# Guidance on customising Bowtie Analysis for use in healthcare

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#### ABSTRACT

Based on the CIEHF white paper 'Human factors in barrier management', NHS Education for Scotland (NES) has been exploring the potential application of Bowtie Analysis (BTA) in healthcare. Both an initial workshop-based study in a primary care context, as well as feedback from training and a series of case studies conducted across primary and secondary care and supporting health functions, suggested BTA has significant potential as an approach to identifying and managing risk in healthcare. It seems realistic to expect that existing healthcare professionals should be able to conduct BTAs to a reasonable quality standard making use of an NES Guide guidance document, together with a relatively small amount of training and support.

#### **KEYWORDS**

Bowtie Analysis, Proactive Risk Assessment, Healthcare; Barrier Management

#### Introduction

For years now, the traditional high hazard industries, nuclear power, aviation, oil and gas exploration and production, rail, etc, have been subject to close scrutiny over how they identify and manage major hazards and risks. These industries use a variety of well-developed approaches both to identifying the major risks associated with their activities, and the systems and practices they have in place to ensure those risks are managed and controlled.

By contrast, although the risks to patient safety in healthcare are widely recognised, and despite the major effort that has and is going in to improving patient safety around the world, healthcare is a long way behind other safety critical industries in how it proactively identifies and manages risk (NHS, 2007). The controls relied on in healthcare to protect against major risk are rarely subject to formal scrutiny or assessment to determine either whether they are as effective as is believed, whether they are actually in place and functional, or under what conditions they can fail. The reported levels of preventable patient harm are testament to this lack of formal action (Panagioti et al., 2017).

Since publication of the CIEHF white paper 'Human factors in barrier management' (CIEHF, 2017), NHS Education for Scotland (NES) has been exploring the potential application of Bowtie Analysis (BTA) in healthcare. BTA is used in many high hazard industries to proactively identify both the threats that could lead to serious loss, and the controls that need to be in place and functional to reduce the risk to an acceptable level. The principal benefit of BTA is the awareness it generates of:

• The key controls relied on to protect against the occurrence of serious adverse events.

- The nature of those controls, how they can be defeated, and what needs to be in place to ensure they have as high a chance as possible of providing the protection expected.
- What action needs to be taken to ensure those controls are in place and effective.

In addition to the CIEHF white paper, the Centre for Chemical Process Safety (CCPS, 2017) has also recently published guidance for the process industries on good practice in BTA. The CCPS guidance is consistent with the CIEHF recommendations on dealing with human factors in an analysis.

When it is done properly, BTA can provide a rich understanding of the controls that are expected to be in place to protect against incidents, how they can fail, and how they need to be implemented, supported and managed. And, contrary to assumptions that are frequently made, based on the visual structure of the representation, that BTA assumes a linear, event-driven model of accident causation, in fact it does not need to make any assumptions about the mechanisms or nature of accident causation.

# NES study workshop on BTA in primary care

McLeod and Bowie (2018) reported on the results of an exploratory workshop to assess the potential value of BTA as a means of proactively identifying and assessing the controls relied on to protect against the risk of a primary care "never event" (i.e. a serious patient safety incident that is judged should never happen). Although the study was informal and limited in scope, it was concluded that BTA has the potential to be applied to serious significant events in primary healthcare as well, potentially, as having wider relevance and applicability as an approach to prospective risk analysis at all operational levels in the National Health Service. Concerns remain however about the level of training, support and resources that would be required for the healthcare community to be capable of conducting BTA to an adequate quality standard without having to rely on external facilitators.

Given the demands and resource constraints on the NHS, other than in exceptional cases, having to rely on specialists – and particularly external contractors – to lead most risk analysis in healthcare was considered a showstopper to the widespread adoption of any proactive risk assessment method. The same is considered to be true of any method that relies on having to procure customised software at significant financial cost.

