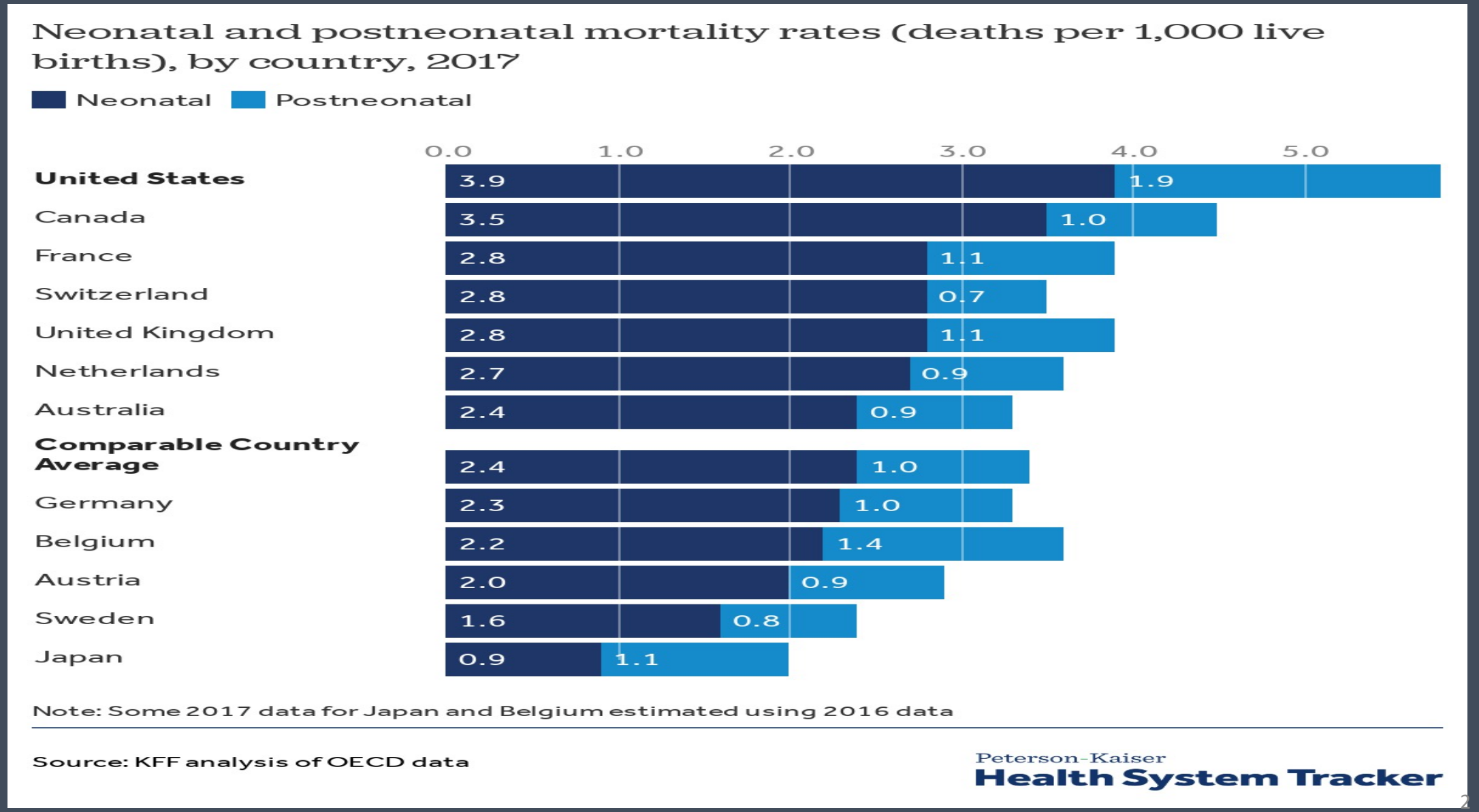
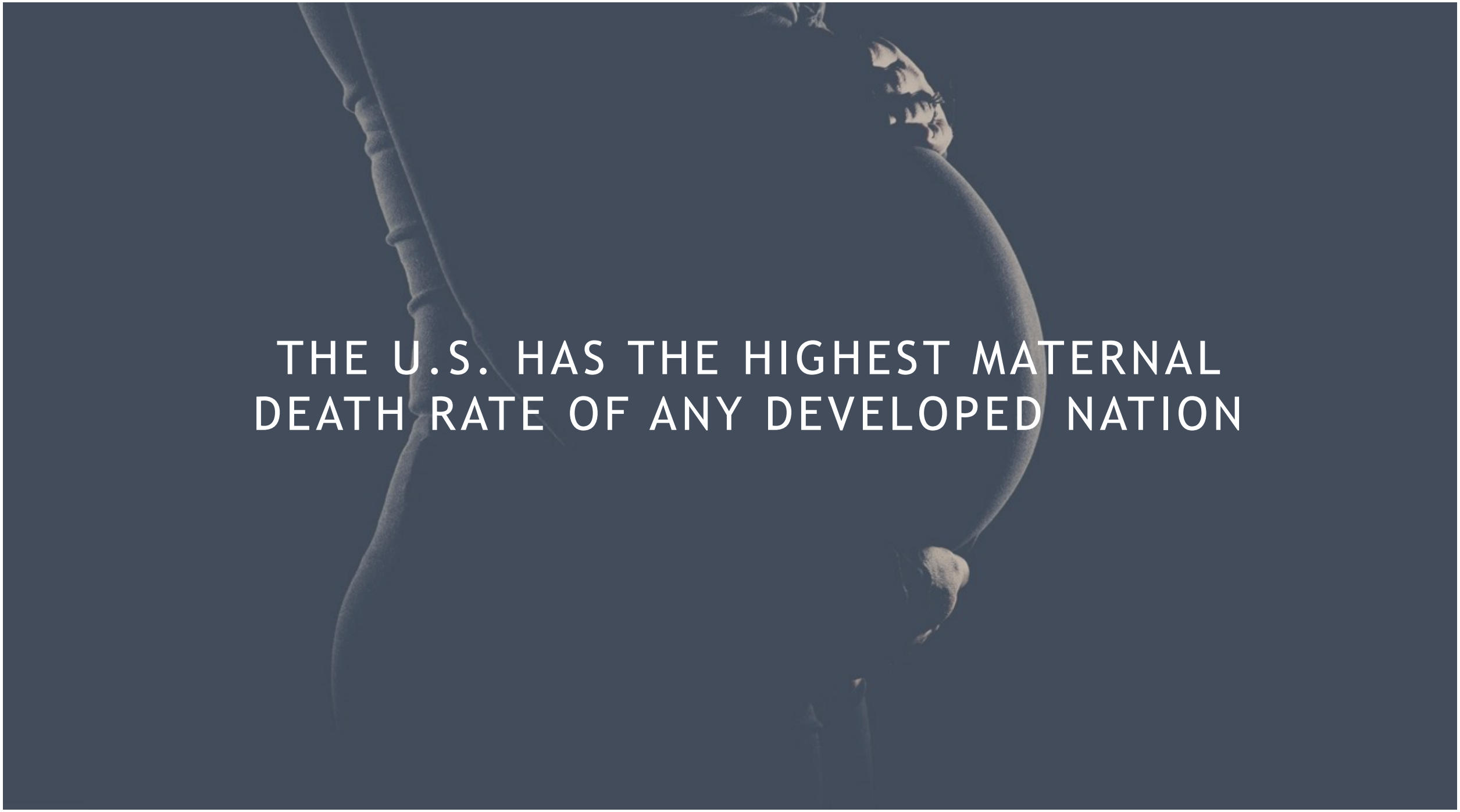
DRIVING BETTER OUTCOMES AND REDUCED RACIAL DISPARITIES IN PREGNANCY

