ENSURING PRAGMATIC TRIALS WORK: THE PRECIS-2 TOOL TO AID THE DESIGN OF SUPERDOT-C, A CLUSTER RANDOMISED CONTROLLED TRIAL IN PHARMACY

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Background: The PRECIS-2 tool has been developed to help trialists design appropriate studies that deliver the intended purpose of the trial. SuperDOT-C is a definitive trial of a pharmacist-led pathway where patients attending community pharmacies for opioid substitution therapy (OST) are tested, diagnosed and assessed for treatment for hepatitis C (HCV) with Direct-Acting Antiviral (DAAs) drugs through modified directly observed therapy (DOT). The key problem to be addressed in the elimination of HCV, in this group is how patients can be encouraged to be tested and enter treatment. The PRECIS-2 tool was therefore used provide assurance that design decisions were concordant with the explicit purpose of the study:

Method: Precis-2 has 9 domains: eligibility criteria; recruitment; setting; organisation; flexibility (delivery); flexibility (adherence); follow-up; primary outcome; primary analysis. Each domain is scored on a Likert scale of 1(very explanatory) to 5(very pragmatic) to facilitate domain group discussion and consensus. The results of this assessment are presented in a wheel diagram. An online toolkit supports researchers in the discussion and consideration of their assessment
Results

Eligibility criteria- all patients prescribed OST are eligible; recruitment- is undertaken at their regular pharmacy; setting - in the pharmacy where they receive OST; organisation- care delivered by the usual pharmacy staff; flexibility (delivery)- care is alongside normal delivery of OST; flexibility (adherence)- care is delivered through modified DOT; follow-up- is simpler than usual car and is delivered in the pharmacy; primary outcome- Is SVR 12 and is assessed in the pharmacy; primary analysis- on an intention to treat basis using all data

Conclusion: The assessment of SuperDOT-C using PRECIS-2 provided a high degree of reassurance that the design decisions that have been made were appropriate to ensure high applicability to real life care and to maximise the chances of demonstrating the effect identified by pilot work through the expected mechanism

Disclosure: SuperDOT-C was funded through grants provided by the Scottish Government, Gilead Inc and BMS.