The University of North Carolina department of radiation oncology has also been undertaking a programme of applied research, based on the guidance in the CIEHF white paper, to investigate whether BTA can have a significant place in improving the control of risk in radiation treatment (Mullins et al., 2019). Having the advantage of a sophisticated quality management system and well-defined care paths, Mullins et al. concluded that "...*BTA excels at providing a standardised language for defining and understanding controls within safety management programs, providing a detailed graphic analysis of all controls involved in care paths..."* (Mullins et al., 2019, p477). However, they recognised a number of limitations of BTA approach, not least that "...*the initial learning curve can be relatively high given that it does require expertise in the language surrounding controls and requires much thoughtfulness in the analysis of threats and human errors*" (p477).

# NES guidance on BTA for healthcare practitioners

Since completion of the initial workshop-based study, NES has been exploring, again in an informal manner, the training and support likely to be needed to allow current healthcare practitioners to carry out BTAs.

Based on the learning and feedback from the informal study of the use of BTA in primary care, a guidance document was prepared intended to support healthcare practitioners in facilitating a BTA in practice. It was expected that users of the guidance would attend a one-day training course where they would be introduced to the key concepts of BTA, the process recommended in the guidance, and the use of a number of standard tables designed to support the analysis.

# Users

The guidance is intended to be used by anyone tasked to lead a BTA in NHS Scotland. This individual is referred to as the BTA lead. No previous background in BTA, or any other structured risk identification or analysis method is assumed of the BTA lead. They may have no clinical background (for example a risk manager). The only requirements for being effective as a BTA Lead are:

- Being organised.
- Being able to think clearly and analytically.
- Having good facilitation skills.
- Being able to communicate effectively with clinical, scientific, managerial and support staff.
- Having experience with the implementation of the local management system.
- Having ready access to all relevant practice staff, both clinical and non-clinical.

# Process

To make the most efficient use of resources, and to ensure the analysis remains focused and valueadding, the BTA process has been simplified into five short stages. Each stage concludes with a review where a decision is made whether there is value in continuing to the next stage, see Figure 1. Contemporary Ergonomics and Human Factors 2020. Eds. Rebecca Charles and Dave Golightly. CIEHF.



Figure 1. The BowTie Analysis process

# Stage 1: Initiation

The BTA process begins with a decision to initiate a BTA based on concern about the risk (or actual previous occurrence) of some serious adverse event. Wherever it comes from, the concern leads to a decision that action is needed to ensure the risks of occurrence of the event are adequately controlled.

A BTA is initiated and individuals are appointed to three roles:

- The BTA Lead.
- A senior member of clinical or scientific staff is assigned as the primary clinical adviser (CA).
- Members of a steering group who will review and authorise the results of the analysis.

#### Stage 2: Develop Bowtie framework

In Stage 2, the hazard and adverse event (the Top Event in traditional Bowtie terminology) are defined, as well as events or situations that could lead to its occurrence (threats), and losses or consequences that could realistically follow should the event occur.

The definition of the hazard and/or hazardous situation and the adverse event(s) may need to be revisited to take account of issues arising as the analysis progresses. A balance needs to be reached

between over-generalising the event and losing the ability to identify controls that are specific to the event as defined.

Threats can be specific events (such as a loss of electrical power), or, perhaps more usually in healthcare, a situation or activity. These should be realistic situations that have, or easily could occur. Examples of threat situations in healthcare might include:

- Major update or introduction of a new clinical IT system.
- A patient with pre-existing serious health condition registering with a new family practice.
- A consultation or interaction with a patient.
- Ordering clinical tests and/or reviewing results.
- Modifying software or updating a database, etc.

If more than one threat is identified, they are reviewed to decide if they are indeed different or are actually instances of the same underlying threat. If all of the controls for two or more threats are likely to be the same, then they should be treated as instances of the same threat.

Consequences are actual harm, losses or damage that could arise if both: a) the adverse event occurred, and b) none of the mitigation controls performed as intended. Losses can take many forms, for example:

- Direct damage to the health or safety of the patient and families involved.
- Financial or other material loss to the patient or organisation.
- Damage to the reputation of the clinician or service.
- Emotional impacts on the staff involved.

As with threats, if the same controls are likely to be relied on to protect against different consequences, consequences should be treated as the same.

# Stage 3: Identify barriers and safeguards

In stage 3, the controls expected to prevent the adverse event or its consequences from occurring are identified and assessed to determine whether any of them are sufficiently robust to be considered as full barriers. Controls can be identified from many sources:

- The local management system.
- Discussions with clinical and non-clinical staff.
- Review of incident investigations.