THE U.S. NEONATAL HEALTH CRISIS

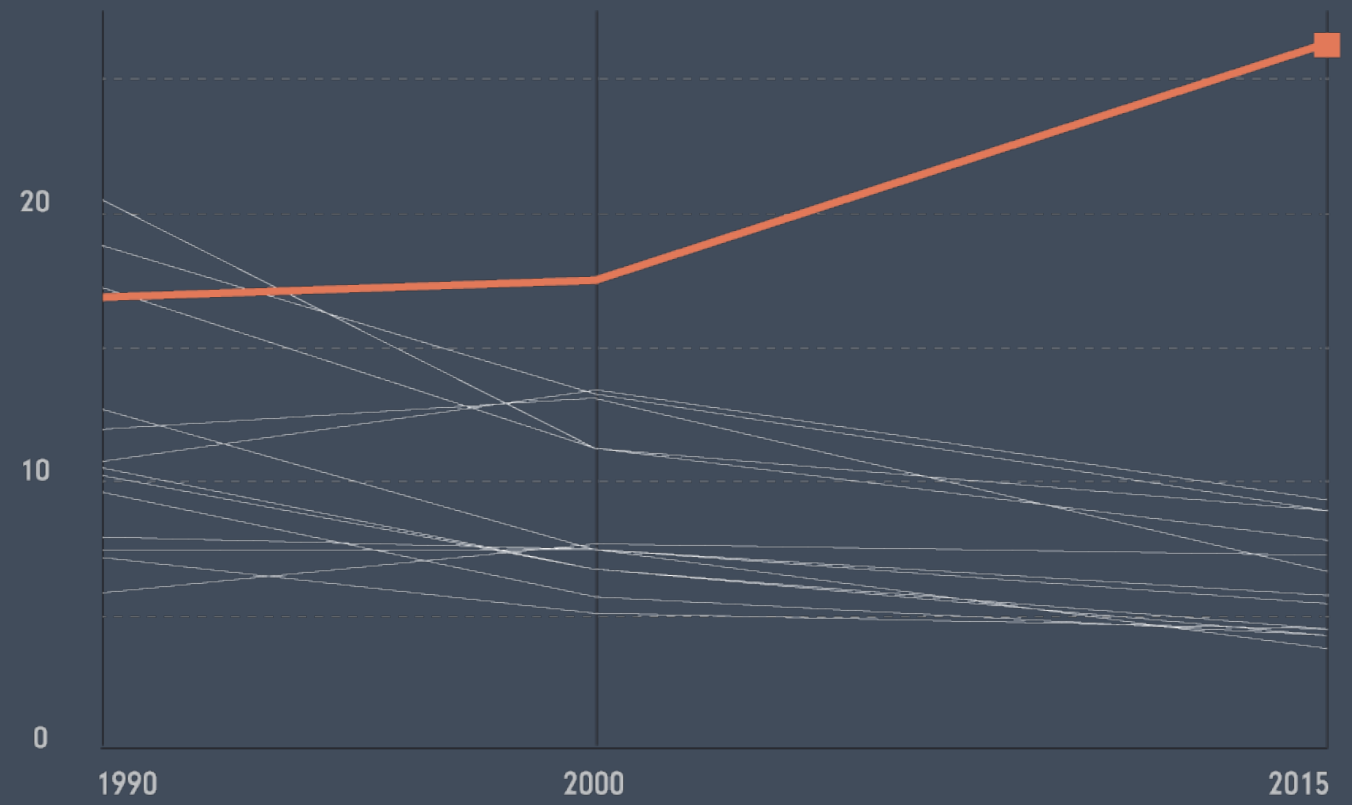




THE U.S. HAS THE HIGHEST MATERNAL DEATH RATE OF ANY DEVELOPED NATION

THE U.S. MATERNAL HEALTH CRISIS

Deaths per 100,000 live births



U.S. 26.4

U.K.	9.2
Portugal	9.0
Germany	9.0
France	7.8
Canada	7.3
Netherlands	6.7
Spain	5.6
Australia	5.5
Ireland	4.7
Sweden	4.4
Italy	4.2
Denmark	4.2
Finland	3.8

1. http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(16)31470-2.pdf

U.S. MATERNAL HEALTH CRISIS BY THE NUMBERS

>60%

Pregnancy-related deaths are avoidable[1]

3-4X

African-American women more likely to experience pregnancy-related mortality[2]

70

Near misses for each maternal mortality[3]

2.6X

Cost of near-miss delivery vs standard delivery[3]

1. https://www.cdcfoundation.org/sites/default/files/files/ReportfromNineMMRCs.pdf
2. https://www.cdc.gov/mmwr/volumes/68/wr/mm6835a3.htm
3. https://orwh.od.nih.gov/sites/orwh/files/docs/ORWH_MMM_Booklet_508C.pdf

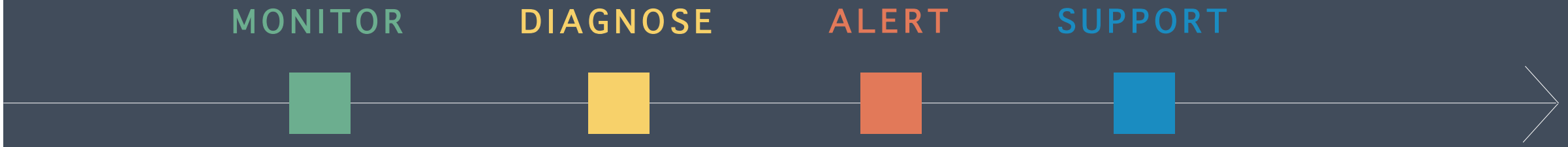
AT-RISK POPULATION AT UNIVERSITY HOSPITALS IN CLEVELAND LED TO THE DEVELOPMENT OF riskLD

UH Population Snapshot

- **63%** insured through **Medicaid**
- **65% African-American**
- 2017 telephone survey of 151 patients:
  - **44%** were **unemployed** at the time of interview
  - **31%** had **difficulty paying utility bills**
  - **30%** reported **food insecurity**
  - **92%** felt they **didn't have enough money to last through the month**
- Significant issues with drug abuse, violence, lack of prenatal care

➢ At the beginning of this process, a harm was occurring every 30 days

riskLD



POINT-OF-CARE ANALYTICS

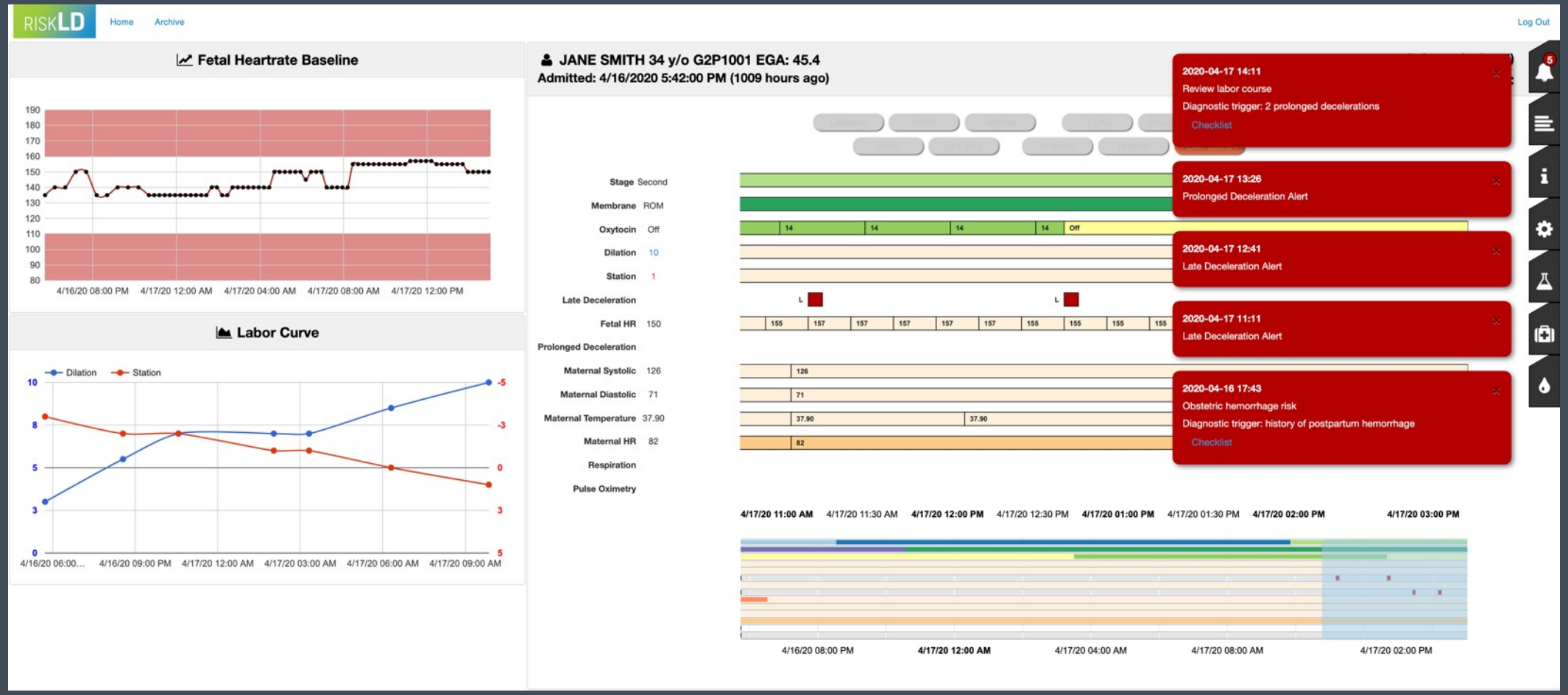
Graphical user interface (GUI) alerts clinicians to situations needing attention

