Safe medication practice – what can we learn from root cause analysis and related methods?

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Patient Safety
NHS Improvement
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NHS Improvement vision for patient safety

- Increasing our understanding of what goes wrong in healthcare
- Enhancing the capability and capacity of the NHS to improve safety
- By tackling the major underlying barriers to widespread safety improvement
Patient Safety in NHS Improvement

- National Reporting and Learning System
- Retrospective Case Record Review
- The Q Initiative
- The Patient Safety Collaboratives
- The National Patient Safety Alerting System
- The Patient Safety Incident Management System
- Standards and standardisation
- Data Transparency
- Serious Incident Framework and Investigation

A system devoted to continual learning and improvement.
Gaining a better understanding of what goes wrong in healthcare.

Tackling the underlying barriers to safety improvement.
Enhancing NHS capability and capacity to improve safety.
The National Reporting and Learning System (NRLS)

Incidents reported to the NRLS (annual figures for England 2015/16)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>No harm to the patient (near misses)</td>
<td>1,281,582</td>
<td>71.9</td>
</tr>
<tr>
<td>Low harm</td>
<td>423,120</td>
<td>23.7</td>
</tr>
<tr>
<td>Moderate harm</td>
<td>65,993</td>
<td>3.7</td>
</tr>
<tr>
<td>Severe harm</td>
<td>6,363</td>
<td>0.4</td>
</tr>
<tr>
<td>Death</td>
<td>4,582</td>
<td>0.3</td>
</tr>
</tbody>
</table>

Total: 1,781,640
What are we up against?

Fundamentally we can’t do Root Cause Analysis (RCA) or any other analysis measure on all error, it's not practically possible.
Think scale! We’ve ‘estimated’ the error in the NHS

**Medication safety in the NHS**

- **20%** of people over 70 years old take five or more medicines. With an ageing population and multiple chronic medical conditions these numbers will just keep increasing.

- **600,000** non-elective hospital admissions are due to medicines. **70%** of these are preventable.

- **1 billion** prescriptions are issued every year in primary care.

- **2.5 million** doses of medicines are administered every year in the average acute hospital. **215,000 errors**.

- **1/2 million** inpatient prescriptions every year in the average acute hospital. **45,000 prescribing errors** with **550 potentially fatal**.

- **40–100 dispensing errors**.

- **2500** preventable deaths across all acute hospitals are due to medicines.

- **400,000** dispensing errors.

- **33 million** prescribing errors.

- **97%** of medication errors reported to the NHS result in no or low patient harm.

- **97,000** patients admitted to all acute hospitals suffer from harm due to medicines.

Acknowledgment: Steve Williams, Steve.Williams3@nhs.net
### National Faults

<table>
<thead>
<tr>
<th>Fault Description</th>
<th>Remedies</th>
</tr>
</thead>
</table>
| 3.3 million prescribing errors each year in the community | National prescribing competency test for medical graduates  
- NIHR Greater Manchester Primary Care Patient Safety Translational Research Centre  
including roll out of PINCER study findings to detect prescribing errors |
| 26 000 – 2.2 million dispensing errors each year in the community | Medication Safety Officers network (including independent pharmacies and large companies) to improve local learning from errors  
- NIHR Greater Manchester Primary Care Patient Safety Translational Research Centre  
including use of Manchester Patient Safety Assessment Framework in community pharmacies |
| 45 000 prescribing errors in an average acute hospital each year | National prescribing competency test for medical graduates  
- NIHR Imperial Patient Safety Translational Research Centre including assessment of electronic prescribing and administration systems and providing immediate feedback to doctors to reduce errors  
- Additional national funding to implement electronic prescribing systems  
-Medication Safety Thermometer to monitor and drive system improvements to reduce patient harms due to high risk medicines  
-Additional national funding to implement safer dispensing systems  
-Medication Safety Officers network to improve local learning from errors |
<p>| 40-100 dispensing errors in an average acute hospital each year | |</p>
<table>
<thead>
<tr>
<th>National Faults</th>
<th>National Remedies</th>
</tr>
</thead>
</table>
| 215 000 medicines administration errors in an average acute hospital each year | -- Medication Safety Thermometer to monitor and drive system improvements to reduce errors e.g. omitted doses  
- Medication Safety Officers network to improve local learning from errors  
- Additional national funding to implement safer administration technologies |
| In hospitals 6500 patients suffer harm due to medicines and 167 patients die avoidably due to medicines each year | - Medication Safety Thermometer to monitor and drive system improvements to reduce patient harms due to high risk medicines e.g. Anticoagulation, Insulin, Opioids  
- Medication Safety Officers network to improve local learning from errors  
- Mortality reviews help identify and drive system improvements to reduce avoidable deaths |
| 40,000 of non elective hospital admissions each year are due to medicines       | -- Medication Safety Officers network to improve local learning from avoidable admissions due to medication errors  
- NIHR Imperial and Greater Manchester Primary Care Patient Safety Translational Research Centres including roll out of PINCER study findings to detect prescribing errors and development and of an Improving Prescribing in the Elderly medication review tool  
- QOF target to reduce unavoidable non elective hospital admissions |
In 2014 the absolute number of medication reports to the NRLS increased more than in any previous year, representing a 15.6% increase on the year before.

