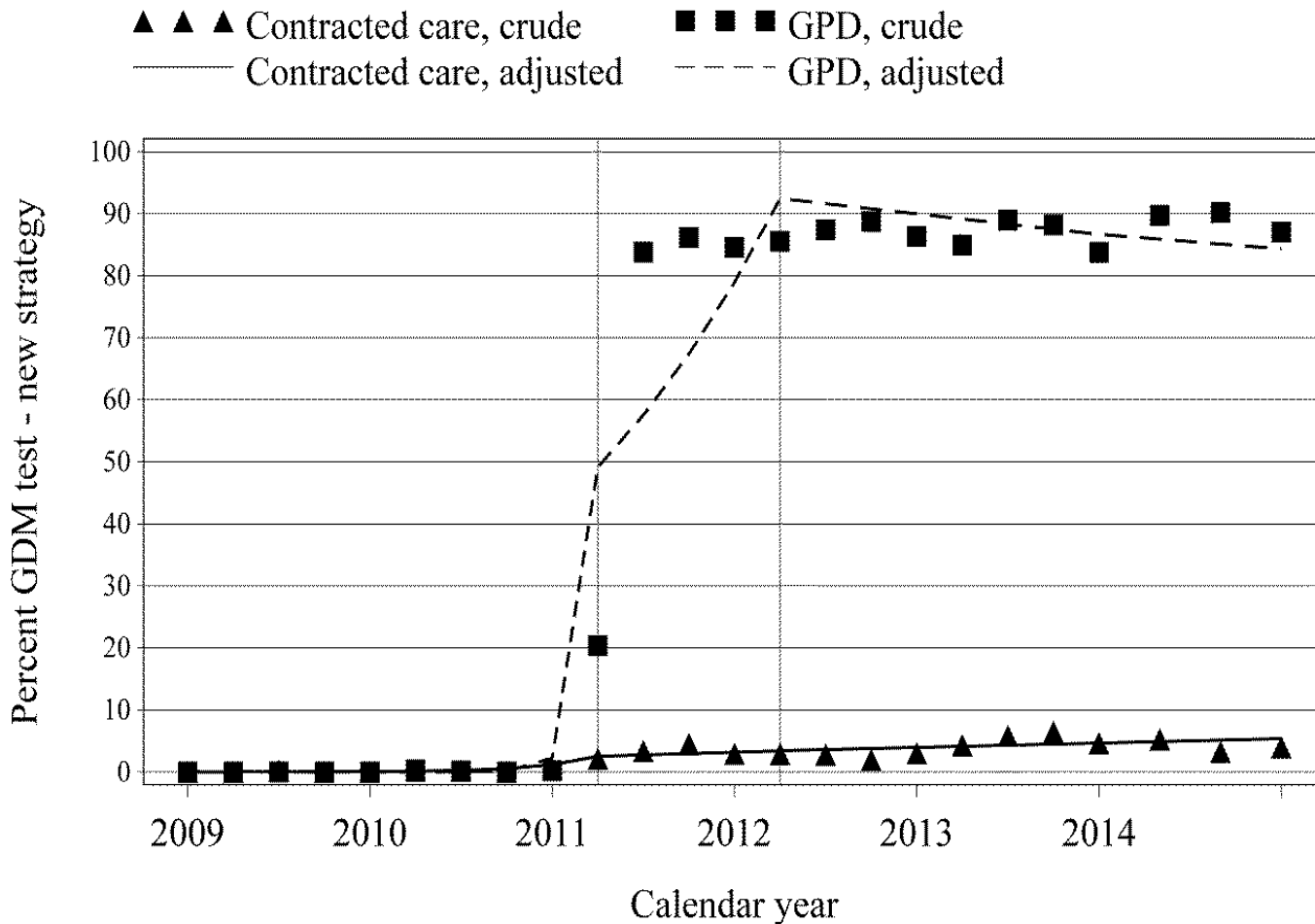
	Group Practice n = 11,314 %	Network n = 7,840 %
Maternal age \geq 35 years	24	19
Race/ethnicity, non-white	30	21
Education: \geq high school	82	80
Smoked during pregnancy	4	4
Prepregnancy obesity	21	23
Nulliparous	49	42

