The Quality in Acute Stroke Care Trial

Professor Sandy Middleton
Director, Nursing Research Institute

Overview

• Implementation research
• Quality improvement study
• Rigorously evaluated using a research framework (single-blind Cluster RCT)
• Funded by NHMRC
• Study design and results
Is current practice out of date?

Evidence of failure to translate research findings into clinical practice

• 30-40% of patients do not get treatments of proven effectiveness\(^1\)
• 20-25% of patients get care that is not needed or potentially harmful\(^1\)
• Participants only received 55% of recommended care\(^2\)

\(^1\)Schuster et al. (1998); \(^2\)McGlynn et al. (2003)
Changing clinician practice

- 57% of Australian adult health care encounters received appropriate care
  - i.e. care in line with evidence-based or consensus-based guidelines

\(^3\) Runciman et al. (2012)
Changing clinician practice

- Changing clinician practice remains a challenge
- Production of up-to-date evidence-based clinical guidelines without targeted implementation strategies do not ensure evidence uptake
Background

• In the first days of an acute stroke:
  • Temperature above 37.5°C occurs in 20-50% of patients\(^4\)
  • Up to 68% of patients become hyperglycaemic\(^5\)
  • 37% to 78% experience dysphagia\(^6\)
• All result in increased morbidity and mortality and enlarged infarct size

\(^4\)Azzimondi et al. 1995; \(^5\)Scott et al. 1999; \(^6\)Martino et al. 2005
Clinical guidelines for stroke

• Recommendations for management of fever, hyperglycaemia and swallowing⁷:
  • Regular monitoring and documentation of temperature and glucose levels
  • Routine antipyretic therapy for fever
  • Appropriate glycaemic therapy
  • Swallowing screen within 24 hrs and before oral intake

⁷National Stroke Foundation 2010
Aim

• To develop and implement a multidisciplinary, team building intervention to improve evidence-based management of fever, hyperglycaemia and swallowing dysfunction in patients following acute stroke

• To rigorously evaluate same using a clustered randomised controlled trial (CRCT) design
Primary Hypothesis:

- **90-days post-hospital admission**, patients who receive care in Stroke Units randomised to receive the **Fever Sugar and Swallow (FeSS)** intervention will have:
  - Decreased death and dependency (mRS)
  - Decreased functional dependency (BI)
  - Increased health status (SF-36)

- Compared to patients who receive care in Stroke Units randomised to the control group
Secondary Hypothesis:

In the first 72 hrs post admission to stroke unit:

- Lower mean temperature
- Lower mean finger-prick blood glucose level

Within 24 hrs of stroke unit admission:

- Increased swallowing screening
QASC CRCT

90-day Patient Outcomes: Death, dependency (CATI)
‘Study innovation at the same time it is occurring and collect data to link new interventions to outcomes’

‘Run adoption and implementation studies using high quality social science methods and theory alongside trials; do not wait until the trial is complete before working out what is needed to adopt and implement the intervention in real life’

8Dixon-Woods et al. BMJ 2011
QASC CRCT

Did clinician behaviour change?
Process Evaluation (medical record audits)

90-day Patient Outcomes: Death, dependency (CATI)
Processes of Care

• Improved monitoring (72 hours)
  • Temperature and finger-prick blood glucose monitoring
  • Time to swallow screen

• Improved treatment (72 hours)
  • Paracetamol; insulin administration
  • Failed screen: referred to speech pathologist
Eligibility

• Stroke unit eligibility: Category A or B acute stroke units in NSW, Australia

• Patient eligibility:
  • Diagnosis of stroke
  • < 48 hours from onset of symptoms
  • Not for palliative care
  • English; aged > 18 years
  • Telephone
  • Unable to provide informed consent/ assent
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Study Design - CRCT

NSW Stroke Units (n=19) → Pre-Intervention Patient Group → Medical Record Audit → 90-day data
Study Design - CRCT

NSW Stroke Units (n=19)

R

Intervention (n=10)    Control (n=9)
Study Design - CRCT

NSW Stroke Units (n=19)