Monitoring and treatment algorithms provide proprietary value for better outcomes

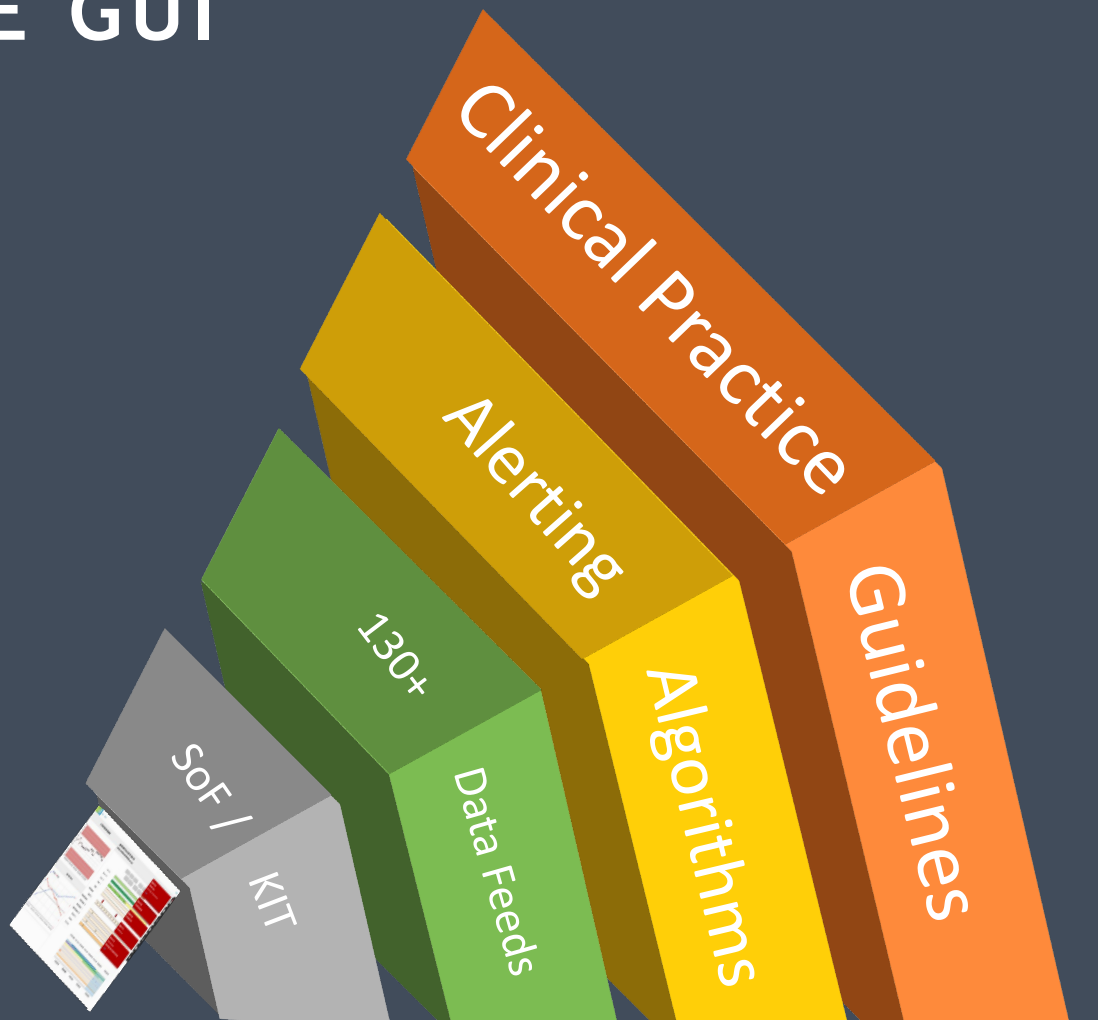
- 12 years of L&D outcomes analysis
- Monitoring algorithms provide early alerting
- CPGs to standardize treatment
- Allows clear visualization of developing issues

RECOGNIZING PATTERNS AND RISKS

- Key parameters are trended over time
- Alerts flag abnormal labor patterns

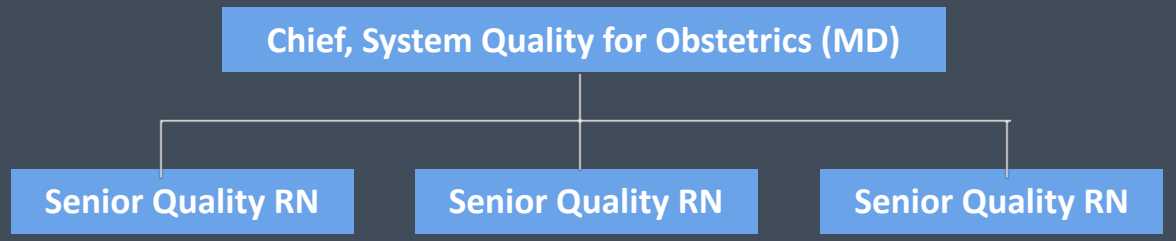


BEHIND THE GUI

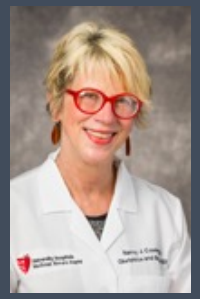


Clinical Practice Guideline Development Process

12 Year Process to Create Pregnancy/Labor & Delivery Clinical Practice Guidelines (CPGs)



Team started in 2009, current 4-person team working full time for 5+ years



Nancy Cossler, MD
Chief, System Quality for Obstetrics
University Hospitals

Identify Problem

- Quality Assurance (QA)
  QA reviews reveal clinical areas lacking standardized care pathways

Clinical Practice Guideline Development Process

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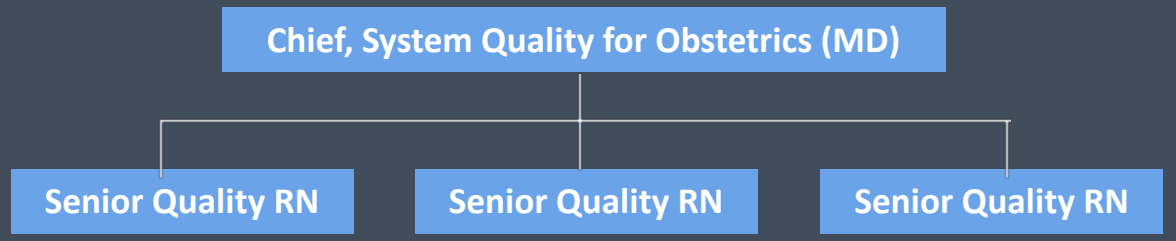

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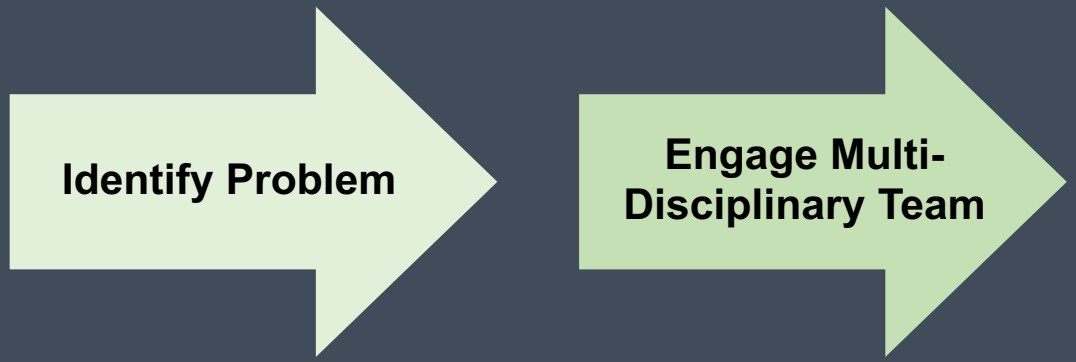
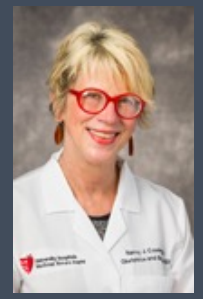




