Anticoagulation therapy: improving processes using risk management tools

Hilary Merrett and Fiona Gale, CHKS
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Risk management tools and anticoagulation therapy

- The applicable processes
- Focus on Failure Mode Effects Analysis
- Key risks and findings in Anticoagulation therapy
- Using analytical tools for improvement
High Risk Drugs
High Risk Drugs

- Drugs that pose the most risk to the organization in terms of harm
- Represent the drugs with “low therapeutic index”—small changes in dose can have severe consequences
Medicines most frequently associated with severe harm were:

- Anticoagulants
- Antibiotics (allergy related)
- Injectable sedatives
- Chemotherapy
- Opiates
- Antipsychotics
- Insulin
- Infusion fluid
Using Analytical tools: prospective
Understanding why things go wrong

- Learning from experience
- Systems thinking
- Prospective and retrospective techniques
- Human reliability analysis: human factors
  - Assessing reliability through an understanding of human behaviours in the context of their environments
Human Reliability Analysis

- Prospective approach
- Error probability – understanding likelihood
- Takes process of care, rather than single case or incident
- Developed in industries where you need to know in advance of operations eg nuclear.
Human Reliability Analysis

- Fault Tree Analysis
- Event Tree Analysis
- Failure Modes and Effects Analysis
- HAZOP
- Hazard Analysis and Critical Control Points
- Probabilistic Risk Assessment
The FMEA process

DEFINE THE ISSUE
ESTABLISH THE TEAM
MAP THE PROCESS
HAZARD ANALYSIS
ACTIONS AND OUTCOMES
FMEA process in a nutshell!


- Identify possible causes for each failure mode
- Identify possible effects
- Scoring of risk of each failure: product of 3 measures – occurrence / severity and detectability – Risk Priority Number
- Identifying highest scoring failures to prioritise for action
Choosing the team

- Individuals closest to the event or issues involved
- Individuals critical to implementation of potential changes
- Leader with a broad knowledge base, who is respected and credible
- Someone with decision making authority
- Individuals with diverse knowledge bases
- Process experts to encourage development of functional processes
Examples in practice
<table>
<thead>
<tr>
<th>Steps</th>
<th>Failure Mode</th>
<th>Failure causes</th>
<th>Failure Effects</th>
<th>Likelihood of Occurrence</th>
<th>Likelihood of Detection</th>
<th>Severity</th>
<th>Risk Priority</th>
<th>Actions to reduce occurrence of failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A</td>
<td>Is diagnosis correct?</td>
<td>Diagnosis tests not performed</td>
<td>Anticoagulant administered when not indicated</td>
<td>1</td>
<td>5</td>
<td>4</td>
<td>20</td>
<td>All caregivers double check diagnosis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No treatment given when indicated</td>
<td>1</td>
<td>1</td>
<td>8</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Failure of test to diagnose</td>
<td>2</td>
<td>9</td>
<td>8</td>
<td>144</td>
<td>Use 2 tests to diagnosis when possible. Repeat inconclusive tests</td>
</tr>
<tr>
<td>1B</td>
<td>Are there contraindications of disease interactions?</td>
<td>Doesn’t meet standards of practice Clinicians unaware of standards</td>
<td>Inappropriate prescribing of anticoagulants</td>
<td>2</td>
<td>1</td>
<td>7</td>
<td>14</td>
<td>Pharmacists check indication Educate prescribers Establish treatment guidelines</td>
</tr>
<tr>
<td>1C</td>
<td>Are there drug or food interactions? Can they be managed?</td>
<td>Incomplete medication history No computer alerts Skipped alert Incomplete alert Herbal / supplement interactions Interactions not considered Didn’t check</td>
<td>Bleeding Death Thrombosis</td>
<td>7</td>
<td>2</td>
<td>1</td>
<td>14</td>
<td>Use pharmacy computer system that screens for drug interactions take a complete medication history including herbal/supplement information</td>
</tr>
</tbody>
</table>

