Utilizing the stepped wedge cluster randomized controlled trial design to test the effectiveness of health systems interventions: A "real-world" implementation research study to assess the effectiveness of a new model of care for community-acquired pneumonia.

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Background
Whilst clinical trials minimize bias through randomization, doing so at an individual patient level is impractical with health systems interventions (which are often delivered at scale) and ethically challenging for treatments already well-supported by evidence. Community-acquired pneumonia (CAP) is the leading non-obstetric cause of hospitalization in Australia. High-level evidence now supports numerous interventions for improving patient outcomes but these are poorly applied in practice, possibly reflecting uncertainty as to whether "efficacy" in clinical trials translates to "effectiveness" in the real world.

Objectives
We designed a novel model of care to improve compliance with evidence based management of CAP. We aimed to evaluate the effectiveness of this in a representative population and in a way that minimized risks of confounding and bias.

Method
By partitioning our general internal medical (GIM) service into 8 "clusters" (based on existing separate operational units), and rolling out our intervention into each unit by a randomly determined sequence over 5 time periods, we implemented a phased introduction of the intervention that would also allow analytically robust comparisons of outcomes between intervention and control groups. A waiver of consent ensured a representative sample.

Results
Over 12-months, 415 and 401 individuals were enrolled in control and intervention groups, respectively. Completion of final outcomes analysis is expected by August 2018.

Conclusions (if applicable)
Our approach exemplifies the concept of "implementation research" and provides proof of principle that this is feasible for assessing the impact of health systems interventions in representative multi-morbid populations in the Australian hospital system.