Nancy Cossler, MD
Chief, System Quality for Obstetrics
University Hospitals

Clinical Practice Guideline Development Process

Each and Every CPG Follows the Same Process – 100+ CPGs

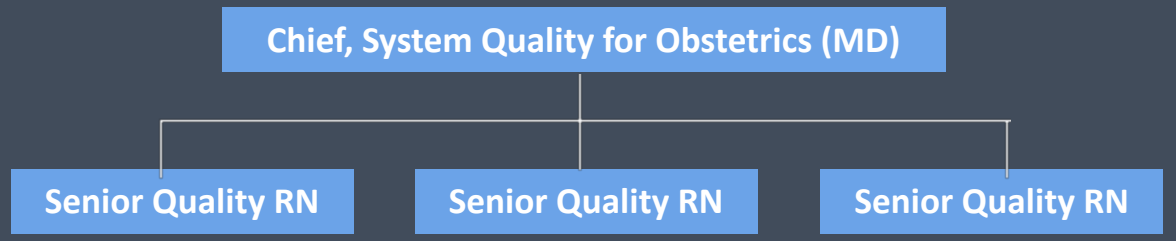
- Multi-disciplinary team
  OB, MFM, Nursing, Midwifery, Risk Management are jointly tasked with developing a CPG based on:
  - Level 1 or 2 evidence (ACOG, SMFM)
  - Internal expert opinion
    (if Level 1 or 2 evidence not available*)

- Candidate CPG is then circulated for feedback
  - Iterated until approval received from all areas

* As few clinical trials enroll pregnant women due to litigation risk, Level 1 or 2 evidence is quite often not available. The Internal Expert Opinion is developed by a thorough literature search coupled with case experiences.

Clinical Practice Guideline Development Process

12 Year Process to Create Pregnancy/Labor & Delivery Clinical Practice Guidelines (CPGs)



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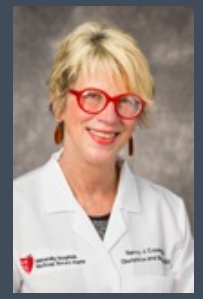

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Clinical Practice Guideline Development Process

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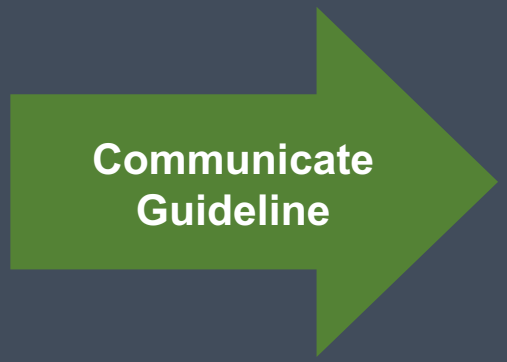


- Once approved through rigorous internal process, CPGs communicated to all providers including:
  - Data to be monitored
  - Trigger points for alerts
  - Explanation of preferred treatment plan and alternative options
- **Provided exclusively to riskLD**

>100+ CPGs SPAN FROM PRENATAL TO POST-PARTUM*

> SUBSET FOR LABOR & DELIVERY

Pre-Labor

1. Triage assessment on L&D
2. Triage evaluation of OB patient in ED
3. Preterm premature rupture of membranes (PPROM) management
4. Preterm labor management
5. Magnesium sulfate for neuroprotection
6. Antenatal corticosteroids

Induction of Labor

1. Misoprostol in pregnancy
2. Cervical ripening balloon

Labor Management

1. Labor management for gestations > 34 weeks
2. Fetal and uterine assessment and documentation
3. GBS prophylaxis
4. Chorioamnionitis
5. TOLAC (trial of labor after cesarean section)
6. Fetal scalp electrode application
7. Operative vaginal delivery
8. Cesarean delivery categories

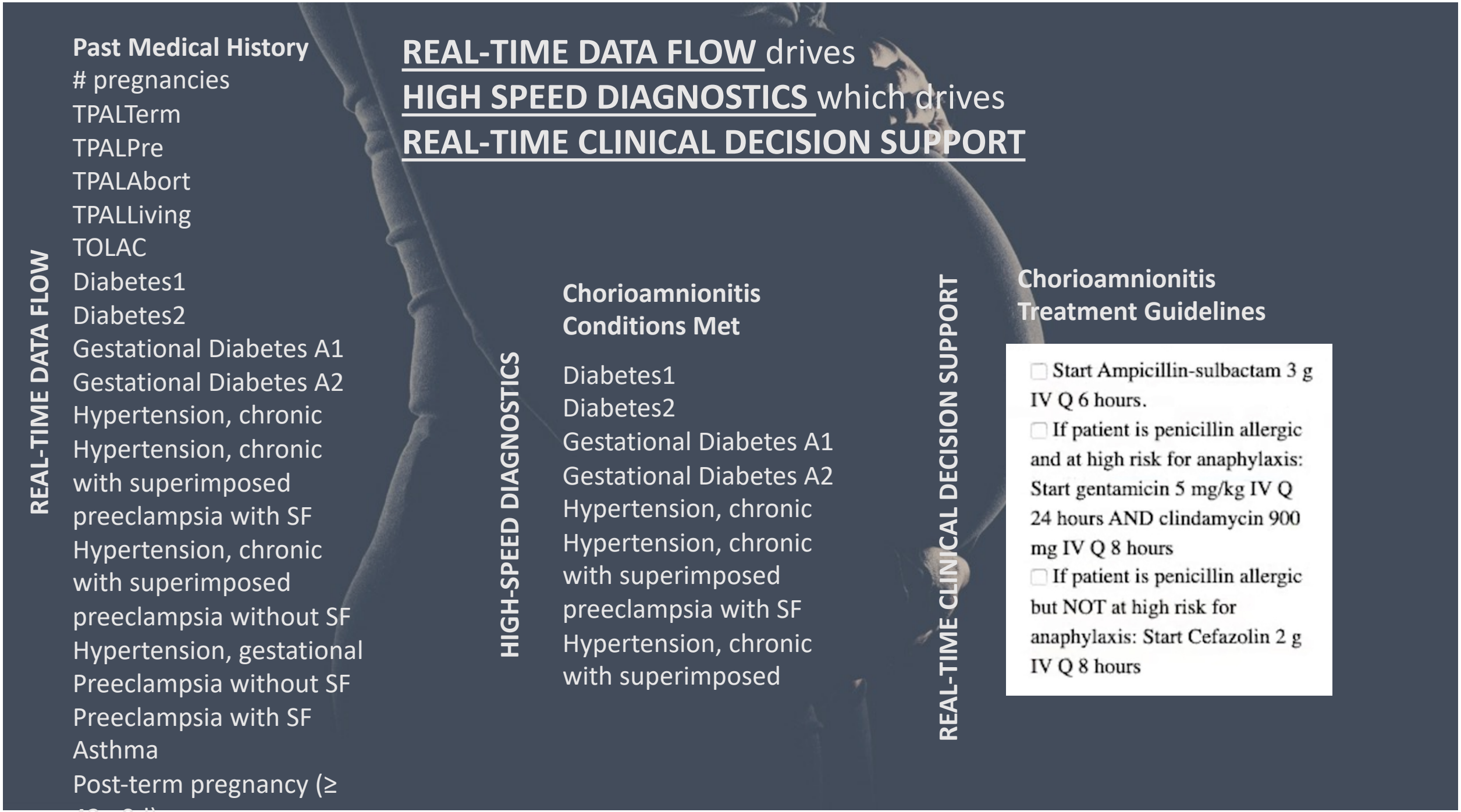
Medical Comorbidities

1. Hypertensive disorders of pregnancy
2. Diabetes management in pregnancy
3. Herpes simplex virus in pregnancy
4. HIV management in pregnancy
5. Opioid use disorder and MAT in pregnancy
6. Hepatitis B, perinatal

Post-Partum Management

1. Post-placental IUD placement
2. Post-partum nursing standards
3. Recovery period on L&D
4. Maternal early warning system (MEWS)
5. Obstetric hemorrhage management
6. Quantitative blood loss
7. Bakri balloon tamponade

*Hospitals can selectively substitute in their own guidelines if they have them



REAL-TIME DATA FLOW drives
HIGH SPEED DIAGNOSTICS which drives
REAL-TIME CLINICAL DECISION SUPPORT

REAL-TIME DATA FLOW

Past Medical History
pregnancies
TPALTerm
TPALPre
TPALAbort
TPALLiving
TOLAC
Diabetes1
Diabetes2
Gestational Diabetes A1
Gestational Diabetes A2
Hypertension, chronic
Hypertension, chronic with superimposed preeclampsia with SF
Hypertension, chronic with superimposed preeclampsia without SF
Hypertension, gestational
Preeclampsia without SF
Preeclampsia with SF
Asthma
Post-term pregnancy (≥ 42w0d)

