Comment
A Cluster Randomized Trial of a Comprehensive Approach for Hypertension Control in Low-Income Patients in Argentina

Otavio Berwanger MD;PhD
Director - Research Institute HCor
Heart Hospital
Sao Paulo-SP, Brazil
Does the Trial Address an Important Problem?

**HYPERTENSION IN LMIC**

- High Prevalence (25-30%) in LMICs like Argentina
- < 10% are controlled (< 5% are aware)
- Need to Narrow the Gap between Evidence and Clinical Practice
Study Design

- **Cluster RCT** = best model to test quality improvement interventions (QIs)

- 18 Primary Healthcare Centers (1,954 eligible participants) randomized to comprehensive intervention or usual care

**Multifaceted and Multilevel QI Intervention:**

- Healthcare provider education (simple algorithms)
- Audit and feedback (to physicians ??)
- Community health care worker-based intervention
- Mobile phone messages to patients
Critical Appraisal

- Concealed allocation?

- Were data collectors (research nurses) involved in patient care?

- How “Usual” was “Usual Care” – 6 month home visits?

- ITT analysis

- How balanced were the clusters at baseline? More clusters are more important than more patients

- Statistical analysis took into account cluster design (mixed effects regression)
Results and Implications

Main Findings

- Primary outcome (net change in SPB of 5.5 mmHg from baseline to 18 months)
- Proportion of controlled HTN at 18 months (20% increase), high adherence to medications, and intensification of BP medications higher in the intervention group
- Any information on CV outcomes ??

Implications

- Feasible and Attractive QI intervention for LMIC
- Sound rationale for larger international Cluster RCTs (> 50 clusters) testing similar interventions in LMICs
- Need for nested cost-effectiveness analysis