“Stillbirth is the most under-studied issue in medicine today”.

“No one professional organization takes responsibility for stillbirth.”

The Lancet (2011) Stillbirth Series Executive Summary
BACKGROUND

the sudden unexpected death data enhancement and awareness act
S.2746/H.R.669

CHALLENGES
BACKGROUND

CDC’s National Center on Birth Defects and Developmental Disabilities Activities to Understand Stillbirth

CDC’s National Center on Birth Defects and Developmental Disabilities (NCBDDD) is working to learn more about the loss of a baby due to stillbirth. Read about their efforts below.

Stillbirth Surveillance Project, 2005 – 2015

From 2005 – 2015, NCBDDD supported the expansion of two birth defects tracking systems to include all stillbirths. These two tracking systems identify babies with birth defects in their study areas by having staff continually review medical records at multiple healthcare facilities. The information gathered is then reviewed by doctors and other specialists. Although time- and resource-intensive, these methods more accurately identify babies with birth defects, as compared to relying only on reports submitted by hospitals or healthcare providers. It was anticipated that by expanding these birth defects tracking systems to include all stillbirths, more accurate and complete data about stillbirths would be collected.
So instead of waiting for the government.....
In 2011 the first Stillbirth Summit brought clinicians, researchers, and families together to “think outside the box”.

One of the results of that meeting was the STARS Study:

STARS (Study of Trends and Associated Risks for Stillbirth) Consortium*
- Partnered with the Star Legacy Foundation and other stillbirth and parental support groups
- This unique partnership allowed bereaved parents to have direct discussions with consortium members regarding common experiences prior to their loss in order to inform the development of the survey

The goal was to investigate trends and risk factors for stillbirth

Particular interest in sleep position due to the findings of The Auckland Stillbirth Study (TASS):
- Women with a late stillbirth (28 weeks or more) were 2.5 times more likely to have gone to sleep on their back (supine position)

The survey included:
- questions about established risk factors (e.g. smoking, reduced movements)
- questions relating to emerging risk factors (e.g. sleep position, gut instinct and an increase in fetal activity in the days immediately prior to the fetal demise).

Several questions in the survey were raised by bereaved parents at the 2011 Stillbirth Summit and had not been previously addressed in large-scale studies.
Median duration of time since the stillbirth was 19.0 months (range 4 weeks – 47.5 years)

Common themes reported by participants:

1. Changes in fetal movements (63% of women)
2. Gut instinct that something was wrong (68% of women)
3. Perception that demise occurred at night (40% of women)
4. Cord accident (27% of families were told a cord accident was the cause of death)
5. 55% of families disagreed with the cause of death told by clinicians
Common themes reported by participants:

1. Changes in fetal movements (63% of women)

   Table 2 Frequency of unusual fetal movement

<table>
<thead>
<tr>
<th>Event</th>
<th>N (%)</th>
<th>( N = 1,714 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>No change in fetal movement</td>
<td>480 (28.0%)</td>
<td></td>
</tr>
<tr>
<td>A little bit less movement</td>
<td>273 (15.9%)</td>
<td></td>
</tr>
<tr>
<td>Significantly less movement</td>
<td>522 (30.5%)</td>
<td></td>
</tr>
<tr>
<td>A little more movement</td>
<td>136 (7.9%)</td>
<td></td>
</tr>
<tr>
<td>Significantly more movement</td>
<td>146 (8.5%)</td>
<td></td>
</tr>
<tr>
<td>Don't remember</td>
<td>103 (5.0%)</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>54 (3.2%)</td>
<td></td>
</tr>
</tbody>
</table>

   “only decreased the week before birth. The day before he died he was especially busy and moving like crazy”

   Significantly more women who reported increased movements, compared to those who reported reduced movements, did not worry about it (14 % vs. 6%, \( p=0.001 \)) and fewer (61% vs. 76%, \( p<0.001 \)) sought professional advice.

   Fewer women with increased movements, compared to those with reduced movements, were either admitted or had some type of monitoring (23% vs. 33%, \( p=0.002 \)).

Although international, women were mostly from:
- United States (72%)
- United Kingdom (14%)
- Australia (6%)
- Canada (6%)

Launched in September 2012 and ran til August 2014

Publications arising from this work published in open-access journals so they are easily obtained by everyone.
Women with stillbirth were:
- less likely to check fetal movements (aOR 0.54, 95%CI 0.35–0.83)
- less likely to be told to do so by professionals (aOR 0.55, 95%CI 0.36-0.86)

Pregnancies ending in stillbirth were more frequently associated with changes in fetal movements in the preceding two weeks:
- significant reduction in fetal activity (aOR 14.1, 95%CI 7.27–27.45)
- sudden single episode of excessive fetal activity (aOR 4.30, 95% CI 2.25–8.24).

