Adverse Birth Outcomes in the TriCounty Health Department Region

Environmental Epidemiology Program
Bureau of Epidemiology

UTAH DEPARTMENT OF HEALTH
Where is the report?

http://health.utah.gov/enviroepi/appletree/TriCountyABO
Tri-County Adverse Birth Outcomes Statistical Review

Daggett, Duschesne, and Uintah Counties

Public Meetings

Documents

Background

Findings

Recommendations

Frequently Asked Questions

Utah counties, with the study area in green.
A Little History

► June 12, 2013: EEP becomes aware of a concern that there are more stillbirths and infant deaths occurring in Vernal Utah.

► March 20, 2014: TCHD contacts EEP with approval to conduct an investigation

► May 7, 2014: EEP presents study plan to TCHD

► May 14, 2014: TCHD requests EEP delay investigation until 2013 data is available.

► October 14-15 2014: EEP received 2013 data

► December 2014: Final analysis

► March 17, 2015: Final Report
TriCounty ABO Statistical Review
Final Report

Data Acquisition
- Characterize Data & Generate Definitions
  - Risk strata
  - Adverse birth outcomes
  - Study and control areas
  - Temporal aggregate units

Data Quality Checks & Standardization
- Recode data
- Merge annual tables
- Georeference

Reference Data

Risk Characterization

Risk Quantification
- Rates
- Risk Ratios
- Temporal Trends

October
- Data Acquisition

November
- Characterize Data & Generate Definitions

December
- Data Quality Checks & Standardization
  - Recode data
  - Merge annual tables
  - Georeference

January
- Reporting Writing
  - Context
  - Methods
  - Interpretation
  - Action plan

March
- Literature Review
  - Review
  - Certification
  - Publication

TriCounty ABO Statistical Review
Final Report
Some Terms

► **RISK:**
   - **Disease Risk:** the probability of acquiring a disease (usually defined as a rate or risk ratio)
   - **Environmental Risk:** a function of (1) exposure and (2) hazard (usually defined as a hazards quotient)
   - **Toxicological Risk:** a function of (1) a dose and (2) an effect on the body (usually defined in terms of a reference dose or dose-response correlation)

► **INCIDENCE:** the number of new cases occurring in a time period (a year)
   - Just a fancy word for “count”

► **INCIDENCE RATE (or RATE):** the number of new cases per time period occurring per a unit (i.e., 1,000) of the population
One Last Term

- RISK RATIO (or INCIDENCE RATIO): A ratio created by comparing the study area incidence to a comparison area incidence.

\[ RR = \frac{Observed}{Expected} \]

- The comparison population incidence (the “expected”) has been re-proportioned to the same scale as the study population.
- The “expected” risk is assumed to be the normal random occurrence of disease.

**Interpretation**

- RR = 1: The risk in the study population and the comparison population are the same
- RR > 1: The study population has more risk than expected
- RR < 1: The study population has less risk than expected
Example

\[ RR = \frac{\text{TriCounty Rate} = 5.9}{\text{Utah Rate} = 4.8} = 1.29 \]

► **Question:** When is a result indistinguishable from 1.0?

1.002? 1.02? 1.2? 2?

► **Solution:** Apply a “95% confidence interval” on the “point estimate”

► **Interpretation:**
  - If the 95% CI does not include 1.0 (between the lower and upper values of the interval) then **SIGNIFICANT**
  - 1.01 – 2.10 would mean significantly elevated
  - If the 95% CI includes 1.0 (between the lower and upper values of the interval) then **NOT significant**
  - 0.65 – 2.10 would mean NOT significant
Interpretation

1.0

Normal Line

Not A Concern

Concern

Confidence Limits Include Normal (1.0)

Confidence Limits Above Normal (1.0)
Also look at the trend through time

Not Significant
But Trending Upward

We were really good, now we’re not. What happened?
Study Design Decision

- Aggregate geography-time to get approximately 2,000 births per analytical unit
  - TriCounty considered as one geographical unit allowed 2-3 year temporal ranges
  - Duchesne and Uintah counties could be evaluated individually if larger temporal ranges employed
  - Individual cities were too small to consider alone

Why?
Effects of population size and case rate on the 95% confidence interval

Stillbirths (rate = 5.9 / 1,000 LB; RR = 1.23)

Tipping Point = 16,836 LB (100 still births)

Small for Gestational Age (rate = 116.2 / 1,000 LB; RR = 1.22)

Tipping Point = 923 LB (108 SGA births)
Study Design Decision

► Use the rest of Utah (except TriCounty) as the comparison population

► Why not use the national rates?
  - The comparison population represents “normal”
  - What should TriCounty’s normal be?
    ► Utah is healthier than the nation
  - National raw birth data are not readily available
    ► Can’t control for behavioral risk factors
    ► Can’t obtain rates in the same temporal scales, etc.
Example
Stillbirth rate in 2012-2013

\[ RR = \frac{\text{TriCounty Rate}}{\text{Utah Rate}} = \frac{5.9}{4.8} = 1.29 \]

\[ RR = \frac{\text{TriCounty Rate}}{\text{National Rate}} = \frac{5.9}{6.3} = 0.94 \]