Obesity was defined as BMI \geq 30 kg/m²

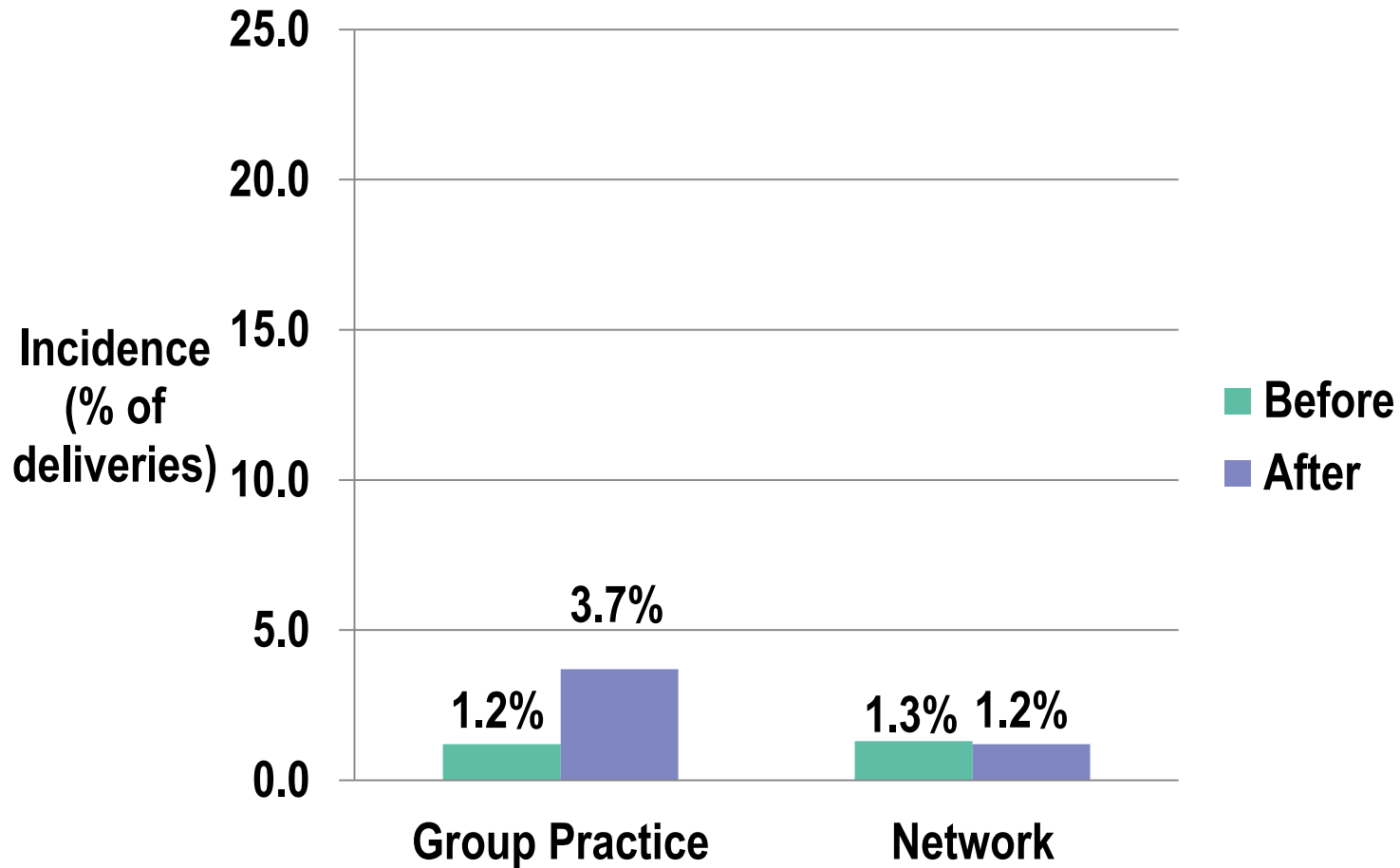
Receipt of 1-step testing for GDM



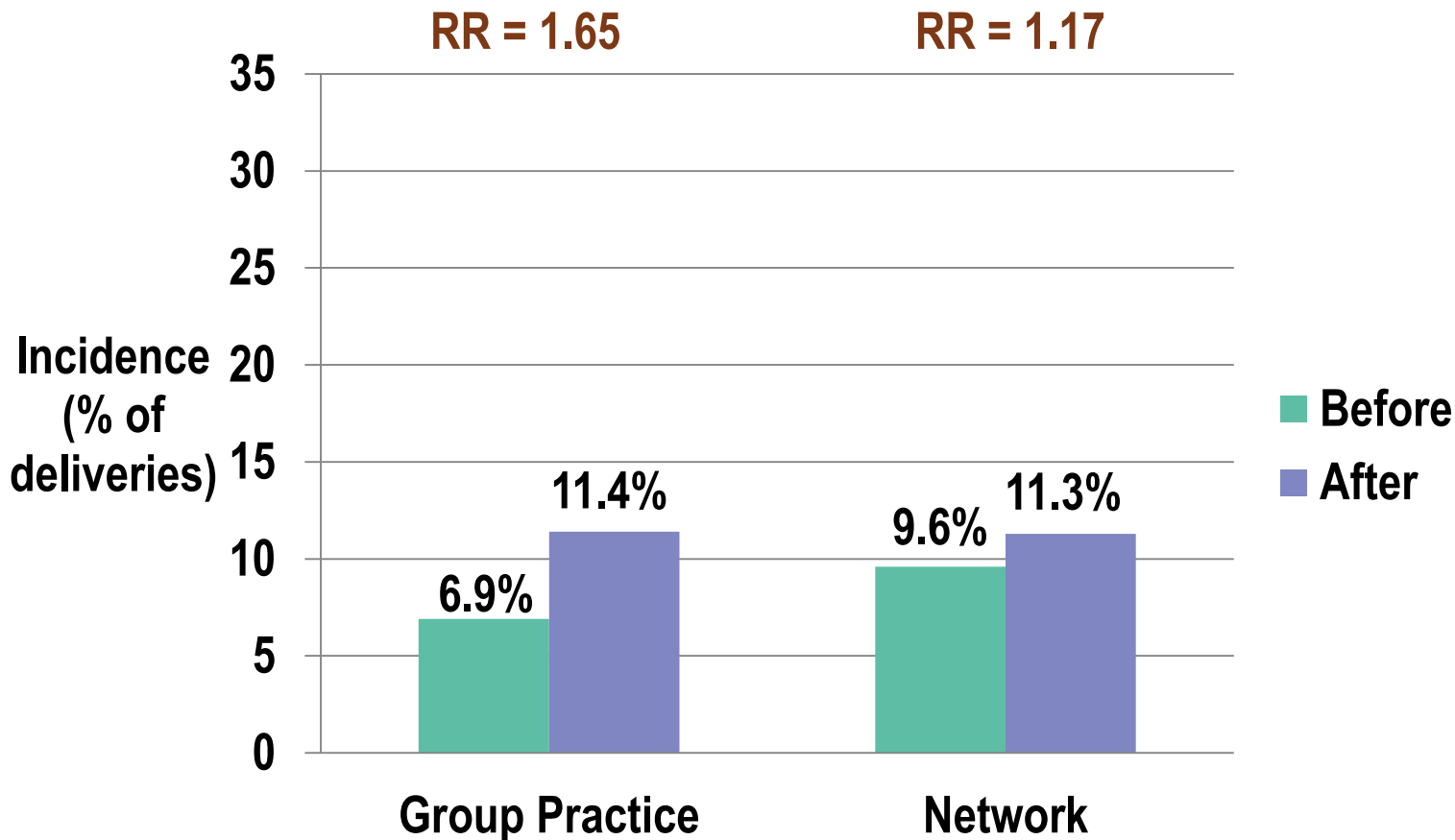
Receipt of 1-step testing for GDM



Use of insulin during pregnancy

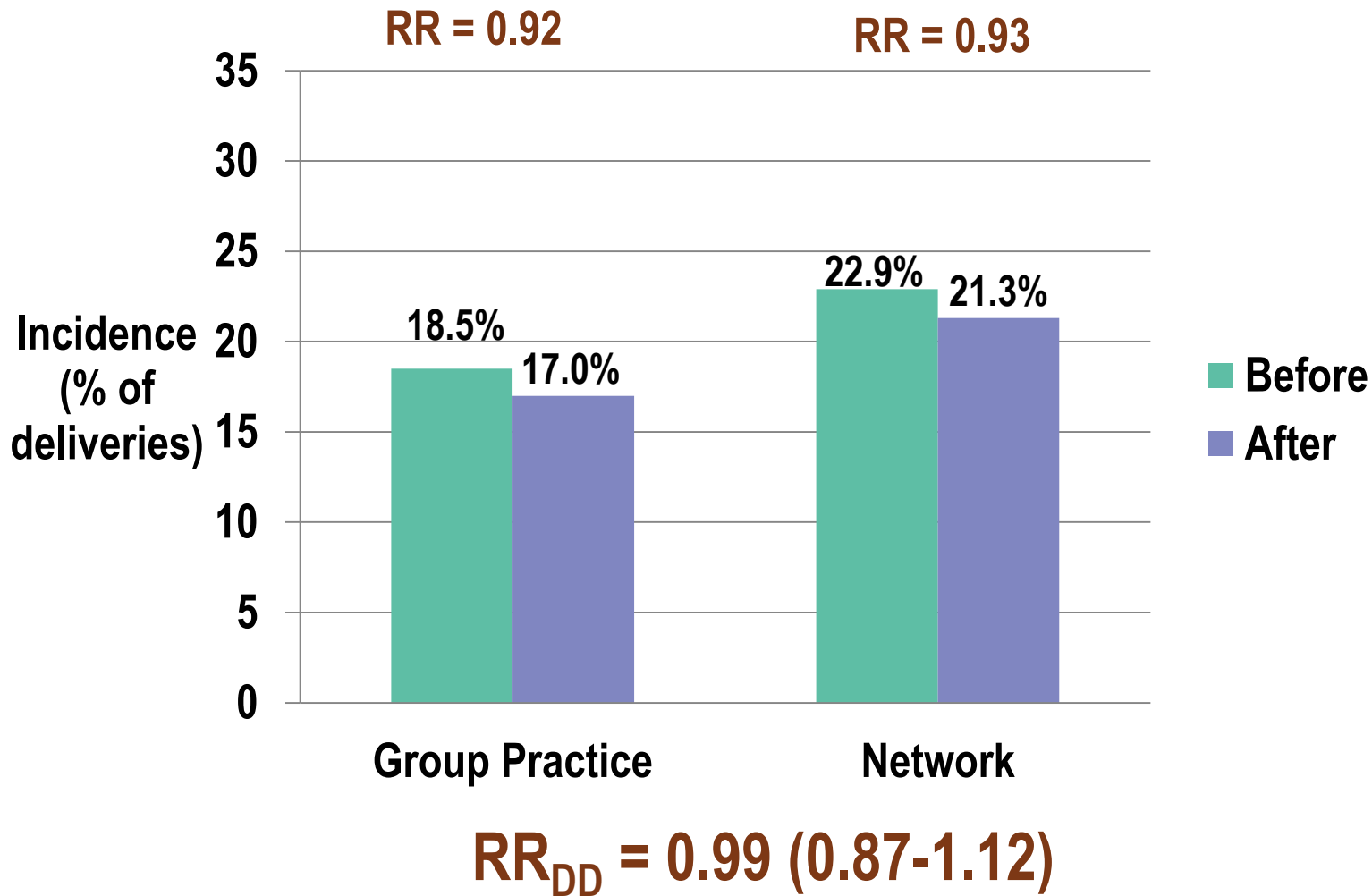


