

EXPERT COMMENTARY

Pregnancy Registries

Pregnancy registries are valuable sources of information, and for many drugs and vaccines they are the primary source of human pregnancy experience. The strengths of these registries are their prospective nature—women are enrolled before the outcome is known—and enrollment is over a wide geographical area.

Typically, two types of pregnancy outcomes are obtained: outcomes with birth defects and outcomes without known birth defects. The latter comprises live births, fetal deaths, and spontaneous abortions.

Registries can identify early signals of teratogenicity, but they have several limitations. They depend on voluntary reporting, which results in selection bias, and they are not representative of target populations.



BY GERALD G. BRIGGS,
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Pregnancies that are lost to follow-up may have had different outcomes than those with documented outcomes. Furthermore, registries lack details on elective terminations and fetal deaths without birth defects, and all spontaneous abortions. Finally, with some exceptions, they usually lack control groups.

Because the total number of exposed pregnancies is unknown, data from a registry cannot be used to calculate prevalence of an outcome, but the data can be used to estimate the proportion of birth defects. Some registries also collect data on retrospective re-

ports, which are less representative of the target population because they can be biased toward the reporting of more unusual and severe outcomes. However, they may be help-

ful in detecting unusual patterns of birth defects.

In the chart below are the pregnancy registries listed on the Food and Drug Administration Web site, which provides additional details on the registries, such as fax numbers, links to other Web sites, and mailing addresses (www.fda.gov/womens/registries).

Because the strength of a registry is based on numbers, I encourage health care professionals to enroll appropriate patients in these registries whenever possible. ■

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Registries/Studies

Organization of Teratology Information Specialists (OTIS)* Autoimmune Diseases Study

(877-311-8972)

Rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis
Leflunomide (Arava), etanercept (Enbrel), adalimumab (Humira), abatacept (Orencia)

OTIS Vaccinations in Pregnancy Study

(877-311-8972)

Tetanus, diphtheria and pertussis, influenza, and/or meningococcal vaccines
*includes control groups and dysmorphology examinations of exposed infants

Motherisk Program*

(800-670-6126)

Vaccines Hepatitis B vaccine (includes Twinrix)
Toe and nail fungal infections Lamisil
Weight loss Meridia (sibutramine)
Asthma Singulair (montelukast)

*includes control groups

Kendle International Pregnancy Registries

HIV/AIDS (800-258-4263)

Migraine headaches (800-336-2176)

Multiple sclerosis (800-478-7049)

Partial onset seizures (888-537-7734)

Partial seizures (800-336-2176)

Hepatitis C (800-593-2214)

Depression (800-336-2176)

Amevive Pregnancy Registry (866-834-7223)

Chronic plaque psoriasis

Avonex Pregnancy Registry (800-811-0104)

Relapsing forms of multiple sclerosis

Cooper Health Cancer and Childbirth Registry

Cancer medicines

Fabry Registry (800-745-4447, ext. 15500)

Fabry disease

Hurler-Scheie Syndrome/Mucopolysaccharidosis I Aldurazyme (laronidase)

Massachusetts General Hospital* AED Pregnancy Registry (888-233-2334)

Antiepileptic drugs

*includes comparison group

Antiretroviral agents

Imitrex (sumatriptan) and Amerge (naratriptan)

Betaseron (interferon beta-1b)

Keppra (levetiracetam)

Lamictal (lamotrigine)

Copegus (ribavirin)

Wellbutrin and Zyban (bupropion)

Amevive (alefacept)

Avonex (interferon beta-1a)

(856-757-7876)

Fabrazyme (agalsidase beta)

Aldurazyme (laronidase)

Merck Pregnancy Registry Program

Chickenpox

MMR and chickenpox

Herpes Zoster

Human papilloma virus (HPV)

Type 2 diabetes

Type 2 diabetes

Migraine headaches

Asthma

MPS VI Clinical Surveillance Program

Maroteaux-Lamy syndrome (polydystrophic dwarfism or mucopolysaccharidosis VI [MPS VI])

Galsulfase (naglazyme)

clinicaltrials.gov/ct/show/NCT00214773?order=2

National Transplantation Pregnancy Registry

Antirejection drugs

(877-955-6877)

Raptiva Pregnancy Registry

Chronic plaque psoriasis

(877-727-8482)

Rebif Pregnancy Registry

Multiple sclerosis

(877-447-3243)

Tysabri Pregnancy Registry

Multiple sclerosis

(866-831-2358)

Neoral Pregnancy Registry

Psoriasis and rheumatoid arthritis

(888-522-5581)

Twinrix Pregnancy Registry

Hepatitis A & B Prevention

(888-522-5581)

Xolair Pregnancy Registry

Asthma

(866-496-5247)

(800-986-8999)

Varivax vaccine

ProQuad vaccine

Zostavax vaccine

HPV vaccine (Gardasil)

Janumet (sitagliptin/metformin)

Januvia (sitagliptin)

Maxalt (rizatriptan)

Singulair (montelukast)

Efalizumab (Raptiva)

Interferon beta-1a (Rebif)

Natalizumab (Tysabri)

Cyclosporine (Neoral)

Hepatitis A/hepatitis B vaccine (Twinrix)

Omalizumab (Xolair)

Simplicity Is Key to Cutting Office Wait Times for Patients

BY TIMOTHY F. KIRN
Sacramento Bureau

The idea seems simple enough, but the improvement in waiting times for lab tests for the patients of Dr. S. Germain Cassiere has been dramatic.

As in many medical offices, his patients for many years had signed in on a sheet of paper to let the receptionist and technicians know they were there, he said. Then the patients waited for an average of 25-30 minutes, and often longer on busier days, such as Monday and Tuesday.

Dr. Cassiere's solution was to put a computer terminal with a touch screen in the waiting room to replace the paper sheet. "The patients use the wall-mounted touch screen as a keyboard to enter

their names and select what services are needed," said Dr. Cassiere, who works in a six-physician general internal medicine practice in Shreveport, La. "The completion of this one-page data entry generates a record in the database for that particular outpatient service center."

The technicians can see on their own computer screens the names of waiting patients and when they arrived. After patients have been called in and had their blood drawn, the technician logs them out with a click on the screen.

A program called LABRATS (Lab Registration Access Touch Screen) tracks each part of the process and can report an hourly patient count, record the number of registration technicians and phlebotomists present, and calculate the aver-

age time for every step. Monthly reports, which allow the lab staff to track trends, showed that Mondays and Tuesdays are the busiest, and therefore may require more personnel.

Because of the system, the average wait time for lab tests has declined 40%, to an average of about 18 minutes. The technicians and phlebotomists appreciate being accountable, knowing how they are doing, and showing their efficiency, Dr. Cassiere said.

He also believes the patients appreciate it. "They notice it takes less time," he said. "No one likes to wait."

After patients are finished having blood drawn for tests, they are deleted from the system, so there is no conflict with HIPAA confidentiality rules, he noted.

When Dr. Cassiere first proposed the computerized system, there was skepticism from some in administration and the information technology department at Willis-Knighton Health Systems, the health services provider he works with, regarding feasibility and patient acceptability of this process.

Dr. Cassiere took that as a challenge. He developed the system himself using the same Nexus Database System he had previously used to develop a message-tracking system to log incoming phone calls so they are returned more reliably.

The LABRATS system has worked so well that it has been adapted for use in the general admission process and is now being deployed for use in all 12 outpatient centers of the health service, he said. ■