Intervention (n=10)
FeSS Ix

Control (n=9)
No FeSS Ix
Study Design - CRCT

NSW Stroke Units (n=19)

Intervention (n=10)  Control (n=9)

FeSS Ix  No FeSS Ix

Post-Intervention Patient Group  Post-Intervention Patient Group
Study Design - CRCT

NSW Stroke Units (n=19)

Intervention (n=10)
- FeSS Ix

Control (n=9)
- No FeSS Ix

Post-Intervention Patient Group
- Medical Record Audit
- 90-day data

Post-Intervention Patient Group
- Medical Record Audit
- 90-day data
Intervention (1): FeSS protocols

**Fever (n=2 elements):**

- 4 -6 hourly temperature readings for 72 hours
- Temperature \( \geq 37.5 \) C treated with paracetamol
Intervention (1): FeSS protocols

Sugar (n=5 elements):

- Formal venous glucose on admission
- 1-6 hourly finger-prick glucose for 72 hours
- On admission: 8-16 mmol/L (ND) or 8-11 mmol/L (D): saline infusion for the first six hours
- Glucose > 16 mmol/L (ND): IV insulin
- Glucose > 11 mmol/L (D): IV insulin
Intervention (1): FeSS protocols

Swallowing (n=2 elements):

Education program and competency assessment for nurses run by speech pathologists:

- Screen within 24 hours of stroke unit admission
- Referral to speech pathologist for full assessment for those who failed the screen
Intervention (2): on-site actions

• Two teambuilding workshops
  • Barrier identification
  • Reinforcement of multidisciplinary teamwork
• Local adaptation
Intervention (2): on-site actions

• Site-based education and support
  • Interactive and didactic educational outreach meetings
• Reminders
  • Six weekly visits
  • Pro and reactive phone calls and emails
Control Stroke Units

• Control stroke units: Abridged NSF Guidelines (no FeSS protocols)

• No support to identify local and unique barriers, disseminate or implement
‘No problem... we do this already’
But we do it already

<table>
<thead>
<tr>
<th>Received paracetamol at first febrile event (n=196)</th>
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</tr>
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<td>No. of patients who received a swallow screening within the first 24 hours of admission to the hospital</td>
<td>174</td>
<td>24</td>
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</table>
Randomisation

Intervention group (n=10)
- Consented (n=626)
  - Lost to f-up (n=68)
    - 90-day data (n=558)
      - Died (n=20)

Control group (n=9)
- Consented (n=500)
  - Lost to f-up (n=49)
    - 90-day data (n=451)
      - Died (n=24)
QASC CRCT

90-day Patient Outcomes: Death, dependency (CATI)
Results

- Pre-intervention cohort: 687 patients
- Post-intervention cohort: 1009 patients
- Total sample size: 1696 patients from 19 NSW stroke units
- Mean age: 70 years; 60% (n=607) male
- Similarities between Ix and control group for age, sex, stroke location or severity, time to arrival at stroke unit
90-day Death and Dependency (mRS)

<table>
<thead>
<tr>
<th>Control (n=451)</th>
<th>Intervention (n=559)</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 2</td>
<td>259 (58%)</td>
<td>236 (42%) 0.002</td>
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</table>

*adjusted for baseline and clustering

Effect was noted for both mild and more severe strokes
# 90-day Functional Dependency (BI)

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<td>≥ 95</td>
<td>254 (60%)</td>
<td>367 (69%)</td>
</tr>
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90-day Health Status (SF-36)

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</tr>
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<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td></td>
</tr>
<tr>
<td>Physical Health (SF-36 PCS)</td>
<td>42.5 (10.5)</td>
<td>45.6 (10.2)</td>
<td>0.002</td>
</tr>
<tr>
<td>Mental Health (SF-36 MCS)</td>
<td>49.4 (10.6)</td>
<td>49.5 (10.9)</td>
<td>0.69</td>
</tr>
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## Fever

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<th>Control (n=483)</th>
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<tr>
<td>Temperature (mean)</td>
<td>36.6°C</td>
<td>36.5°C</td>
<td>0.001</td>
</tr>
<tr>
<td>Febrile (&gt; 37.5)</td>
<td>131 (27%)</td>
<td>105 (17%)</td>
<td>&lt;0.001</td>
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## Glucose