HIGH-SPEED DIAGNOSTICS

Chorioamnionitis Conditions Met

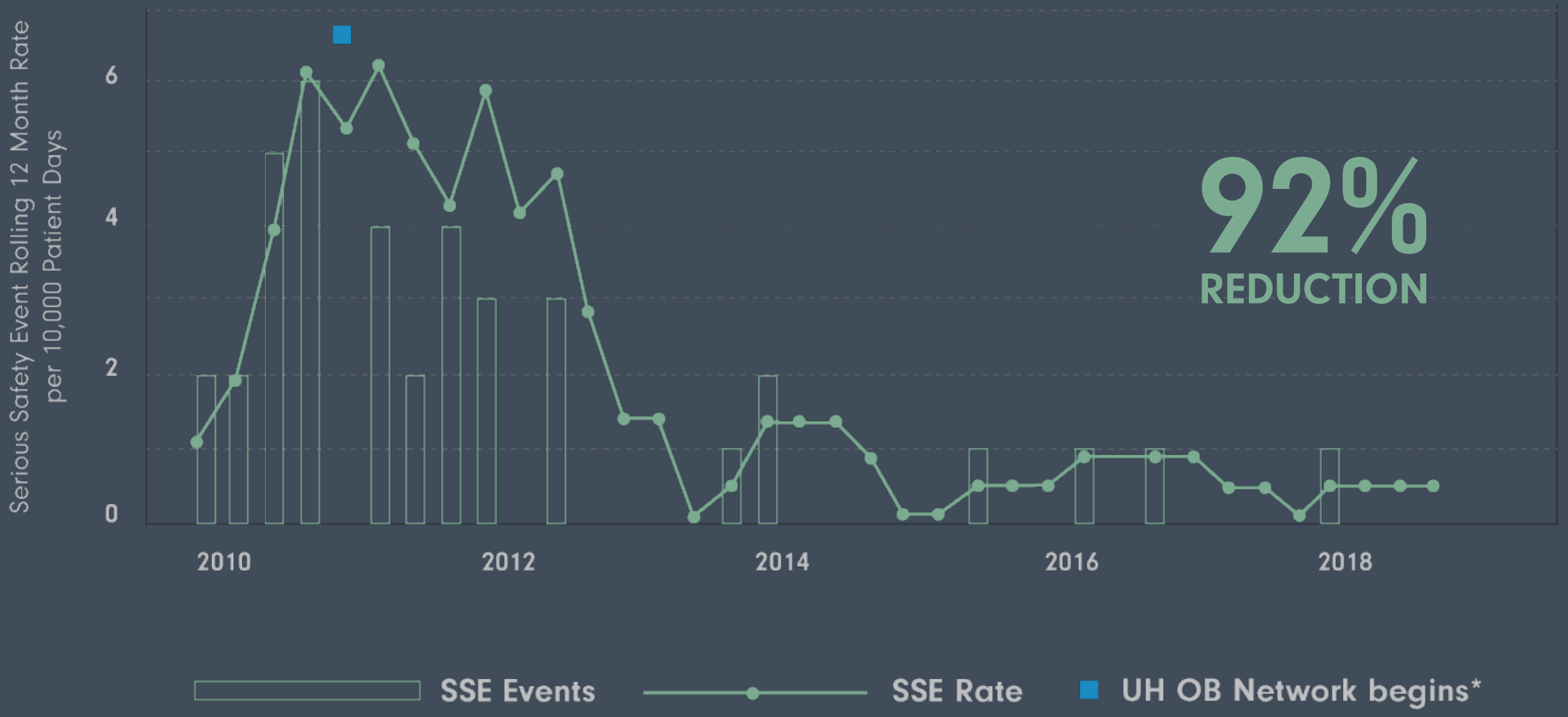
Diabetes1
Diabetes2
Gestational Diabetes A1
Gestational Diabetes A2
Hypertension, chronic
Hypertension, chronic with superimposed preeclampsia with SF
Hypertension, chronic with superimposed

REAL-TIME CLINICAL DECISION SUPPORT

Chorioamnionitis Treatment Guidelines

- ☐ Start Ampicillin-sulbactam 3 g IV Q 6 hours.
- ☐ If patient is penicillin allergic and at high risk for anaphylaxis: Start gentamicin 5 mg/kg IV Q 24 hours AND clindamycin 900 mg IV Q 8 hours
- ☐ If patient is penicillin allergic but NOT at high risk for anaphylaxis: Start Cefazolin 2 g IV Q 8 hours

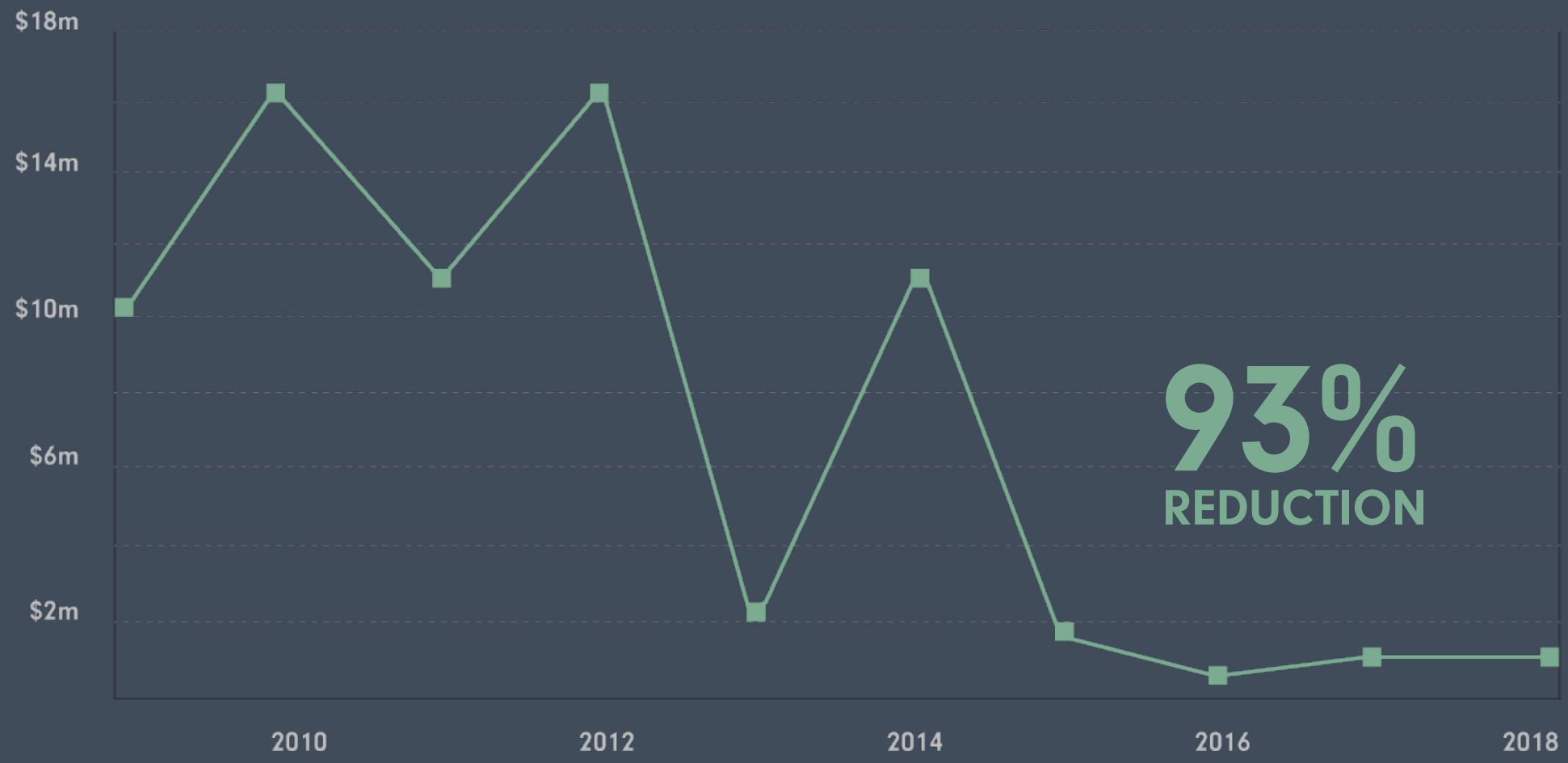
CPGs DRASTICALLY REDUCE SERIOUS SAFETY EVENTS AT UH



*The UH OB Network's quality work began in earnest in Q1 2010. Prior to Q1 2010, there were few guidelines, nor was there a robust QA process that included levels of harm. The initial spike in SSEs from Q2 2010 to Q1 2011 is to be expected, given increased case detection following the formalization of this quality work.

