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Safety of medications in pregnancy - a novel approach to improving shared decision making

Plain English Summary:

Aim To develop a system to help doctors and women understand the safety of taking different medicines in pregnancy. Background During pregnancy, some women may need to take medicines for their own health or that of their baby. However, for some medicines, there is very little information about the safety for mother or baby during pregnancy. One way to understand how safe a medicine is in pregnancy is to look at information from women who took the medicine while they were pregnant and their babies. Information from medical records can be used to see what happens when women take medicines during pregnancy, but the information needed is held in different places including general practice (GP) records, hospital records and birth registries. At the moment, these are not connected, which makes

it hard to look at the safety of medicines in pregnancy. In this study, we will develop a system to make it easier to look at the safety of medicines in pregnancy. Methods The study will have 7 stages taking 5 years: Find out what research already exists about medicines used to treat depression, epilepsy and nausea and vomiting in pregnancy. We will also ask doctors, nurses and midwives which of these conditions they need more information on and how they would like to receive that information. Link GP records to pregnancy-related information including hospital records, maternity records, infant/child and schooling records to make it possible to study both mother and baby/childhood outcomes. Use these new linked data to study health outcomes when medications are taken during pregnancy. We will select two of the conditions from (1), to see how safe they are to use in pregnancy. We will look at how safe it is to take certain medicines in pregnancy and the risks if women stop taking these medicines in pregnancy. Work with patient contributors from diverse backgrounds and experiences to design easy-to-understand tools to explain individualised risks and benefits of taking the medication during pregnancy to help women decide whether to stop, continue or change their medication. Share what we found and work with charities, diverse patient support groups and community groups to understand their perspectives and discuss our findings. Work out the costs of this new data system Develop a database that researchers can use to study the safety of other medicines in pregnancy. Dissemination We will work with pregnant women, mothers and their families to develop materials in different languages to help people from different backgrounds and disabilities understand what we have found. These will include leaflets, videos and animations to share with antenatal groups, mother-baby groups, charities, community groups, faith groups and social media. We will publish our results in medical journals.

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Abstract:

Background: Medication use in pregnancy is common, yet current knowledge of the clinical risk/benefit and safety profiles of these medications remains very limited. As a result, making decisions about starting, continuing and stopping medications during pregnancy can be challenging and these decisions are likely to impact the long-term health and well-being of women and their children. Thus, comprehensive population-based, longitudinal data systems are urgently required to address this knowledge gap. In the United Kingdom, availability of extensive electronic healthcare, civil registration and educational data offer a unique opportunity to develop such data systems. Aim and Objectives: To establish and evaluate a novel data system to determine the uptake and safety of medications during pregnancy. Specific objectives are to 1) establish the current evidence on the prevalence, clinical benefit/risk and safety profiles of medications used in pregnancy, 2) develop a new data system, 3) use this data system to explore the clinical benefit/risk and safety profiles of selected medications, 4) develop risk communication tools for these medications and evaluate their use by women and healthcare professionals, 5) explore health economic impacts of the data system, 6) ensure that the data system becomes an accessible national resource and, 7) integrate active patient and public involvement in each objective. Methods: First, in order to establish the most current evidence on the prevalence, clinical benefit/risk and safety profiles of medications used during pregnancy, a systematic review and subsequently a cohort study will be carried out. Current clinical decision-making practices will be explored using qualitative interviews. Second, additional data linkages to one of the most comprehensive primary care databases in the UK, QResearch Database, will be used to develop a novel data system. These linkages will be in addition to currently available data links to hospital, civil registration and cancer records and will include data linkages to maternity, birth registration, hospital prescribing, teratology, maternal confidential enquiry and schooling records. This data system will be subsequently tested on selected medications to explore their clinical risk/benefit and safety profiles. Third, risk communication tools and decision aids for the above selected medications will be

developed and their use evaluated by women and healthcare professionals. Fourth, the health economic impact of the development of this new data system will be explored through economic analyses. Fifth, routes for the data system to be made available to the wider research community and regulatory authorities will be established through links with and support from Health Data Research UK and UK Biobank. Finally, all steps will include active involvement of a diverse and large panel of patient and public contributors to ensure the development and evaluation of this novel data system is patient and public centred. Anticipated Impact: We anticipate that the generation of this novel data system will improve the health of pregnant mothers and their babies by significantly advancing our understanding of the effects of medications taken during pregnancy, improving clinical and patient-centred decision making and driving future research in this field.

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