- Same relationship for every category of ABO
- Alternatives: Use another local health regions in Utah
  - Turned out to be equally challenging

Not as good as Utah
Better than the nation
Controls

- Rate Ratio (RR) uses stratified state rate that has been proportioned to mimic the study area population ("standardized")

- The strata controlled for:
  - Mother’s age
  - Mother’s weight
  - Mother’s race / ethnicity
  - Mother’s access to health care
  - Mother’s health status
  - Maternal use of tobacco, drugs, and alcohol
Significant versus Meaningful

Not Significant

Significant
Not Meaningful

Significant
Meaningful

► When does a concern become a problem?
► Is it a big enough problem to become a priority?
► Can public health do something about it?
Interpretation Rules for Meaningful Results

- Two or more sequential analytical periods with statistically elevated risk ratios
- One or more analytical periods with a power score greater than 80%
- Statistically significant last analytical period with an increasing trend
Low Birth Weight

Statistically Elevated Rate

TriCounty ABO Statistical Review
Final Report
Premature Birth

Statistically Elevated Rate
Small-for-Gestational-Age

Statistically Elevated Rate

Power > 80%
Infant Mortality

Statistically Elevated Rate

Power > 80%

All above the “normal” line
Diagnostic Causes of Infant Mortality (n = 118)

- 58% due to a developmental or genetic defect at time of birth
- 22% due to a complication or injury that occurred at birth
- 11% resulted from an injury (physical & chemical) after birth
- 9% resulted from an infectious disease
Stillbirths

Statistically Reduced Rates
All below the “normal” line
Diagnostic Causes of Stillbirth
(n = 85)

► 74% due to a complication at the time of birth involving the cord or placenta

► 12% due to developmental anomalies

► 7% were attributed to a pre-existing maternal health condition (i.e., diabetes)

► 3% resulted from either Edward’s or Patau’s syndrome (types of trisomy)

► 2% due to Rh-factor sensitivity

► 2% not classifiable
Birth Defects

► Separate report by Utah Birth Defects Network
  - All birth defects combined
  - Congenital heart defects
  - Orofacial clefts
  - Genitourinary defects
  - Gastrointestinal defects
  - Limb defects
  - Chromosomal birth defects

► No significant findings
Conclusion

► **Statistical Findings:**
  - Past problem with SGA births
    - Not persistent to the present time
  - No concern for other kinds of ABO

► **Observational Findings:**
  - Infant deaths rates are consistently non-statistically higher than corresponding state rates
  - Stillbirths rates rose from consistently below the state rates to above the state rate for the 2012-2013 analytical period
  - This finding **confirms** the initial observation of more infant deaths and stillbirths than would be expected recently
County Level

► Analysis for Duchesne and Uintah Counties were consistent with the findings for the TriCounty study area

► Same conclusions
Some Points

► Statistical reviews cannot attribute risk to any causal factor

► The most important causal factors (discovered in the literature review) are:
  ▪ Socio-economic factors, particularly access to health care
  ▪ Maternal age, race, and ethnicity
  ▪ Parity
  ▪ Maternal health status during pregnancy
  ▪ Maternal lifestyle before and during pregnancy
  ▪ Inherited (genetic) risks
Study Limitations

- Power is limited by the population size
- Cannot discover Utah mothers who give birth outside of Utah
- The population risk can not be applied to the individual ("ecologic fallacy")
The Hard Question:
Why didn’t you do an environmental risk assessment investigation?

► Hard to justify until the problem is quantified
  - Very invasive to personal privacy
  - Would require 100% participation
  - After the fact = recall bias problem

► Not guaranteed to be able to find the risk
One Rebuttal

“UDOH recently acknowledge the statistical spike in perinatal deaths in Uintah basin, then mentioned everything but air pollution and environmental contaminants as possible explanations.”

Salt Lake Tribune, April 16, 2015

Risk Factors for Adverse Birth Outcomes (pages 19-21)

<table>
<thead>
<tr>
<th>Category of Risk</th>
<th>Word Count</th>
<th>References</th>
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</thead>
<tbody>
<tr>
<td>All Risks</td>
<td>994 (100%)</td>
<td>78 (100%)</td>
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<tr>
<td>Environmental</td>
<td>624 (63%)</td>
<td>64 (82%)</td>
</tr>
<tr>
<td>Air Pollution</td>
<td>273 (27%)</td>
<td>39 (50%)</td>
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If mothers are predisposed for genetic or other reasons, poor air quality “could throw you over the edge.”

Robert M Silver, MD, University of Utah Professor of Obstetrics and Gynecology as reported in the Salt Lake Tribune

Which is better?

Move mom back from the edge.

Or remove the wind
Some follow-up options

► We hope this report is empowering for further investigation
  ▪ Request UDOH Maternal and Infant Health Program conduct a review of infant mortalities and local programs
  ▪ Request that EEP conduct a follow-up statistical review in 2 years
  ▪ Seek resources for a case/cohort investigation to establish causality

► Make available to mothers the list of services in Table 7
Your Turn!