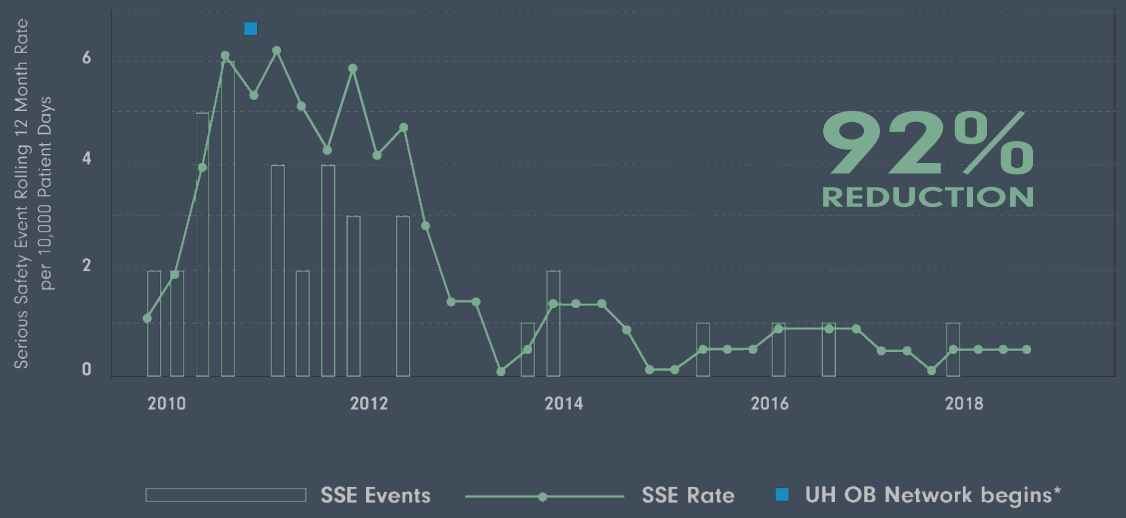
CPGS DRASTICALLY REDUCE OBSTETRIC LITIGATION COSTS AT UH

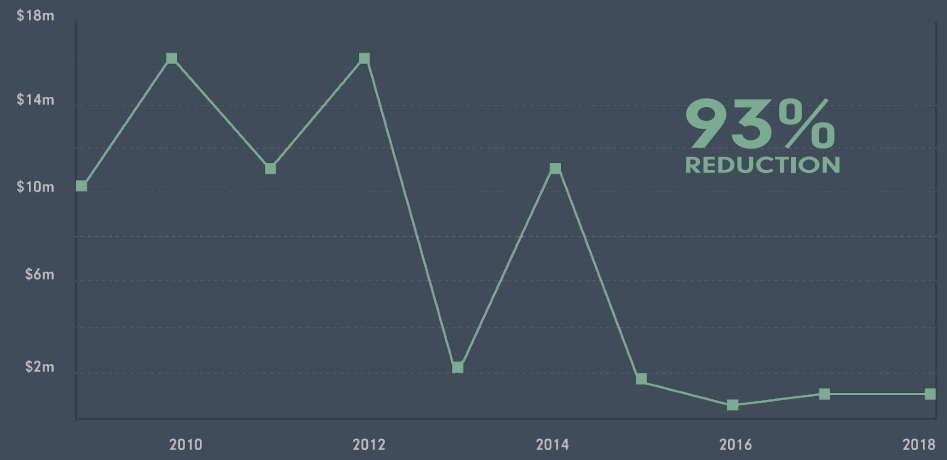
93% Reduction in OB Litigation Costs at UH



CPGs REDUCE COSTS FOR HEALTH INSURERS!

93% Reduction in OB Litigation Costs at UH





- Suboptimal outcomes lead to ICU, NICU and lifetime care costs
- Suboptimal outcomes lead to societal costs (both monetary & non-monetary)

- Avoiding suboptimal costs saves money for both health insurers and government (41% of births in Ohio are paid for by Medicaid)

Clinical Practice Guideline Update Process

Time Basis

- Every CPG is scheduled for review in 18-24 months

Edge Case Suboptimal Outcome

- These are cases where the CPG did not provide adequate alerting or the guidance did not prevent the suboptimal outcome
- An Edge Case triggers an emergency review by the 4 person team
- By definition, there is no way to predict these rare events
  - They are only spotted by having sufficient volume, sufficient variation in pregnant population and vigilance
  - Edge cases are suspected to be responsible for a disproportionate number of suboptimal outcomes

Revised CPG candidate is iterated until ready for dissemination

- Updated CPG is provided solely to riskLD for dissemination

FEDERAL FOCUS ON MATERNAL MORTALITY & RACIAL DISPARITIES; riskLD POSITIONED AS SOLUTION

BLACK MATERNAL HEALTH MOMNIBUS

February 2021

Sponsored by Sen. Kamala Harris (CA), Reps. Alma Adams (NC-12) & Lauren Underwood (IL-14), Sen. Booker (NJ)

March 2020 — MOMNIBUS introduced

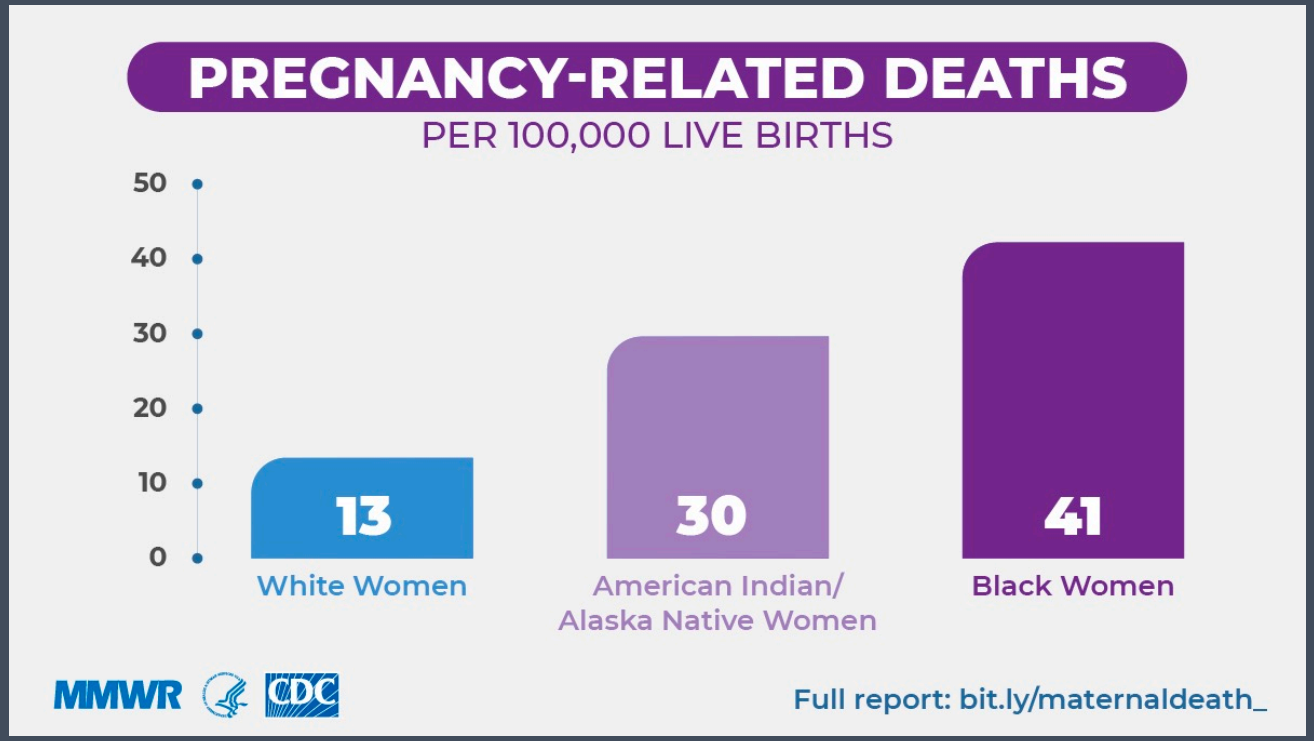
April — riskLD meets with offices of Reps Adams & Underwood and Sen Harris

