Registries and Potential Data Sources

Regarding Medication Use in Women of Childbearing Age Before, During and After Pregnancy

Women of childbearing age need accurate information concerning the benefits and risks of medication use before, during and after pregnancy. For many medications there is a lack of clinical research to guide practice. There is an urgent need to improve the evidence base concerning the use of medications, both prescription and over-the-counter, as well as supplements and herbal products, by women of childbearing age. Health providers can help by reporting outcomes and facilitating enrollment into clinical trials and pregnancy exposure registries. Following are some resources for referring clients, reporting outcomes and gathering clinical evidence concerning medication and supplement use:

U.S. Food and Drug Administration (FDA)
List of (pre-) pregnancy exposure registries:
http://www.fda.gov/ScienceResearch/SpecialTopics/WomensHealthResearch/ucm134848.htm
"In their daily lives, women use many products that are regulated by the FDA including medicines, cosmetics, pregnancy kits, microwaves, pet foods, and vaccines..." Don't wait for pregnancy to enroll!
Report adverse events to the FDA online by going to: http://www.fda.gov/Safety/MedWatch/default.htm

Vaccines and Medications in Pregnancy Surveillance System (VAMPSS)
http://www.otispregnancy.org/vaccine-and-medications-in-pregnancy-surveillance-system-vampss--p135759
A nationwide post-marketing surveillance system established to monitor the use and safety of vaccines and medications during pregnancy, coordinated by the American Academy of Allergy Asthma and Immunology (AAAAI).

The following are potential sources of population-based data concerning broad categories of risk, such as chronic diseases (e.g., diabetes and asthma) and adult immunization among women of childbearing age and women's experience concerning discussion of medication use prior to and during pregnancy with their health provider:

Behavioral Risk Factor Surveillance System (BRFSS)
http://www.cdc.gov/brfss/
BRFSS is a state-based system of health surveys that collects information on adult health risk behaviors, preventive health practices, and health care access primarily related to chronic disease and injury. There are questions concerning adult immunization. State level data on trends are available on line. Data sets are available for analysis. There is some variation from state to state. For more detailed data requests, also contact your state program.

Pregnancy Risk Assessment Monitoring System (PRAMS)
http://www.cdc.gov/prams/
PRAMS is a surveillance project of the CDC and state health departments. PRAMS collects state-specific, population-based data on maternal attitudes and experiences before, during, and shortly after pregnancy. Data sets are available for analysis. There is some variation from state to state. For more detailed data requests, contact your state program (some states do not participate).

National Health and Nutrition Examination Survey (NHANES)
http://www.cdc.gov/nchs/nhanes/about_nhanes.htm
National Health and Nutrition Examination Survey (NHANES) is a program of studies designed to assess the health and nutritional status of adults and children in the United States.

FDA Classification of Drug Safety in Pregnancy	
Category	**Description**
A	Controlled studies in women fail to demonstrate a risk to the fetus in the first trimester (and there is no evidence of risk in later trimesters) *and* the possibility of fetal harm appears remote.
B	Either animal reproduction studies have not demonstrated a fetal risk but there are no controlled studies in pregnant women, *or* animal reproduction studies have shown an adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the first trimester (and there is no evidence of risk in later trimesters).
C	Either studies in animals have revealed adverse effects on the fetus (teratogenic or embryocidal or other) *and* there are no controlled studies in women, or studies in women and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the fetus.
D	There is positive evidence of human fetal risk, but the benefits from use in pregnant women may be acceptable despite the risk (e.g., if the drug is needed in a life-threatening situation or for a serious disease in which safer drugs cannot be used or are ineffective.)
X	Studies in animals or human beings have demonstrated fetal abnormalities *or* there is evidence of fetal risk based on human experience, and the risk of the use of the drug in pregnant women clearly outweighs any possible benefit. The drug is contraindicated in women who are or may become pregnant.
References	Food and Drug Administration - Code of Federal Regulations Title 21 (official language): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=201.80 National Women's Health Information Center (easier-to-read version): http://www.womenshealth.gov/faq/pregnancy-medicines.cfm