Gestational diabetes diagnoses

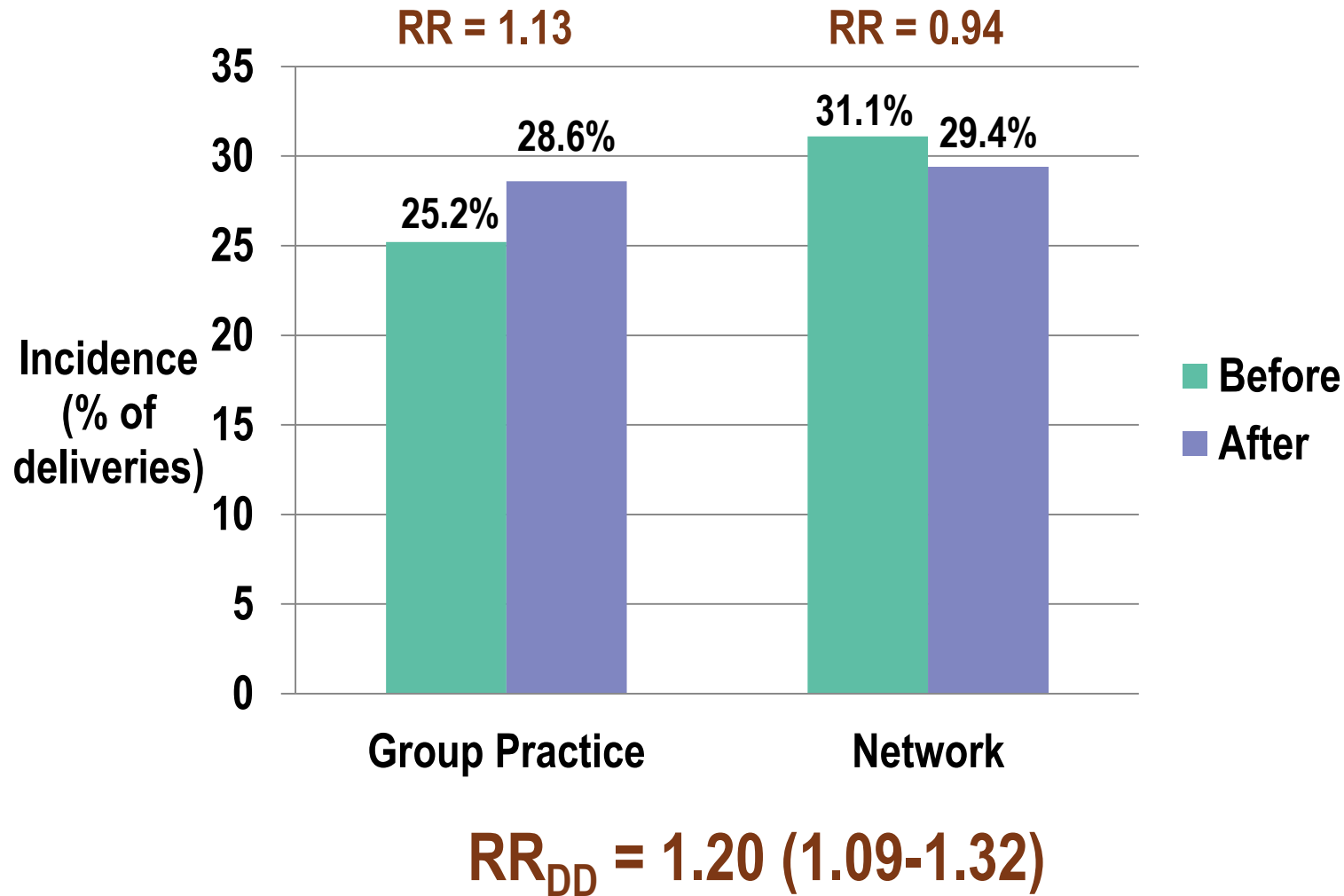


$$RR_{DD} = \frac{1.65}{1.17} = 1.41 \text{ (95\% CI: 1.17-1.69)}$$

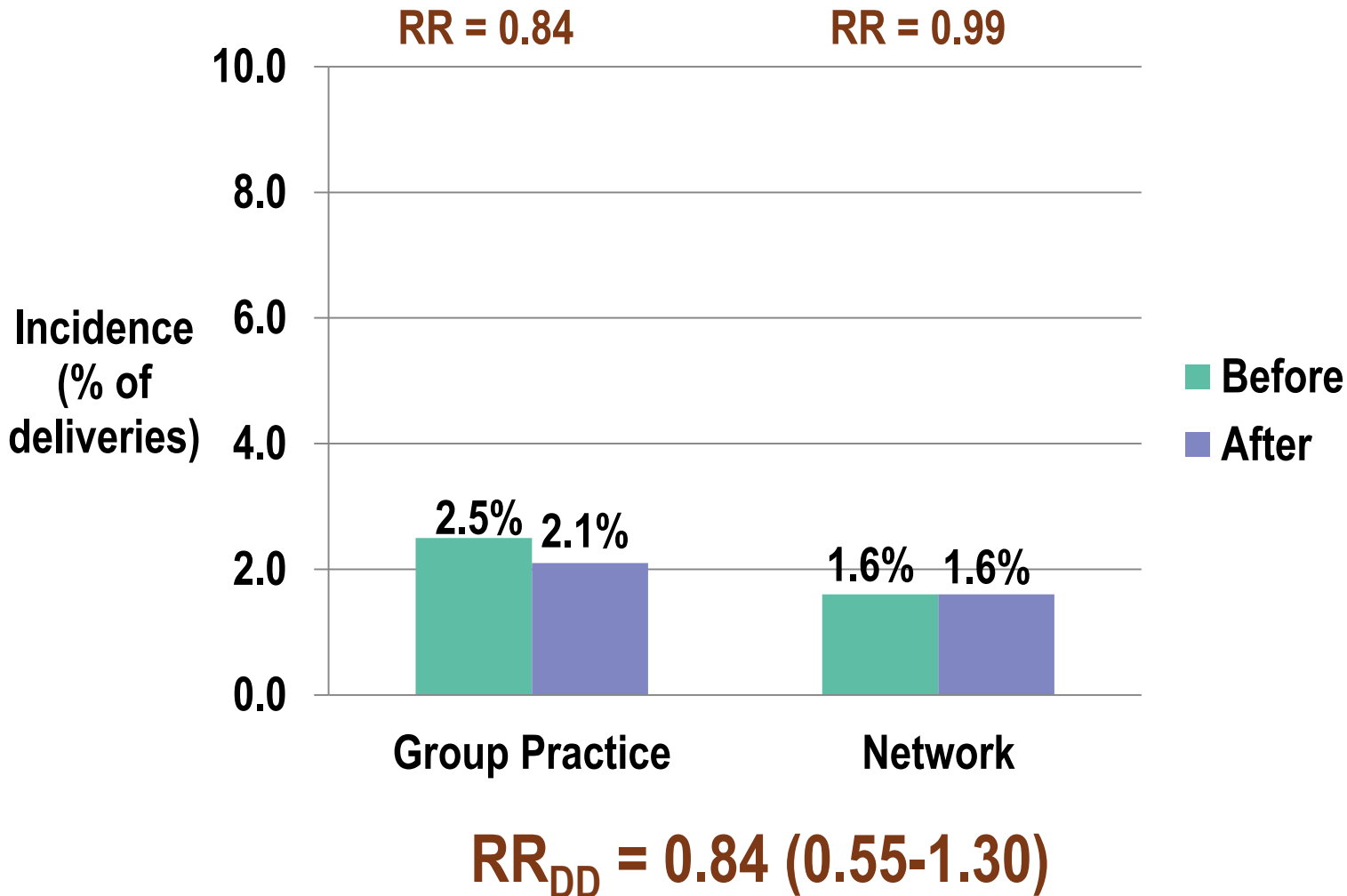
Primary cesarean delivery



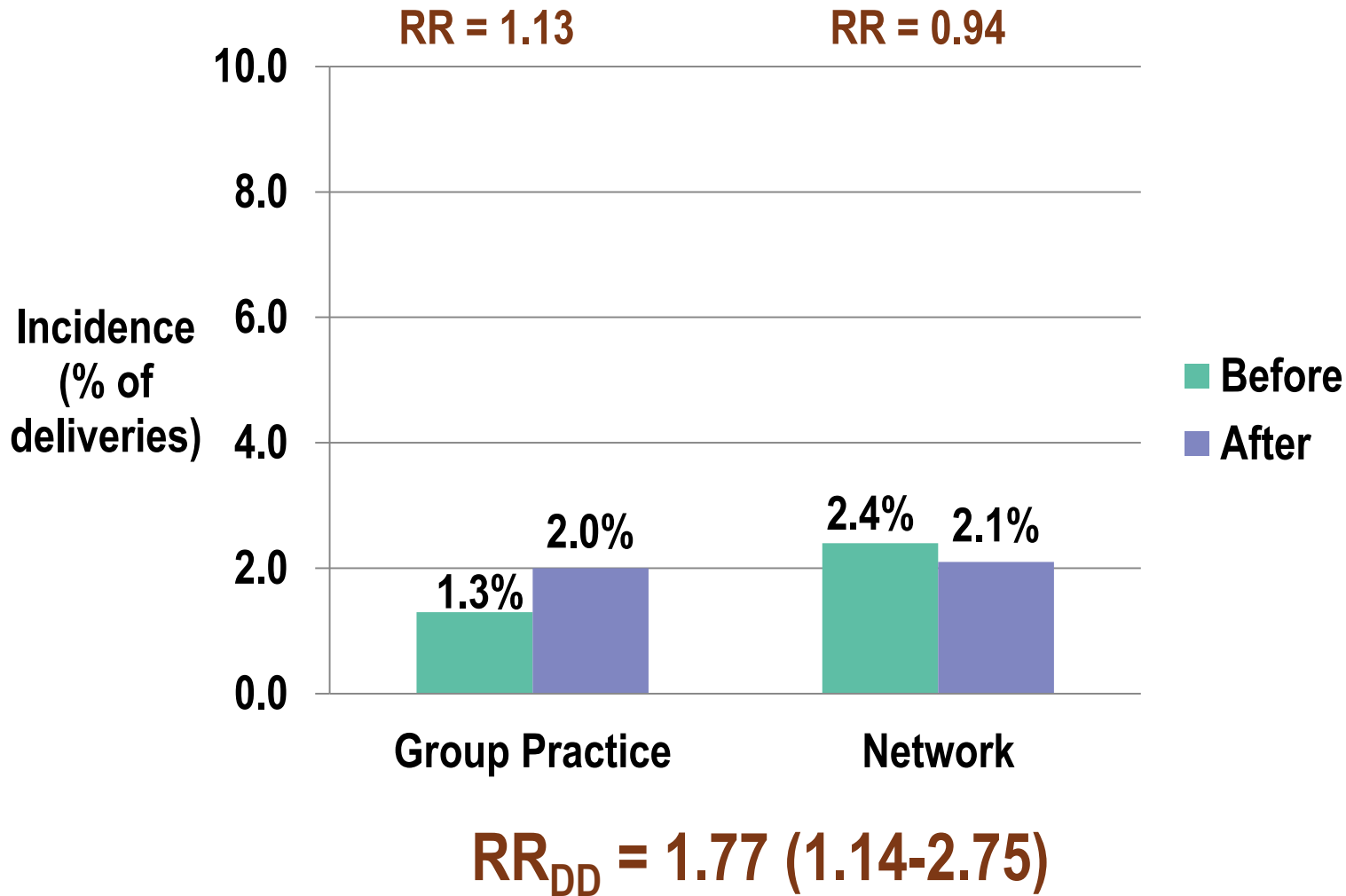
Induction of labor



Macrosomia (birthweight $\geq 4,500$ g)



Neonatal hypoglycemia



Association between guideline and **primary** outcomes

Increased risk

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

No association

- Primary cesarean
- Macrosomia ($\geq 4,500$ g)
- Large-for-gestational age
- Small-for-gestational age
- NICU admission

Association between guideline and **secondary** outcomes

Increased risk

- Outpatient nonstress testing: ↑ 12%

No association

- Gestational hypertension
- Preeclampsia
- Ultrasound in 3rd trimester
- Preterm birth
- Perineal tear
- Vaginal delivery after cesarean
- Operative vaginal delivery
- Neonatal jaundice
- Birth injury
- Other NICU

Discussion

Summary

Guideline adopted	Increased risk	No association
<ul style="list-style-type: none">▪ 2-step → 1-step approach▪ ↑ use of insulin during pregnancy	<ul style="list-style-type: none">▪ GDM diagnoses▪ Labor induction▪ Outpatient nonstress testing▪ Neonatal hypoglycemia diagnoses	<ul style="list-style-type: none">▪ 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 3rd 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

