The ACS QUIK Cluster
Randomized, Stepped Wedge Trial

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On behalf of the ACS QUIK investigators
Disclosures

Grants
NHLBI R00 HL107749, significant
Northwestern Global Health Initiative, significant
Northwestern Clinical and Translational Science Institute (UL1TR001422), significant
FIC D43TW010543, modest
NCI CA184211, significant
World Heart Federation, via Boehringer Ingelheim & Novartis, significant
European Society of Cardiology, significant
Center for Medicare and Medicaid Innovation, significant
Cochrane Collaboration, significant

Travel
American Heart Association, World Heart Federation

Consultancy, speakers’ bureau, advisory board
None
Background

Programs for improving process and outcome measures for patients with acute myocardial infarction are widely deployed in wealthy countries.

Randomized trials of quality improvement interventions in Brazil and China have demonstrated improvements in process measures but have not been powered to detect differences in clinical outcomes.

Our team has previously demonstrated areas for improvement in acute coronary syndrome care in India based on data from 25,748 participants enrolled in the Kerala ACS Registry (2007-2009).

**ACS QUIK: trial overview**

**Objective:** Evaluate the effect of a quality improvement toolkit adapted to Kerala.

**Design:** Cluster randomized, stepped wedge clinical trial (63 hospitals)

**Study period:** November 2014 to November 2016, 21,374 participants enrolled

**1° outcome:** Rate of major adverse cardiovascular events (MACE)

**2° outcomes:** Health-related quality of life; microeconomic costs

<table>
<thead>
<tr>
<th>Step</th>
<th>0-4 months</th>
<th>4-8 months</th>
<th>8-12 months</th>
<th>12-16 months</th>
<th>16-20 months</th>
<th>20-24 months</th>
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<tbody>
<tr>
<td>Step 5</td>
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<td>Step 1</td>
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</table>

Participants: Patients with acute myocardial infarction admitted to participating hospitals

Intervention: Multi-faceted, locally-adapted quality improvement toolkit based on key features of the American Heart Association’s Get With The Guidelines program

Comparator: Usual care

Outcome: 1º: MACE defined by death, re-infarction, stroke, major GUSTO bleeding; 2º: Individual MACE components, quality of life (SAQ), microeconomic costs

Time course: 30 days

Setting: Kerala, India

ACS QUIK toolkit components

1. Audit/feedback reporting mechanism to inform monthly quality improvement meetings for Plan-Do-Study-Act cycle

2. Standardized admission and discharge order sets; clinical pathways

3. Patient education materials: diet, activity, and tobacco cessation adapted to Keralan context

4. Linkage to code and rapid response team training

Communication within cohorts in intervention phase; online QI training
ACS QUIK hospitals

Private (n=49, 78%)
Government (n=9, 14%)
Semi-Government (n=5, 8%)
ACS QUIK cRCT SW CONSORT flowchart

**Control**

- **Step 0**: Nov 2014 – Mar 2015
  - N = 63 Clusters; 2915 Participants
- **Step 1**: Mar 2015 – Jul 2015
  - N = 51 Clusters; 2649 Participants
- **Step 2**: Jul 2015 – Nov 2015
  - N = 38 Clusters; 2251 Participants
- **Step 3**: Nov 2015 – Mar 2016
  - N = 25 Clusters; 1422 Participants
- **Step 4**: Mar 2016 – Jul 2016
  - N = 12 Clusters; 829 Participants
- **Step 5**: Jul 2016 – Nov 2016
  - N = 63 Clusters; 3735 Participants

**Intervention**

- **Step 0**: Nov 2014 – Mar 2015
  - N = 12 Clusters; 662 Participants
- **Step 1**: Mar 2015 – Jul 2015
  - N = 25 Clusters; 1265 Participants
- **Step 2**: Jul 2015 – Nov 2015
  - N = 38 Clusters; 2432 Participants
- **Step 3**: Nov 2015 – Mar 2016
  - N = 51 Clusters; 3214 Participants
- **Step 4**: Mar 2016 – Jul 2016
  - N = 63 Clusters; 3735 Participants

**Cumulative Participants**

- **Step 0**: N = 2915
- **Step 1**: N = 6226
- **Step 2**: N = 9742
- **Step 3**: N = 13596
- **Step 4**: N = 17639
- **Step 5**: N = 21374

**Analysed**

- Control: n=10066
  - Complete Follow up=9896
  - Loss to Follow up=54
  - Missing Follow up=116
- Intervention: n=11308
  - Complete Follow up=11183
  - Loss to Follow up=26
  - Missing Follow up=99
## Baseline characteristics (adjusted, 95% CI)

