Evaluating Diuretics in Usual Care (EVIDENCE) - piloting a novel methodology for comparative effectiveness research in hypertension

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Background
- The randomisation of prescribing policies has the potential to answer important clinical questions in the absence of head-to-head comparative effectiveness data.
- 2011 NICE hypertension guidelines in the UK recommended:
  - indapamide or chlortalidone (thiazide-like diuretics) should be used in preference to bendroflumethiazide (a thiazide diuretic) for the management of hypertension
- This recommendation has been criticised for lacking evidence
- It has not been fully implemented:
  - bendroflumethiazide remains the most widely used thiazide or thiazide-like diuretic across Scotland
- The EVIDENCE study:
  - Evaluating Diuretics in Normal Care
  - will demonstrate whether cluster randomising prescribing policies can be used to assess the comparative effectiveness of prescribed medicines
  - compares bendroflumethiazide & indapamide
  - is embedded in the routine practice of NHS Scotland
  - will be analysed using anonymised, routinely collected data

Methods
- EVIDENCE uses a cluster randomised, parallel group design to evaluate the NICE recommendation
- Randomisation is at GP practice level
- Practices are allocated to a prescribing policy of:
  - bendroflumethiazide or indapamide
  - as first-line diuretic in hypertension
- Where necessary routine prescriptions are switched
  - to comply with the policy
  - using established “drug switch” mechanisms
    - typically used in the NHS for cost saving
- The effectiveness and impact of the intervention will be assessed using routinely collected data
  - record linkage of:
    - prescribing
    - outcomes data (hospitalisation & mortality)

Results
- The EVIDENCE study protocol has been approved by a Research Ethics Committee and the initial pilot phase has commenced in Tayside, Scotland
- Initial experience suggests that implementation of the intervention can be delivered at a practice level
- The feasibility of a GP-practice level drug switch is confirmed
- The numbers of patients prescribed study medications before and after the policy implementation along with measures of adherence to applied switching and reasons for non-adherence will be analysed
- It is likely that cardiovascular events in this pilot phase will be few, but results will demonstrate the utility of routinely collected data

Acronyms
- EVIDENCE: The Evaluating Diuretics in Normal Care
- GP: General Practitioner (family doctor)
- NICE: National Institute for Health and Care Excellence
- ISD: Information Services Division (of NHS Scotland)

Conflict of Interest Statement
Author Disclosure Information:
The authors have no relevant conflicts of interest to declare