May — riskLD provides descriptive CDS language for inclusion in Tech to Save Moms Act

June-Present — riskLD engages health systems to be beta sites

Feb 2021 — MOMNIBUS re-introduced

SUPPORT FOR INNER-CITY HOSPITALS



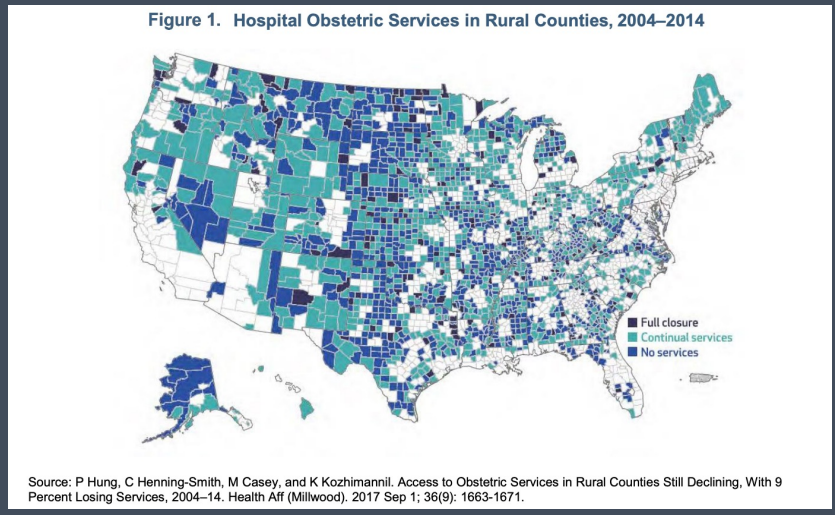
- Blacks & Hispanics are over-represented in Urban areas
- Medicaid pays for 66% of Black pregnancies and 60% of Hispanic pregnancies
- Black women have 3x-4x worse outcomes

Sources:
https://www.pewsocialtrends.org/2018/05/22/demographic-and-economic-trends-in-urban-suburban-and-rural-communities/

https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_01.pdf

SUPPORT FOR RURAL HOSPITALS

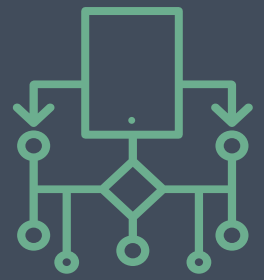
- 60% of births in the US are at hospitals that do 3 or fewer deliveries per day
- More and more areas are becoming “maternity deserts” / lack of OBs
- Need ”Eye in the Sky” help
  - E-OB for Labor & Delivery



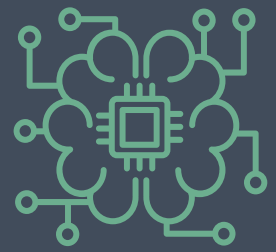
Source: CMS https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/rural-health/09032019-Maternal-Health-Care-in-Rural-Communities.pdf

VISION

Monitoring & Visualization
(dashboards)



Diagnostics &
Decision Support
(algorithm engines)



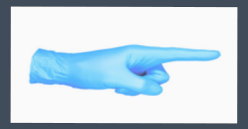
Diagnostics / Therapeutics
(Ml / Al on dataset)

BUILDING THE DATASET

The core information is contained in an end-to-end, standardized, interrogatable pregnancy process dataset

DATASET ALSO MAKES CDS UNMATCHABLE

v1.0
Monitoring
[dashboards]



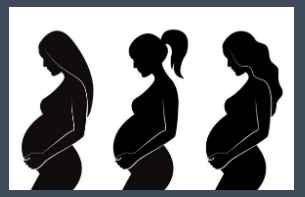
v1.8+ Monitor, Diagnose, Alert, Support with CPGs
[clinical decision support]

Data Repository
There is limited data for pregnancy from randomized trials
[build data set for analysis]

AI supported CPGs
Next gen support for OB Departments
[AI insights platform]

ML / AI Usable Insights
[complete thought leadership]

LARGE UNMET NEED FOR STANDARDIZED DATASET WITH INTERVENTIONS & RESULTS



The core information is contained in an end-to-end, standardized, interrogatable pregnancy process dataset

"…1636 drugs under development for neurological conditions but only 17 for maternal health conditions…"*

SIGNIFICANT NEED

- Gestational Diabetes
- Preterm labor
- Preeclampsia
- Heart Disease
- Asthma
- Back Pain
- Hyperemesis Gravidarum

- Dataset to be licensed to diagnostics and drug developers
- RK shifting focus to this ("Dataset designed by data scientists for data scientists")

* SOURCE: https://www.rcog.org.uk/globalassets/documents/guidelines/scientific-impact-papers/sip-50.pdf

EXTENDING THE DATASET

CURRENT

- Base Dataset covers all pertinent history
- Base Dataset has real-time, pre- to post-partum labor & delivery conditions, interventions & outcomes

FUTURE

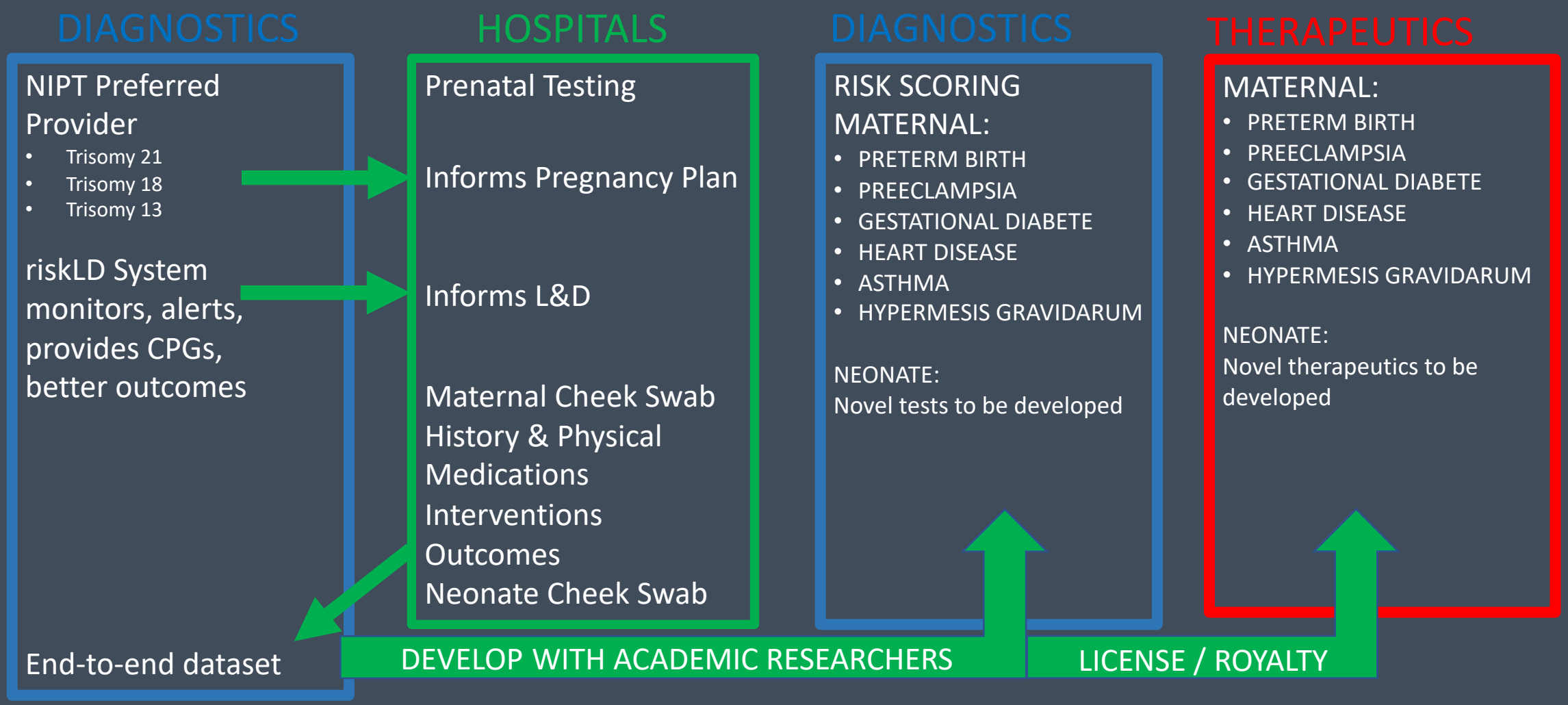
Genomics matched to anonymized patient data to extend Dataset

