White Paper

Drug Safety in Pregnancy: Methods and Challenges

A review of evaluating maternal exposures and infant health outcomes

JOYDEEP SARKAR, PhD
KARIN DE HAART, MSc
ANNE BROE, PhD MD
IAN BONZANI, PhD
EMILY BRATTON, PhD

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Executive summary

This article reviews the current landscape, challenges, and advancements in evaluating drug safety during pregnancy. Particularly for individuals managing chronic illnesses that require ongoing pharmacological treatment, and both maternal and infant health might benefit from continued drug exposure during pregnancy.

However, with a lack of data upon drug approval, health care providers lack an evidence base to balans maternal health needs with fetal safety remains a critical concern. Regulators provide guidance on pregnancy exposure study design, implementation, and drug labeling. Ongoing revisions to these guidelines are fostering greater international collaboration and an emphasis on harmonizing methodologies. Despite these advancements, persistent challenges include ethical considerations, data privacy issues, and the need for standardized protocols.

Traditional clinical trials often exclude pregnant individuals due to ethical concerns, resulting in a reliance on real-world data and observational studies to generate evidence on medication safety. Recent technological advances, including mobile data collection and expanded real-world data sources, have opened new opportunities to address these evidence gaps and respond to evolving regulatory demands.

Overall, the review highlights the importance of leveraging real-world data, innovative methodologies, and global regulatory collaboration to enhance the evidence base, thereby supporting safer and more effective drug therapy decisions for pregnant individuals and their infants.

Introduction

Drug exposure during pregnancy is an area of critical concern, particularly for individuals managing chronic illnesses that necessitate ongoing treatment. It is estimated that approximately 10% of pregnancies involve individuals with chronic conditions such as asthma, diabetes, or hypertension.[1,2] These conditions often require pharmacological intervention, which poses unique challenges in balancing maternal health needs with fetal safety.

For instance, asthma treatment during pregnancy offers a compelling example of the complexities involved. Since the 1960s numerous epidemiological studies have demonstrated that asthmatic females are at increased risk of complications such as preterm birth, low birth weight, or even maternal respiratory distress. Effective treatment plans, including the use of inhaled corticosteroids and bronchodilators, are critical to maintaining stable respiratory function and ensuring positive pregnancy outcomes.[3]

These therapeutic approaches highlight the importance of an evidence base for individualized care and the careful evaluation of drug safety for pregnant individuals.

Since the Thalidomide tragedy,[4] there has been heightened scrutiny regarding the effects of drug exposure during pregnancy, emphasizing the necessity of balancing maternal treatment benefits with potential risks to the developing fetus. The exclusion of pregnant individuals from most clinical trials due to ethical considerations complicates the landscape of evidence generation. This gap necessitates reliance on real-world data studies to identify the safest and most effective therapeutic options. Based on US Food and Drug Administration (FDA) Postmarketing Requirements and Commitments Database (PMR/PMC database), we can see that especially in the last 15 years an increasing number of requests for pregnancy outcome studies.[5]

Advances and expansion in the availability of real-world data and mobile data collection technologies has provided new opportunities to address challenges with generating real-world evidence on pregnancy outcomes, while responding to evolving regulatory demands.

This review explores the regulatory guidance, methodologies employed for data collection, and examines innovations and trends. We highlight the role of real-world data and innovative technologies in advancing research.

Regulatory trends and challenges

Both the European and United States regulatory guidance play a pivotal role in shaping the conduct of pregnancy exposure studies. Current regulatory guidance provides detailed instructions on numerous aspects, including the implementation of findings in drug labeling, the design and execution of exposure registries, and methodologies for conducting these critical studies.

Furthermore, revisions to these guidelines are ongoing, fostering broader collaboration among regulatory agencies to harmonize approaches. Agencies worldwide emphasize the importance of real-world evidence and innovative methodologies to improve understanding of drug safety. However, challenges remain, including ethical considerations, data privacy concerns, and the need for standardized protocols.

The most commonly required study approach has been pregnancy exposure registries; in the last 5 years, database studies have been required by FDA to complement registries or even favoured by EMA. Additionally, for rare disease treatments, single-arm safety studies have been required instead of the registries with exposed and non-exposed prospective cohorts.