Cases described their perception of activity differently to healthy controls e.g. vigorous activity was described as “frantic”, “wild” or “crazy” compared to “powerful” or “strong”.

Gut instinct occurred in response to a change in fetal movements for 40% of case and 26% of controls
It had been present for the whole pregnancy for 21% of cases and only n=1 control
Occurred in the night before birth in 23% of cases and 11% of controls.
In the case-control arm, median duration of time since the stillbirth was 13 days (range 1–29 days).

Queried about sleep practices before pregnancy, in the previous month, and previous night (or night before stillbirth)

No differences in sleep before pregnancy in cases or controls

Stillbirths had significantly higher odds of long sleep duration >9 hours 1.8 (1.1-2.8)
and significantly higher odds of NON-restless sleep 1.7 (1.0-3.0)
and significantly higher odds of good/very good sleep quality OR 1.69 [95%CI 1.0-2.8]

Significantly LESS likely to wake up on the last night (aOR 2.03 [95% CI 1.24-3.34]).

Not enough position data.....

Lessons learned from STARS:

- Women want to tell their stories (even decades later)
- We learned from listening to the stories
- We want to drill down deeper on some issues given the STARS findings:
  - significantly increased fetal movement
  - Intuition
- Some questions were asked of control women after delivery (e.g., gut instinct) that would have been better asked during pregnancy before the outcome was known
- A lot of hands-on work that could have been automated and more efficient
- Technical glitches from Survey Monkey made it challenging for analyses
- Would be good to have documented medical data
  - many women don’t have things like BP written down, tests taken

Need to work with partners to maximize response
The Pregnancy Research Project will now build on the STARS study by obtaining more details in several key areas:
- sleep practices
- fetal movements
- maternal intuition

The Pregnancy Research Project collects data on:
- other stressors
- depressive symptoms
- paternal demographics
- imaging data (number and frequency of ultrasounds)
- details about previous pregnancies and their outcomes
- more detailed autopsy information

You are eligible to participate if:
- You are at least 18 years of age or older
- You have had a stillbirth (pregnancy loss at or after 20 weeks gestation) at any time in the past
- You have delivered a living baby within the last five (5) years
- You are currently pregnant at 12 weeks gestation or more

The currently pregnant control group allow us a comparison whereby outcomes are not known at the time of survey responses so that recall bias can be minimized.
http://www.pregnancyresearchproject.org
After reading the consent page with all the legal stuff……

By clicking this link you agree to participate in this study.

……. you are linked to a REDCap database on a secure server behind Michigan Medicine HIPAA compliant firewalls

Thank you for giving us the opportunity to learn from your experiences!

If you decide to share your experience with us today, answer for one pregnancy only. Later, after you have finished, you can always come back and answer the survey again for other pregnancies that you would like to share with us.

It can take between 30 - 45 minutes to complete the survey today, depending on your experiences and what you choose to share with us.
At the end of the survey women are invited to share their prenatal and delivery records

- this requires separate consent and women will need to sign a Release of Information form which will be sent to their care provider

- medical records will provide objective information captured in real time during the pregnancy such as:
  - frequency and results of ultrasounds
  - number of presentations to healthcare providers (and why)
  - routine vital signs
  - results of autopsy (stillbirths)

At the Stillbirth Summit in 2017 we polled attendees re: medical records, and in both mothers who had experienced a stillbirth as well as those who had not, there was an overwhelmingly positive response in favor of sharing documented evidence from health care providers if this could avert another tragic outcome for a family.

Option to check a box to participate in other research – efficient way to connect families to researchers and vice versa.

We want this to be a living database which will continue to grow and ultimately be the largest, most robust dataset of its kind – which will allow to find some answers at a population level that smaller studies cannot.

We plan to expand to other languages; while anyone anywhere in the world can take part in the survey, the medical record portion is currently only available to those in the US. That's something we are working on.

Designed to be collaborative; de-identified data will be ultimately opened up to other researchers through Star Legacy Foundation (with appropriate permissions)
OPPORTUNITIES FOR PARTNERSHIP

* Enroll in the study
* Encourage friends, family to enroll
* Share information where pregnant women are (clinics/organizations)
* Brochures/social media ads/newsletters (available from Star Legacy)
* Partnerships available
* Add the link/embedded code to your website

Thank you!