<table>
<thead>
<tr>
<th></th>
<th>Control n=10,066</th>
<th>Intervention n=11,308</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, years</strong></td>
<td>60.7 (60.0, 61.3)</td>
<td>60.7 (60.1, 61.3)</td>
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<tr>
<td><strong>Men, %</strong></td>
<td>75.3 (73.2, 77.4)</td>
<td>75.7 (73.8, 77.6)</td>
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<tr>
<td><strong>STEMI, %</strong></td>
<td>66.5 (60.7, 72.3)</td>
<td>64.7 (58.8, 70.5)</td>
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<tr>
<td><strong>Tobacco use, %</strong></td>
<td>30.9 (27.2, 34.5)</td>
<td>29.1 (25.6, 32.6)</td>
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<tr>
<td><strong>Diabetes, %</strong></td>
<td>45.4 (42.6, 48.2)</td>
<td>47.9 (45.2, 50.6)</td>
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<tr>
<td><strong>Transferred, %</strong></td>
<td>28.5 (23.4, 33.5)</td>
<td>35.2 (29.7, 40.7)</td>
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<tr>
<td><strong>No insurance, %</strong></td>
<td>78.5 (72.5, 84.5)</td>
<td>78.0 (72.0, 84.0)</td>
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<tr>
<td><strong>Weight, kg</strong></td>
<td>64.6 (63.8, 65.5)</td>
<td>63.7 (62.9, 64.6)</td>
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<tr>
<td><strong>SBP, mmHg</strong></td>
<td>140.0 (137.7, 142.2)</td>
<td>139.4 (137.3, 141.6)</td>
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<tr>
<td><strong>Heart rate, bpm</strong></td>
<td>80.7 (79.6, 81.8)</td>
<td>80.9 (79.8, 81.9)</td>
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<td>96.7 (95.0, 98.5)</td>
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<td>In-hospital 2nd antiplatelet, %</td>
<td>97.0 (95.3, 98.7)</td>
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<td>81.1 (75.6, 86.6)</td>
<td>82.9 (77.7, 88.1)</td>
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<td>Echocardiography, %</td>
<td>86.3 (80.7, 92.0)</td>
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<td>Thrombolysis, %</td>
<td>25.2 (18.5, 31.9)</td>
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<td>Primary PCI, %</td>
<td>34.4 (27.1, 41.7)</td>
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<td>41.8 (34.8, 48.9)</td>
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<td>30-day MACE, n (%)</td>
<td>645 (6.4)</td>
<td>602 (5.3)</td>
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<td>30-day death, n (%)</td>
<td>509 (5.1)</td>
<td>445 (3.9)</td>
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<tr>
<td>30-day reinfarction, n (%)</td>
<td>121 (1.2)</td>
<td>135 (1.2)</td>
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<tr>
<td>30-day stroke, n (%)</td>
<td>60 (0.6)</td>
<td>90 (0.8)</td>
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<tr>
<td>30-day major bleeding, n (%)</td>
<td>19 (0.2)</td>
<td>30 (0.3)</td>
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MACE = major adverse cardiovascular events (death, reinfarction, stroke, and major bleeding)
Primary outcome (adjusted)

Adjusted analyses were performed using mixed effect logistic regression models.
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<table>
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<th>Adjusted odds ratio (95% CI)</th>
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<tr>
<td>30-day MACE</td>
<td>0.98 (0.80, 1.21)</td>
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<tr>
<td>30-day death</td>
<td>0.94 (0.74, 1.19)</td>
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<tr>
<td>30-day MACE + HF + shock + cardiac arrest (post hoc)</td>
<td>0.84 (0.70, 1.00)</td>
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Interpretation

The ACS QUIK intervention led to improvements in in-hospital and discharge medication use; the favorable observed effects on the rates of 30-day MACE and mortality were attenuated after adjustment.

We observed higher quality of care and lower event rates in the control group than in previous reports; data compare favorably with US rates.

ACTION-GWTG 2014 in-hospital mortality: 6.4% for STEMI, 3.4% for NSTEMI

The intervention may not have been effective due to insufficient training, implementation or adoption of the intervention, or period of exposure to sufficiently change hospital practice.

Strengths and limitations

Strengths
Longitudinal partnership with Cardiological Society of India – Kerala chapter
Large sample size with low loss to follow-up rate
Trial design that accounted for temporal trends
Central statistical, risk-based trial monitoring to minimize study costs

Limitations
Higher quality care and lower than expected event rate in the control group
Heterogeneous implementation of the intervention
Risk of recruitment bias due to need for individual-level consent
Conclusions and future directions

The ACS QUIK toolkit intervention led to improvements in in-hospital and discharge medications but not in the adjusted rate of 30-day MACE.

We are studying factors that influence implementation, maintenance, and effect of the intervention across sites to identify conditions when the intervention is most likely be to effective and sustained.

Future interventions can be derived from our process evaluation to test their effects in different locations (e.g. other states in India), diseases (e.g. heart failure, stroke), and targets (e.g. health system managers) for better, safer care in India and other low- and middle-income countries.
Acknowledgments

Northwestern
Don Lloyd-Jones
Abi Baldridge
Lihui Zhao
Bob Bonow

Cardiological Society of India–Kerala
PP Mohanan
MN Krishnan
ACS QUIK Steering Committee

Centre for Chronic Disease Control (Delhi)
D Prabhakaran
Raji Devarajan
Dimple Kondal
Mumtaj Ali
Kavita Singh
Shifalika Goenka

Sponsors & DSMB
NIH: NHLBI (Lawton Cooper)
Northwestern Global Health Initiative
Cardiological Society of India-Kerala
Centre for Chronic Disease Control
John Spertus/CV Outcomes, Paul Chan
Brahmajee Nallamothu (DSMB chair)
Karla Hemming, KR Sundaram
Thomas Alexander, Simon Thom
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