While pregnancy studies have traditionally been the focus of safety evaluations, there is growing interest among regulators in lactation studies. These investigations aim to assess the transfer of drugs through breast milk and their potential effects on nursing infants. Their importance is increasingly recognized as part of a comprehensive approach to maternal and infant health.[6]

Methodologies

In the 19th century, pregnancy research relied heavily on case-based observations that lacked standardized protocols or large sample sizes. These studies often documented isolated incidents without broader population-level data. Despite their limitations, such observations were instrumental in highlighting potential risks and encouraging further investigation into the safety of drugs during pregnancy.

With digital and mobile data collection technologies, data standardization tools and changes in patient data sharing policies, current research methodologies have evolved significantly from their historical counterparts. The use of real-world data, including electronic health records and patient-reported outcomes, has revolutionized the collection, monitoring, and analysis of pregnancy-related information. These advancements enable researchers to examine large and diverse populations and datasets, improving the reliability of results and supporting evidence-based decision-making.

Key outcome measures for pregnancy outcome studies include:

Maternal health outcomes

Pregnancy complications
Monitoring for outcomes like preeclampsia, gestational diabetes, preterm labor, or emergency c-section

Drug adherence
Timing of drug administration relative to pregnancy stages

Fetal and infant health outcomes

Pregnancy loss
(stillbirth or miscarriage)

Congenital malformations
Identifying major and minor birth defects or structural abnormalities

Neonatal outcomes
Evaluating birth weight, small for gestational age, apgar scores, and overall developmental milestones (growth, motor neurodevelopmental skills)

These outcome measures form the cornerstone of pregnancy outcome studies, providing comprehensive data that supports evidence-based decision-making and informs regulatory guidelines.

Drug utilization studies

Drug utilization studies are critical tools for understanding patterns of medication use and assessing potential risk of exposed pregnancy. The primary objective of a drug utilization study is to determine whether pregnant individuals are consuming the drug of interest and, if so, to assess the frequency and demographic characteristics of usage. This information serves as a foundation for further investigations into safety profiles and comparative outcomes.

Drug utilization studies employ retrospective data collection methods or rely on existing data sources, to determine the extent and duration of drug exposure among pregnant people. They may leverage electronic health records, pharmacy databases, and prescription claims to analyze of prescriptions, dosages, timing of administration relative to gestational stages, providing a snapshot of medication use across pregnant populations. With the focus of a drug utilization study on understanding the extend of drug exposure of pregnancies; quantifying the potential risk in terms of probability of occurring, this study type lack of ability to assess the actual risk of the exposure on the pregnancy and infant outcomes. If a drug utilization study determines that pregnancy exposure is likely; understanding the outcomes of exposed pregnancies will be of high importance and pregnancy outcome studies should be recommended.

Prospective pregnancy registry study design

A prospective pregnancy registry involves the collection of data from pregnant individuals and live born infants, usually until their first birthday. Generally, pregnancy registries include at least 1 cohort of exposed pregnancies and 1 cohort of unexposed pregnant individuals with the same (on-label) indication. However, there are several larger registries established that include a multitude of cohorts, allowing comparisons across different indications for an individual product or comparing different products for the same indication.

Considering the unpredictability of involved health care providers of (unintentionally) exposed pregnancies, many registries are relying on a central

site model where one Principal Investigator remotely enrolls eligible patients and collects data directly from them and their health care providers. To ensure the enrollment of rare eligible patients, it is important to spread awareness of the registry with the indication specialists. This will support early enrollment of both exposed and unexposed pregnant individual as well as comparators with the underlying condition.

The enrolled cohorts of pregnant individuals are followed up during the standard pre-natal, birth, post-natal and infant care, spanning various different health care providers. The variability of the health care providers involved in pregnancy and infant care is even further increased when registries include multiple countries and health care systems.

Data is collected on exposures of treatment, but also alcohol and other relevant product usages, pre-natal outcomes, pregnancy complications, birth outcomes (e.g. natural or cesarian), and infant outcomes including gestational age, growth metrics and major and minor malformations.

This approach offers the advantage of focusing on specific outcomes and facilitating accurate risk assessments. However, it has limitations, including the high costs and long timelines required to enroll participants and complete the data collection process. Due to these challenges, evidence from such studies may not be available in a timely manner, often emerging many years after the drug has already entered the market. Despite these constraints, prospective pregnancy registries remain a valuable tool for building robust safety profiles and informing regulatory decisions.