There are a lot of potential investigations!!
Key points

- Too many can’t investigate every error, have to be selective
There are a lot of potential investigators!!

<table>
<thead>
<tr>
<th>Organisation</th>
<th>count</th>
<th>count aggregate</th>
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<tbody>
<tr>
<td>NHS Acute Medium</td>
<td>46</td>
<td></td>
</tr>
<tr>
<td>NHS Acute Large</td>
<td>41</td>
<td></td>
</tr>
<tr>
<td>NHS Acute Teaching</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>NHS Acute Small</td>
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<tr>
<td>NHS Acute Specialist</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>NHS Acute Trust</td>
<td>158</td>
<td></td>
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<tr>
<td>CCG</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>NHS Mental Health Trust</td>
<td>51</td>
<td></td>
</tr>
<tr>
<td>Community pharmacy sector</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>Other Independent Sector</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>NHS Community Trusts</td>
<td>18</td>
<td></td>
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<tr>
<td>NHS England Area Team</td>
<td>14</td>
<td></td>
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<tr>
<td>NHS Ambulance Trust</td>
<td>9</td>
<td></td>
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<tr>
<td>Community Interest Company</td>
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</tr>
<tr>
<td>Independent</td>
<td>2</td>
<td></td>
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<tr>
<td>Cosmetic Surgery</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Mental Health</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>NHS Acute</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Online Pharmacy</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Social Care Enterprise</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Grand Total</td>
<td>387</td>
<td></td>
</tr>
</tbody>
</table>

Registered Medication Safety Officer
As of August 2016
• The perfection myth
  – if we try hard enough we will not make any errors

• The punishment myth
  – if we punish people when they make errors they will make fewer of them
Two approaches

Person centred approach

• Individuals who make errors are ‘careless, at fault, reckless’
• Blame and punish
• Remove individual = improve safety

Systems approach

• Poor organisational design sets people up to fail
• Focus on the system rather than the individual
• Change the system = improve safety
Analysis options

1. Fault Tree Analysis (FTA)
2. Failure Modes Effect Analysis (FMEA)
3. Root Cause Analysis (RCA)
Attendees at workshops said (n=100+, 5 events)

FTA only 5% had ever heard of it

FMEA: needs to be proactive and multidisciplinary and multi-sector, Better alternative (UKMi risk assessment tool). Quantifies and is also Industry recognised. Little published application

RCA: All heard about it. A ‘waste of time and money’ unless done well, it’s a week, it’s a big undertaking. Reactive, not proactive. Part of the process, doesn’t lead anywhere
Bell Telephone Laboratories developed the concept in 1962 for the US Air Force for use with the Minuteman system.
Later adopted and extensively applied by the Boeing Company.
Fault tree analysis is one of many symbolic ‘analytical logic techniques’
little application in Health, but extensively used elsewhere
mathematically orientated, uses symbols to denote relationships
Has been assessed for use in healthcare

Symbols

- Basic event
- External event
- Undeveloped event
- Conditioning event
- Intermediate event

- OR gate
- AND gate
- Exclusive OR gate
- Priority AND gate
- Inhibit gate

- Transfer in
- Transfer out
Often there is an activity and you have to ask... Why?

