SWAT 148: Optimising data capture of prescribed medication in pregnancy

Objective of this SWAT
To compare a participant-reported digital method to capture prescribed antihypertensive medication and related data (e.g. side-effects) in pregnancy versus traditional case note review.

Study area: Follow-up, Data Quality
Sample type: Participants, Researchers
Estimated funding level needed: Low

Background
Medication prescribing in pregnancy can be electronic or on paper, with variation by healthcare provider and setting. Although not routinely collected, self-reporting is one of the methods used to determine medication use, including prescriptions filled and adherence to the prescribed medications, and might be an important outcome in randomised trials. Potential issues with patient-reported medication use more generally include recall bias and difficulties with medication names and active substances. This is particularly important in pragmatic trials and difficulties can arise when unpicking the influence of a data capture method on the intervention being assessed and when a method of data collection becomes part of the intervention. Digital platforms and applications are widely used in pregnancy and are seen as acceptable. Accurately capturing antihypertensive medication prescribed within a larger trial is essential for several important patient centred secondary outcomes, including prescription of additional or alternative antihypertensive drugs, persistence with allocated antihypertensive (time from randomisation to first discontinuation), discontinuation of allocated antihypertensive and adherence to allocated (and other) antihypertensives.

Interventions and comparators
Intervention 1: Intervention: Digital data capture platform of participant-reported antihypertensive medication prescribed and medication side-effects, for example by text messaging or within a digital application (designed and user tested in partnership with patient and public representatives). Prescribing and side effects data will be collected two weeks after consent, with prescribing data then collected at 4-week intervals up to birth.
Intervention 2: Comparator: case note review.

Index Type: Method of Follow-up

Method for allocating to intervention or comparator
Data will be gathered for all participants using both methods

Outcome measures
Primary: Agreement between participant-reported anti-hypertensive medication prescriptions and hospital prescription records: proportion of women who self-report type, dose and frequency of antihypertensive treatment in agreement with case note records; and agreement between participant-reported side effects and hospital case note records.
Secondary:

Analysis plans
Summary statistics and kappa statistics.

Possible problems in implementing this SWAT
The SWAT requires women to complete details of prescribed antihypertensive medication (and side-effects) through digital methods (text, email), to enable comparison against conventional routes of ascertaining medication through case note review. Completeness will be evaluated during the internal pilot.

References
N/A

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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Revisions made by:
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