Single-arm safety — pregnancy surveillance

To address the limitations posed by rare conditions or patient populations including very few individuals of childbearing potential, regulators have adopted pragmatic study designs, such as single-arm surveillance programs. These designs facilitate both retrospective and prospective data collection, do not include an internal comparator and instead are more descriptive. Considering the rare occurrence of cases, regulators require sponsors to enable inclusions from any eligible case globally.

Pregnancy outcomes intensive monitoring

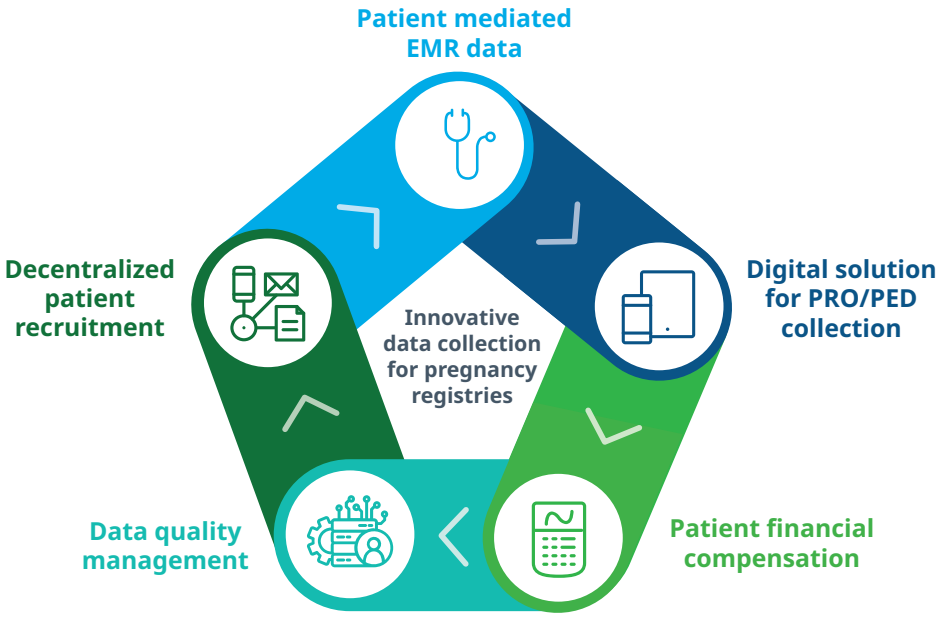
An alternative to prospective registries or single arm safety studies, is the Pregnancy outcomes Intensive Monitoring (PRIM) method, that was first established for fingolimod (Gilenya™). Where data on exposed pregnancies is collected through an enhanced pharmacovigilance process. This method relies on spontaneous reports of exposed pregnancies, with an enhanced structure to collect the necessary data elements, during the pregnancy and follow-up of the infants, needed to quantify the risks of reproductive toxicity. These analyses are considered secondary use of pharmacovigilance data.[7]

PRIMARY DATA COLLECTION CHALLENGES

While primary data collection allows for tailored approaches to pregnancy studies, it brings its own set of challenges. Firstly, it can be hard to identify and enroll eligible cases. Secondly, the design and execution of these studies must balance the need for comprehensive data with the burden placed on participants, during a relatively challenging and vulnerable period in their life. Innovative tools, such as mobile applications and region-specific outreach programs, have been developed to streamline data collection and enhance compliance. However, the process remains resource-intensive and may depend heavily on participant engagement, particularly in areas where technological access may be limited.

INNOVATIONS IN DATA COLLECTION

The industry continues to look for new ways and approaches to enable robust capture of safety data in the context of pregnancy exposure to more rapidly generate the real-world evidence. One of the approaches to get robust data capture in a scalable manner is decentralized or Direct-to-Patient (DtP) studies. For the successful execution of such DtP studies, a few components need to work in unison:



Decentralized patient recruitment

Recruitment rate into pregnancy studies can be increased through supplementation of site-based recruitment with direct-to-patient recruitment approaches. Typically, this includes modeling of consumer and other forms of data appropriate for a specific study, identifying the right channels and study-specific engagement strategies. Channels include social media and digital search targeting as well as access to health networks, patient communities, lab pharmacy databases, or biomarker partners. These approaches are still new and there is ongoing research on factors that affect enrollment to a DtP study .[8] While there is no immediate evidence around factors affecting pregnant individuals to participate in DtP pregnancy outcome studies, such decentralized approaches, including digital outreaches, have proven to be quite effective in recruiting wider patient populations vs traditional methods alone in other areas.