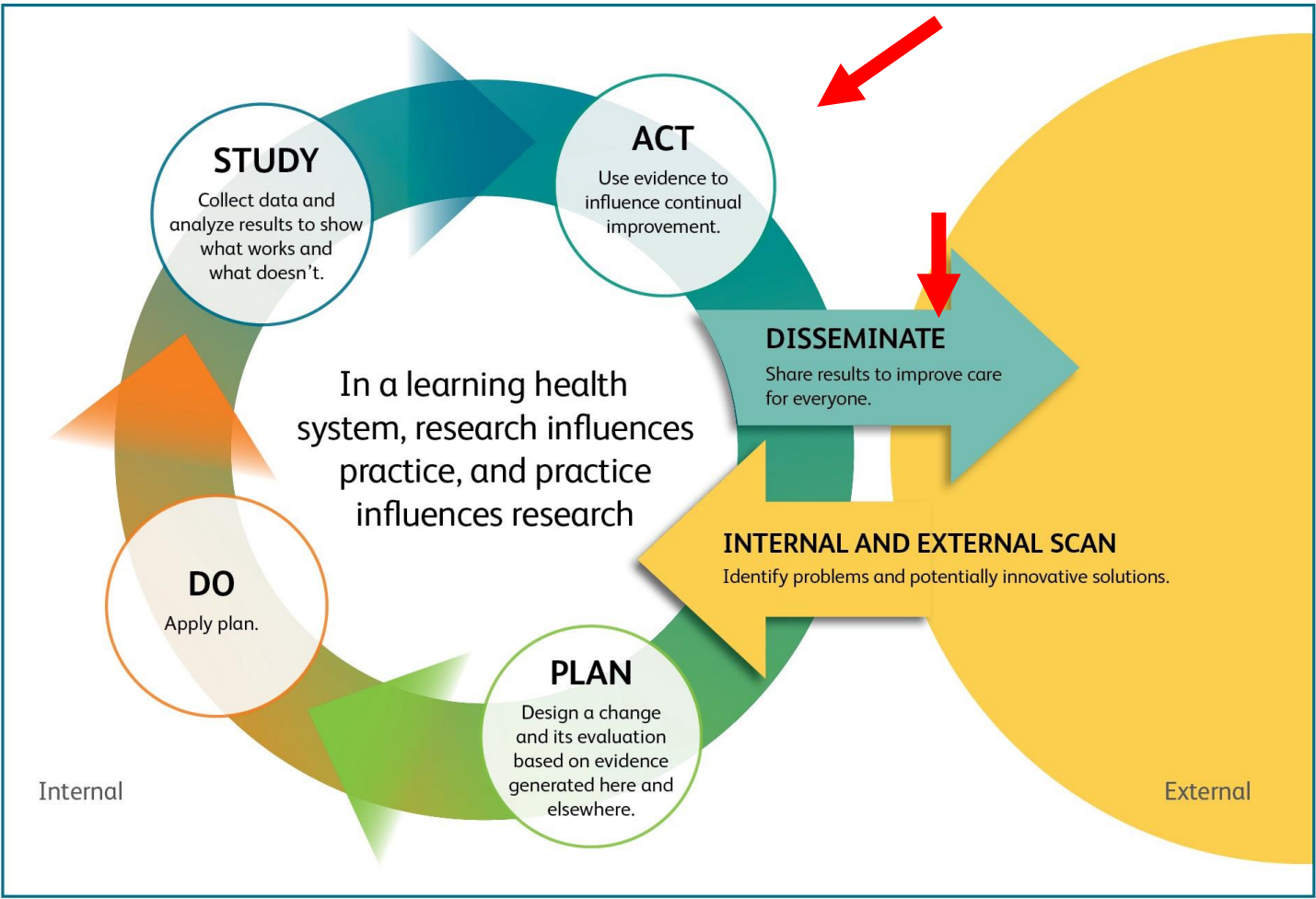
- **Large sample size**
- **Rich data on population characteristics and covariates**
- **Could study both processes and outcomes of care**
- **Control group unexposed to guideline change**
 - **Accounts for background time trends**

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

Clinical Update

news for patient care

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**

August 2018

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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

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- Paige Wartko, MPH (Doctoral Student)
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Questions?