Consider a genuine, current, patient-safety situation:

- 'nurse drawing up insulin with a syringe out of [insulin Brand] pen.’
- ‘[insulin Brand] was being given by drawing up a dose from an insulin pen-fill cartridge using an insulin needle. These cartridges are only intended for use with a re-usable insulin pen, not for directly drawing up doses’
- ‘In addition the insulin was being drawn up into an insulin syringe from an insulin cartridge designed to be used in a pen-style delivery device’

WHY, WHY, WHY
Prescription for insulin pen, self-administration but patient is not able to inject – HCP is called, HCP is required to administer Insulin with products at hand

Decision:
- Withdraw from pen
  - Stick needle in pen and withdraw
- Previous needle stick injury, patient's given non-safety needles
  - Error may fail to change the volume to account for differing strengths

Inject insulin

EU regulations on needle stick injury Sharps containers, Safety needles
FMEA

- Prospective
- Has a linguistic semantics
- Not comprehensive (holistic) – healthcare is complex
- Has ‘types’ functional, concept design, process
- Has been applied (limited) to medication

http://www.ihi.org/resources/Pages/Tools/FailureModesEffectsAnalysisComparisonFiveMedicationDispensingScenarios.aspx

Think that you know of the perfect storm, insulin pens, EU regulations, multiple strengths.

Could ‘you’ have predicted what HCPs would do?

We asked >100 HCPs
What they (100+ HCPs) said

FMEA could have got there with the right people at the table
Predicting human behaviour is challenging
Predict interesting work arounds!
Means different things to different people
Need a National one page description of FMEA and a template.
The UKMi ‘FMEA-like’ assessment -

RCA

- …is useful because its ‘holistic’. It enables the structured assessment of human factors (also known as Ergonomics) in a PSI.

- Still looks for a ‘root cause’ – but that may be multi-factorial (insulin pens).

- But there are still too many medication errors.
It's critical to understand which incidents to undertake an RCA.

Classify according to:

- the degree of harm or damage caused at the time

- its realistic future potential for harm if it occurred again

- Better to do fewer RCAs well than consider it as an ending in its own right.
It's critical to understand which incidents to undertake an RCA

Classify according to

- Need to accept that RCA is not the automatic ‘turn to’ solution
Root Cause Analysis Investigation

Fishbone Diagram - tool

Patient factors:
- Clinical condition
- Physical factors
- Social factors
- Psychological factors
- Interpersonal relationships

Individual (staff) factors:
- Physical issues
- Psychological
- Social/domestic
- Personality
- Cognitive factors

Task factors:
- Guidelines
- Procedures
- Protocols
- Decision aids
- Task design

Communication factors:
- Verbal
- Written
- Non-verbal
- Management

Team factors:
- Role congruence
- Leadership
- Support + cultural factors

Problem or issue (CDP/SIP)

Education + Training Factors:
- Competence
- Supervision
- Availability / Accessibility
- Appropriateness

Equipment + resources:
- Displays
- Integrity
- Positioning
- Usability

Working condition factors:
- Administrative
- Design of physical environment
- Environment
- Staffing
- Workload and hours
- Time

Organisational + strategic factors:
- Organisational structure
- Priorities
- Externally imposed risks
- Safety culture
Analysis – beware of what you find, or think you have found
Extracts from MSOs RCAs

- Process for checking medication prior to spinal injections was not followed.
- Failure to follow hospital policies and procedures.
- No omissions or errors in care or treatment were identified which would have led to this incident occurring.
- It is common practice throughout the NHS to give verbal advice, this is often done without adequate safeguards.
What was learnt...

“'A medication administration error (potential prevented never event) was not reported at the time that it was detected’’

Standardisation of practices for handling medication (storage, checking)

“There is no policy within the Trust for the administration of nebulisers and therefore confusion may arise as to how certain drugs should be delivered and whether this can be overridden in an emergency”
Key points

- Too many can’t investigate every error, have to be selective
- The nature of error may determine the method of analysis
System-wide learning from root cause analysis: a report from the New South Wales Root Cause Analysis Review Committee

Jonny Taitz,1 Kelvin Genn,2 Vanessa Brooks,2 Deborah Ross,2 Kathleen Ryan,2 Bronwyn Shumack,1 Tony Burrell,1 Peter Kennedy,1 on behalf of the NSW RCA Review Committee

‘Conclusion’ given the number of hours per RCA, it seems a shame that the final output of the process may not in fact achieve the desired patient safety improvements’
Key points

► Too many can’t investigate every error, have to be selective
► The nature of error may determine the method of analysis
► Investigations to determine the cause of error should be just the start of the undertaking
► We are guilty of failing to learn from the plethora of investigations
What we’d like the audience to remember

- Reserve investigations for things that might make a difference to patient care, and do it properly
- If there are actions, do them
- Share the findings