Patient mediated EMR data access

The Health Insurance Portability and Accountability Act (HIPAA) of 1996, modified by HITECH Act of 2009, established the patient's right of access to their personal health information (PHI), including the right to receive a paper or electronic copy in US.[9,10] The 21st Century Cures Act of 2019[11] provided additional provisions and together with the incentives provided by Center for Medicare & Medicaid Services (CMS), access to one's EMR data has become more of a reality in recent years.[12] No doubt hurdles still exist, but with a patient's consent, a patient's recent and detailed medical records across multiple providers can now be collected in an electronic format. In many cases, due to wider adoption of FHIR HL7 interoperability standard, the data is received in a standardized format making its ingestion and processing more streamlined.[13,14]

With the establishment of the General Data Protection Regulation (GDPR) and the recent European Health Data Space (EHDS),[15] patient mediated EMR data access is likely to become streamlined in EU as well. While challenges remain in some countries, receiving paper copies with patient medical release is allowed in most countries of interest. Our Future Health, Patients Know Best in UK and the government initiative in Catalonia are the latest example of progress to electronic data access outside US.

In the case of pregnancy studies, patient mediated EMR data access provides a unique opportunity whereby the detailed longitudinal medical records of the pregnant individuals can be obtained with their consent and avoid site-based data collection. In the US, this data can be refreshed on a regular basis and the records incorporated into the pregnancy study database. Such approaches greatly reduce the burden on sites to enter data and can capture data across providers and care settings, thereby providing a more robust view of the pregnant individuals healthcare journey.

Patient records are not always available as electronic copies and paper copies are sometimes provided to the patient only. In such cases, the patient's ability to easily upload electronic copies (scanned copies, pictures etc.) provides an important and essential alternative to get recent and detailed medical records of pregnant individuals. Such records can be reviewed by appropriate staff and transcribed into the systems on behalf of the pregnant individuals, reducing the burden on the patients.

Patient e-questionnaires/ePROs

An important aspect of DtP studies is going beyond collecting the medical records directly through patients but collecting data directly from the pregnant individuals. In all DtP studies, including pregnancy outcomes studies, there are electronic questionnaires or patient reported outcomes (PROs) which are included.

Significant research is ongoing on linguistic and scientific validity of the questionnaires designed to get accurate data from patients (including pregnant individuals).[16-18] Designing questionnaires, especially for patients like pregnant individuals, should be done with the patient experience in mind and to reduce time commitments, cognitive burden etc.[19,20] Overall completion rate of questionnaires, PROs, patient experience data (PED) in most clinical studies, including pregnancy studies do demonstrate patient willingness in providing the data and overall minimal burden to patients.[21,22]

Further, to keep in sync with the patient's user experience with other consumer applications, clinical studies should offer electronic reminders, such as emails, texts, and push notifications. Electronic reminders tied to real-time monitoring of patient completion rates have been associated with significantly improved completion rates.[23]

Financial compensation

Financial compensation has been shown to significantly improve the recruitment of patients into clinical studies as well drive higher rates of completion of associated activities.[24,25] For pregnancy outcome studies, which require continued engagement of the pregnant woman well past birth of the infant, incentives can play a significant role in improved data entry completion rates. Compensation can be tied to different activities of study, e.g. patient mediated EMR data access, completing a questionnaire, or site-visit when needed. However, compensation needs to be designed carefully. A recent study provides a framework of 8 questions that should be answered in order to properly design compensation including size of compensation and how to avoid downstream consequences e.g. participants joining studies for pure economic motivation[26].

Data quality management

Underpinning any clinical study, including pregnancy outcomes studies, is collection of high-quality of data that can be readily used for evidence generation and regulatory submissions. With the changing methods of data collection including patient mediated data, e-questionnaires, etc., the process and approaches to quality checks, validation of data need also need to be adapted.