- IRB approval
- Patient signs informed consent
- Store anonymized cheek swab for DNA

- Combined information helps provide illumination on heretofore unseen insights

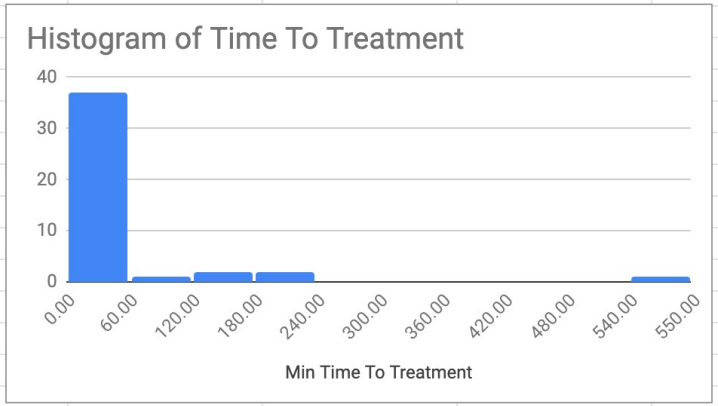
Get to scale quickly, build largest integrated, standardized data set that allows for ML/AI on pregnancy process for diagnostic and pharma companies

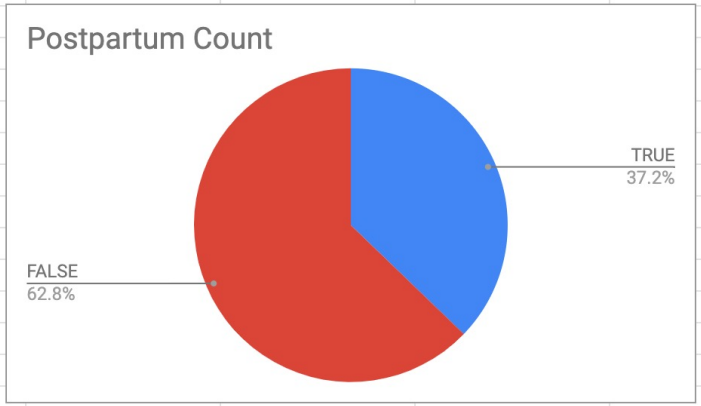
USING THE DATASET

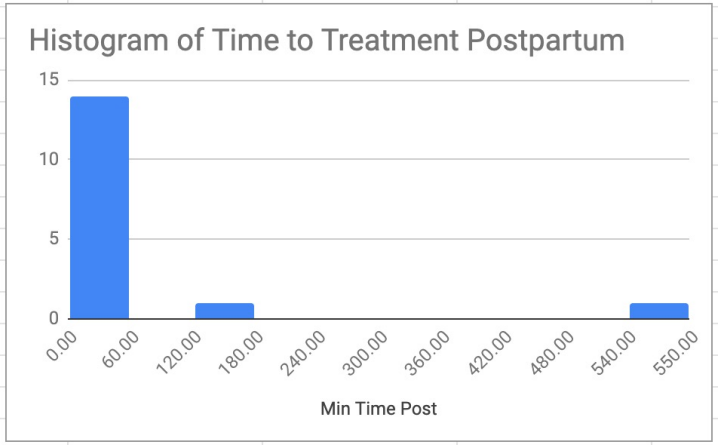


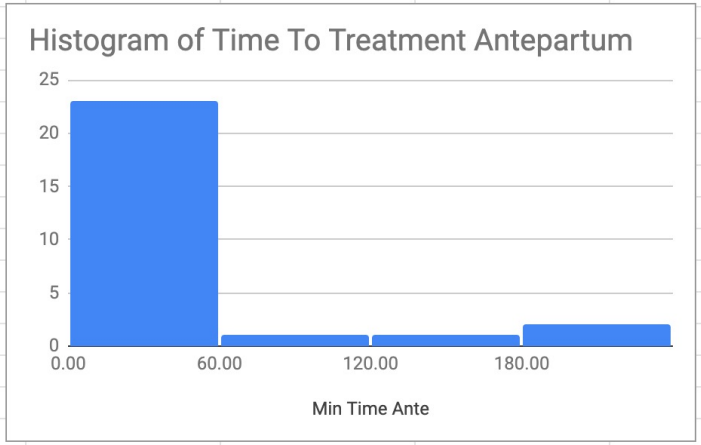
RISKLD REPORT: TIME TO TREATMENT

Hospital: Groveland Maternity Hospital
Month: May 2020
Deliveries: 500
Severe range blood pressures: 10%









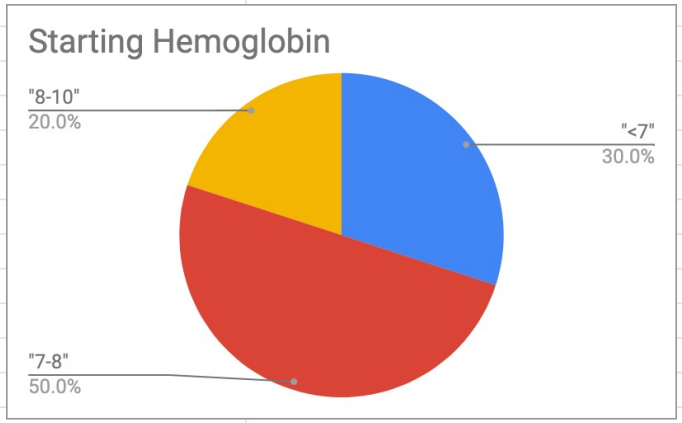
RISKLD REPORT: TRANSFUSION

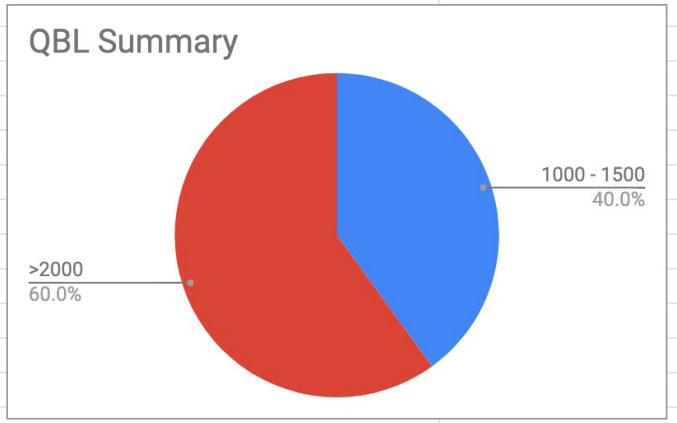
Hospital: Groveland Maternity Hospital

Deliveries: 500

Month: May 2020

OBH: 5%Transfusion ≥ 4 units packed red blood cells: 2%





Patient	Admit	Units	Starting Hemoglobin	QBL
1	2021-05-01 21:02:00	4	7-8	1000 - 1500
2	2021-05-03 1:12:00	5	7-8	1000 - 1500
3	2021-05-04 9:42:00	4	8-10	>2000
4	2021-05-10 10:04:59	11	<7	>2000
5	2021-05-11 9:02:41	4	8-10	>2000
6	2021-05-11 10:54:31	4	<7	>2000
7	2021-05-12 17:23:44	6	7-8	>2000
8	2021-05-13 9:10:51	4	7-8	1000 - 1500
9	2021-05-20 18:52:00	5	7-8	1000 - 1500
10	2021-05-28 22:17:36	4	<7	>2000

HOSPITALS CAN DOWLOAD FROM THEIR EMR APP STORE

RISKLD SYSTEM

- Write to the SoF interface
- Port to different EHRs

SMART ON FHIR STANDARDIZED INTERFACE

Cerner

MEDITECH
GREENFIELD

Allscripts

- Focused on health systems that use Epic

6 AREAS WHERE riskLD MAKES A DIFFERENCE

- The US has the worst maternal mortality rate in the developed world
- The US has the worst neonatal mortality rate in the developed world
- The US has huge racial disparities in outcomes
- riskLD provides “eye-in-the-sky” expertise for rural “maternity deserts”
- riskLD provides “eye-in-the-sky” expertise for busy urban centers with higher risk patients
- By avoiding suboptimal outcomes, riskLD SAVES THE SYSTEM MONEY

- ➢ Ohio Medicaid pays for 41% of the births in Ohio
  - ➢ Let’s measure decrease in ICU / NICU days using riskLD

THANK YOU

RISKLD

RK Khosla
Founder
rkkhosla@riskLD.net
(216) 223-8778

Steve Porter, MD, MBA
Chief Executive Officer
sporter@riskLD.net
(518) 424-6249