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<tr>
<td>Glucose reading</td>
<td>7.02</td>
<td>6.81</td>
<td>0.02</td>
</tr>
<tr>
<td>(mean)</td>
<td></td>
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## Swallowing

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<tr>
<td>Screen within 24 hrs of admission to</td>
<td>(n=350)</td>
<td>(n=522)</td>
<td></td>
</tr>
<tr>
<td>stroke unit</td>
<td>24 (7.0%)</td>
<td>242 (46%)</td>
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<tr>
<td>Screen or SP assessment within 24 hours of admission to hospital</td>
<td>419 (87%)</td>
<td>554 (92%)</td>
<td>&lt;0.001</td>
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## Length of stay

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<td>Hospital LOS</td>
<td>13.7 days (12.7)</td>
<td>11.3 days (10.3)</td>
<td>0.144</td>
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How did this happen?

‘Yet, one wonders how these important interventions achieved such improved outcomes?’

\(^9\)Alberts. Annals of Internal Medicine 2012
QASC CRCT

90-day Patient Outcomes: Death, dependency (CATI)

Did clinician behaviour change?
Process Evaluation (medical record audits)
Process Evaluation

• Process evaluations are studies that are conducted parallel to or follow intervention trials to help in the interpretation of the outcome results.  

• Aim: was to examine protocol adherence by measuring proportion of patients managed according to the protocols

10Grant et al. (2013)
Method

• Retrospective medical record audits, using prospectively documented data, of the QASC trial pre and post intervention patient cohort
## Results: Protocol Adherence (n=1086)

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<th>Outcome (ICC^)</th>
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<tr>
<td>Proportion of patients who met all fever clinical care elements (n=2)</td>
<td>74 (15%)</td>
<td>186 (31%)</td>
<td>&lt;0.001</td>
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<tr>
<td>Proportion of patients who met all sugar clinical care elements (n=5)</td>
<td>217 (45%)</td>
<td>398 (66%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Proportion of patients who met all swallow clinical care elements (n=2)</td>
<td>19 (4.0%)</td>
<td>241 (40%)</td>
<td>&lt;0.001</td>
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† P-values are for the interaction term between intervention group and time period (pre or post intervention) and are adjusted for clustering within stroke units
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What did we learn?

FeSS intervention resulted in 90-day:

- **Decreased** death and dependency
- **Effective for both** severe and mild strokes
- **Improved** physical functioning
- **Decreased** mean temperature and mean glucose
- **Improved** fever and glucose monitoring but room for improvement
- **Improved** swallow screening in stroke unit within 24 hours
Clinical Significance

- 15.7% FeSS Intervention
- 10% Thrombolysis < 4.5 hrs
- 5% Stroke Unit
- 1% Aspirin

NNT
- 79
- 18
- 14
- 6.4
Our Results

• Robust evidence for a complex, multifaceted Ix to change clinician behaviour and improve patient outcomes
• Multidisciplinary organised care, in particular, teamwork delivers significantly better outcomes and processes of care
• Augments the benefits of stroke unit care
• Good pro-active nursing care can deliver major benefits
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• Multidisciplinary organised care, in particular, teamwork delivers significantly better outcomes and processes of care
• Augments the benefits of stroke unit care
• Good pro-active nursing care can deliver major benefits
Our Results

• FeSS clinical protocols were pragmatic and many thought they already were doing this before the study

• Measure and keep measuring
Implementation of evidence-based treatment protocols to manage fever, hyperglycaemia, and swallowing dysfunction in acute stroke (QASC): a cluster randomised controlled trial

Sandy Middleton, Patrick McElmuff, Jeanette Ward, Jeremy M Grimshaw, Simeon Dale, Catherine D’Este, Peta Drury, Rhonda Griffiths, N Wah Cheung, Clare Quinn, Malcolm Evans, Dominique Cadilhac, Christopher Levi, on behalf of the QASC Trialists Group
References

Any Questions ?