In summary, pregnancy outcome studies depend on new approaches for decentralized/direct-to-patient studies to enable scalable, and accurate data collection. These require systems that can support the mentioned components and a team that can support the abovementioned approaches and that can adapt to the changing needs of design, operations, and clinical data management to deliver a cost-effective study with reliable data.

Database studies

Using existing data sources for pregnancy outcome studies presents an alternative, complementary approach to prospective pregnancy registries. By leveraging electronic health records and other real-world data, researchers can circumvent the financial and temporal constraints associated with participant enrollment. This method minimizes selection bias and allows investigators to access already collected data, which, can provide valuable insights into drug safety profiles and maternal health outcomes.

LIMITATIONS OF SECONDARY DATABASES

Use of existing data is not without its challenges. The key requirement for real world data sources to be relevant for fetal and infant outcomes in pregnancy outcome studies is linkage of mother and baby. Existing Real-World data, often developed for administrative purposes, are foundational to many pregnancy safety studies. However, these data sources frequently lack linkage of mother and infant, and lack certain critical details, such as information on early pregnancy losses, environmental factors, or socioeconomic variables. Data that is not relevant to the medical care of the mother may not be collected, such as duration of pregnancy at time of miscarriage, or a missing pregnancy start date. Miscarriages could also be seen by a GP, whose records are not included in the main real-world dataset the study is relying on.

For these potential gaps in the data of pregnancy care and outcomes, it is important to consider both primary and secondary care data, which may require linkage across different data sources for a single pregnancy case.

Moreover, data availability often comes at the end of predefined observation periods, potentially delaying actionable outcomes. Interim analysis and reports enable monitoring of pregnancy outcomes during the study period.

This presents significant hurdles in creating a complete picture of pregnancy outcomes, especially when addressing regionally specific health concerns.

DATA VALIDATION AND RELIABILITY

Ensuring the accuracy and reliability of data within these databases is another challenge. Researchers often employ comparative prevalence studies or create algorithms to define exposure windows and validate diagnoses. Despite these measures, there remains a gap in capturing nuanced events, especially in instances requiring minimal medical intervention or where diagnoses are composite. Regionally specific nuances, such as varying healthcare access or cultural behaviors, further complicate validation efforts.

Future directions

International collaborations, such as IMI Conception, pave the way for large-scale, multi-country studies that enhance statistical power and data reliability. By standardizing guidelines and methodologies across research groups, these collaborations create frameworks for comparable and high-quality evidence generation. The harmonization of data collection and incorporating regionally specific resources and outreach initiatives will also ensure that pregnancy safety studies remain inclusive and adaptive to diverse populations.

Recent trends reflect a growing emphasis on merging primary and secondary data sources to create more robust datasets. Combining registry-based data with participant-provided information through digital tools, such as mobile applications, enables researchers to address key gaps in existing datasets. This integration enhances the breadth and depth of pregnancy safety data, ensuring methodological rigor and comprehensive insights. The inclusion of regionally relevant data further adds value by addressing unique local challenges.

Data on lactation and broadening outcomes of focus beyond congenital malformations, will further increase the value of the evidence for treating physicians and patients considering exposing pregnancies to necessary treatments for maternal health. Some studies are looking at neurodevelopment, which requires follow-up of live born infants well beyond their first birthday.

Conclusion

Pregnancy safety research has come a long way since its inception in the mid-19th century. From anecdotal case reports to sophisticated, data-driven methodologies, the field has evolved to enhance robust evidence generation to meet regulatory guidance and provide an evidence base for individualized care for pregnant individuals. The main limitation to pregnancy studies remain on ability to use existing real-world data, including the ability to link individuals, exposures and sufficient follow-up.

Pregnancy safety research continues to advance, driven by technological innovations, integrated data approaches, and methodological refinements. Addressing challenges in both primary and secondary data collection, fostering international collaborations, and embracing novel study designs position the field to generate impactful evidence that informs clinical practices and enhances maternal and infant health outcomes globally.

Additionally, leveraging regionally specific resources and addressing local challenges ensures that diverse populations benefit equitably from these advancements and study evidence.

Pregnancy studies continue to be a cornerstone of evidence-based healthcare practices informing the safety of use of medicines in pregnant and lactating individuals and their infants. Embracing innovation and new tools to capture pregnancy and outcome information enables more timely, effective data collection, analysis and evidence communication.

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