Severity can range from 1 - 10
<table>
<thead>
<tr>
<th>Steps</th>
<th>Failure Mode</th>
<th>Failure causes</th>
<th>Failure Effects</th>
<th>Likelihood of Occurrence</th>
<th>Likelihood of Detection</th>
<th>Severity</th>
<th>Risk Priority</th>
<th>Actions to reduce occurrence of failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Initiate therapy: Write order</td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>2A</td>
<td>Initiate policy, pre-printed orders or protocol if exists</td>
<td>Don’t exist Not followed Outdated, inaccurate Providers use differently Unclear when to use Pre-printed order wrong Haven’t standardised</td>
<td>Wrong drug Wrong dose</td>
<td>7</td>
<td>8</td>
<td>4</td>
<td>224</td>
<td>Establish guidelines. Use inpatient warfarin protocols Do not use sliding scale warfarin schemes</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>2B</td>
<td>Select drug</td>
<td>Not formulary Not available Wrong drug for this patient Drug specific contraindication exists</td>
<td>Increase bleeding risk</td>
<td>1</td>
<td>3</td>
<td>9</td>
<td>27</td>
<td>Check for allergies Diagnose heparin induced thrombocytopenia appropriately</td>
</tr>
<tr>
<td>2C</td>
<td>Select dose</td>
<td>Wrong dose Wrong route Age, size, renal function not considered Mixed up drug or strength Order of magnitude error in writing dose</td>
<td>Increase bleeding risk</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td>Pick one drug for formulary for LMWH Pharmacist picks dose</td>
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</tr>
<tr>
<td>2D</td>
<td>Write order</td>
<td>Illegible Inappropriate abbreviations Order unclear Key elements of order omitted Left out sections of pre-printed orders Transcription errors No read back on verbal Orders</td>
<td>Wrong dose or drug administered. Bleeding</td>
<td>7</td>
<td>1</td>
<td>6</td>
<td>42</td>
<td>Avoid verbal orders. If do need to use, use read back procedure. Follow do not use abbreviations use pre-printed order forms.</td>
</tr>
</tbody>
</table>
## Going through the process

<table>
<thead>
<tr>
<th>Steps in process</th>
<th>Failure Mode</th>
<th>Failure Causes</th>
<th>Failure Effects</th>
<th>Likelihood of Occurrence</th>
<th>Likelihood of Detection</th>
<th>Severity</th>
<th>Risk Priority Number</th>
<th>Actions to reduce occurrence</th>
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Lessons from other settings

- Must have backing and involvement of senior management
- Is there anyone who understands the whole process?
- Improvements often about simplification and standardisation
Why use FMEA?

- Proactively prevents harm
- Analyses system for vulnerabilities
- Identifies ways to help prevent harm
- IHI methodology and templates exist
- Has been shown to reduce variances and number of serious harm incidents
- Helpful in complex processes
- Substantial investment of time and resource – high priority issues only therefore
- But ....consider retrospective analysis
A Root Cause Mentality

An insatiable desire to understand why things go wrong, why people do what they do, and how things got into their present state.

A realistic awareness of WHY things go wrong – not just the physical reasons, but the human, latent, and root reasons also.

A Reluctance to Blame – A Desire to Understand

Robert Nelms
RCA approach: deconstructing “failure cause”

Key problems

Acts or omissions in care which led to the events (= failure mode)

Examples:

- Patient received wrong medication
- Conveying the wrong information
- Not following policy/protocol
- Working beyond competence
RCA approach: for each key problem - contributory factors

- Team and Social
- Task
- Individual
- Patient
- Equipment and Resources
- Education and Training
- Organisation
- Communications
- Working Conditions
Case study

- Elderly gentleman admitted 22.10.08 - breathing difficulties
- COPD; epilepsy; type II diabetes ; renal and heart failure
- Previous DVT – on warfarin long term
- Injectable heparin prescribed on admissions instead
- No note of change of anticoagulation regime in notes
- Warfarin not included on discharge summary sent to GP 25.10.08
- 8.12.08 patient had breathing difficulties. Ambulance called
  Could not be resuscitated
- PM showed cause of death 1) pulmonary embolism 2) DVT limb
## Factors contributing to failure / problem

<table>
<thead>
<tr>
<th>Problems/Issues (CDP / SDP)*</th>
<th>Patient</th>
<th>Task</th>
<th>Individual Staff</th>
<th>Team and Social</th>
<th>Education and training</th>
<th>Equipment/Resources</th>
<th>Communication</th>
<th>Working Condition</th>
<th>Organisational and strategic</th>
</tr>
</thead>
<tbody>
<tr>
<td>FAILURE TO REPREScribe WARFARIN</td>
<td>NO COMPUTER ALERT</td>
<td>LACK OF KNOWLEDGE</td>
<td>TOO MANY STAFF INVOLVED – NOONE TAKING RESPONSIBILITY</td>
<td>LACK OF TRAINING</td>
<td>INADEQUATE HANDOVER</td>
<td>STAFF SHORTAGES</td>
<td>CLINICAL GOVERNANCE STRUCTURES UNCLEAR</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Improvement actions: strengthening controls

- Prospective and reactive barrier analysis
- Failsafe analysis
  - what has failed in the past
  - is it easy to follow guidelines?
  - do the guidelines always apply – are they out of hours proof?
  - will the right people get the right training?
  - will people be able to point up problems or potential problems?
Retrospective analysis or prospective?

Experience is a comb which nature gives us when we are bald