



Variability Across Current Pregnancy Registry Designs

Impact on Interpretation of Results

Laura McKain, MD ¹; Jessica Albano, PhD ²;
Susan Roberts, PhD ³; Deborah Covington,
DPH ¹

¹Kendle International, Inc., Wilmington, NC, United States, ²Kendle
International Inc., Durham, NC, United States, ³University of North
Carolina Wilmington, Wilmington, NC, United States



Disclosure

- The authors of this research have no financial or other interests which pose a conflict of interest.
- This research was funded by *Kendle International Inc.*

Background

- 1984-Acyclovir Pregnancy Registry
- 1989-Zidovudine Pregnancy Registry
(becomes the Antiretroviral Pregnancy Registry)
- 1991 National Transplant Pregnancy Registry
- 1996 North American AED Registry
- 2002 FDA Guidance document for
Establishing Pregnancy Registries
- 2007 FDAAA
- 2008 Proposed Pregnancy Labeling Rule

3

3

Background

What is a pregnancy exposure registry?

A prospective observational study that actively collects information on medical product exposure during pregnancy and associated pregnancy outcomes.

*FDA Guidance for Industry: Establishing pregnancy exposure registries.

4

Pregnancy Registry Survey

Purpose

- To survey actively enrolling pregnancy registries
 - Examine the similarities, differences and comparability of study designs
 - Explore how the interpretation of results may be impacted

5

5

Pregnancy Registry Survey

Methods

- Survey of methods employed by actively enrolling pregnancy registries based in North America
- Registry Representatives were contacted in person, by telephone, mail and email for their responses
- Published reports describing registry methods were used to augment data, as needed.

6

6

Results

- 42 Registries Identified

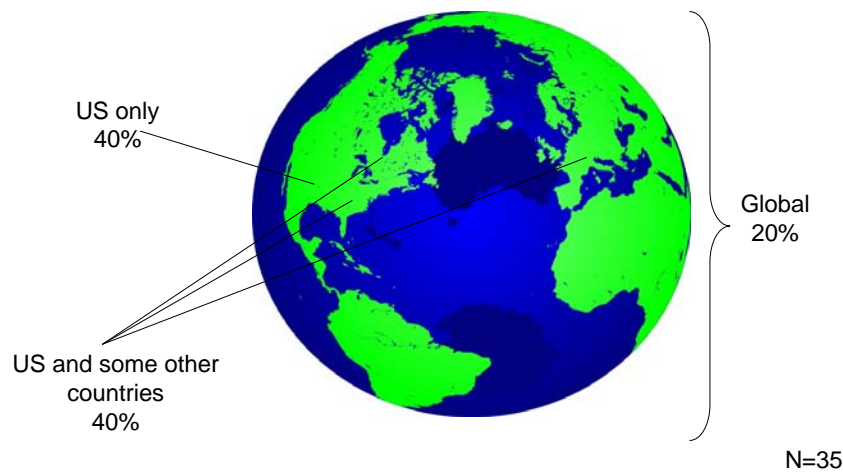
- 35 Responses
- 83% Response Rate

- Registry Management

- 49% Academic/Non-profit
- 51% Private/For-profit

7

Registry's Targeted Population



8

Types of Exposures

Registries N=35



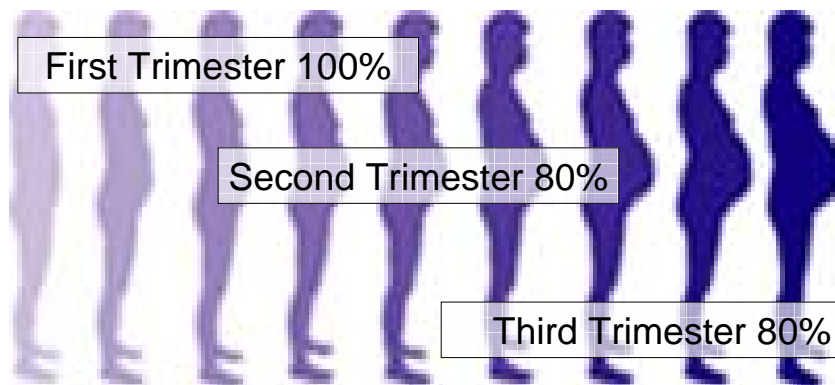
Single Drug
20

Multiple Drug
15



Disease
13

Exposure Window



Exposure Window

Does the registry
include exposures
prior to LMP or
Conception?

No 63%

Yes 37%

Range 1 week to 24 months
prior to conception

N=35

11

Male Exposures



Pregnancies
exposed through
the male partner?

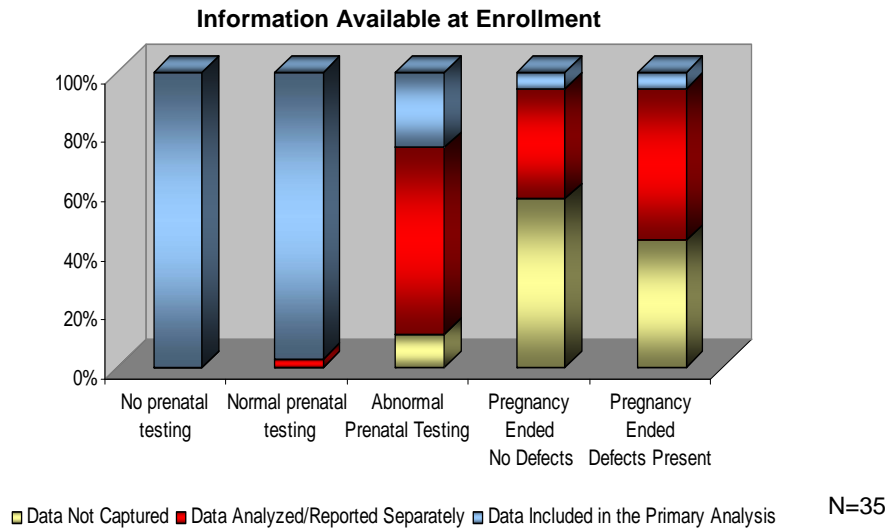
No 87%

Yes 13%

N=35

12

Report Classification



13

Conclusions

- Pregnancy registries differ widely in design and methods
 - Pharmacologic properties
 - Characteristics of eligible population
 - Registry objectives
 - Degree of scientific rigor employed by the investigators
- Ability to make comparisons across registries may be impacted
- Ongoing survey of registry designs and methods is necessary

14



QUESTIONS?