Identifying the expected controls is most easily done in discussion with relevant stakeholders, either individually, or in a meeting. Recognising the controls that are believed to be in place – whether or not they are actually in place and how effective they are – can, in itself, be important learning from a BTA. The initial focus is on uncritically identifying and documenting the expected controls without passing judgment on whether they are realistic or effective.

Once they have been identified, suggested preventative and mitigation controls are evaluated against six barrier quality criteria:

- 1) Is someone responsible for its implementation and performance?
- 2) Is it directly traceable to the local management system?
- 3) Is it specific to blocking the threat or preventing the consequence?
- 4) Is it independent of all other barriers expected to protect against the same threat or consequence?

- 5) Provided it does what is expected, is it, if every other control failed, capable of preventing the threat from leading to the adverse event or from the event leading to the consequence?
- 6) Is it capable of being audited to confirm it is in place and working as expected?

Given the highly complex and dynamic nature of most healthcare, unlike many other high hazard industries, it is entirely possible that the evaluation of controls will conclude that there are in reality no full barriers able to protect against an event or consequence. In this situation, those controls that come closest to meeting barrier criteria are identified as 'key safeguards': they are recognised as not having the strength of full barriers but are none the less the key defences relied on to protect against the event or consequence. They need to be recognised as being of special importance.

# Stage 4: Identify and evaluate degradation factors

Stage 4 focuses on identifying degradation factors that could cause barriers or key safeguards to completely or partly fail to provide the protection expected. For each degradation factor, safeguards that could prevent it from defeating the barrier are also identified together with where responsibility is likely to lie for assuring each safeguard is in place and capable of doing what is expected of it. A method is suggested to allow the analyst to prioritise safeguards to identify where the most effective action can be taken (as recommended by McLeod and Bowie, 2018).

Once a reasonable list of potential degradation factors has been identified, they are reviewed to decide if they justify being included on the BTA. Considerations include:

- 1) Is it a generic safety issue (training, competence, workload, attention to detail, etc.) or is it something that justifies specific attention over and above normal management systems, to ensure the associated control does what is expected of it?
- 2) Is there a clear relationship between existence of the degradation factor and some reduction in capability of the associated control?
- 3) Is the analysis team aware of situations or incidents where the controls that were expected to protect against incidents were known not to have worked and where the reason for the failure was recognised?
- 4) Are there factors critical to the performance of a barrier that are owned or controlled by stakeholders who are remote from the clinical frontline and who may not be aware of the direct impact their decisions or actions can have on the performance of a barrier?

Many – perhaps most – degradation factors will be issues that are fundamental to good clinical practice: a culture where safety is valued and taken seriously; clinical competence; professional standards of behaviour; cleanliness; diligence and care; attention to detail; maintaining accurate records; communicating and reporting information clearly and accurately; contracts that reward good safety performance and don't incentivise cutting corners or taking risks with patient safety. These and many other issues are controlled and managed through existing standards, processes and practices. There is little value to be gained in a BTA by simply listing all of the factors that might influence a particular control.

The most important factor in deciding whether or not to include a particular degradation factor in the BTA is the answer to the following question:

"Does the analysis team believe that if this factor is not included, the analysis will not show all the areas where regular action is needed to protect against the adverse event?"

Safeguards are relied on to prevent main controls from being defeated by degradation factors. Safeguards are crucial in any barrier management system: they are controls that are important but cannot meet the standards needed to be considered as full barriers. Safeguards can be generic management system items (such as training and competence, cross-checks, learning from incidents, management reviews). But they can only be considered as safeguards if they are implemented in a way that makes them specific to the hazardous situation being analysed (as defined in Stage 1).

Two classes of safeguards are considered;

- 1) Those that are known, or believed, already to be in place (such as checklists, or cross-checks).
- 2) Those that are not currently in place, but, in principle at least, could be implemented.

The insight into new and more safeguards that could in principle be introduced can be one of the most useful outputs that a BTA generates.

#### Stage 5: Barrier management plan

The final stage in the BTA guidance is to create a barrier management plan for the adverse event. The purpose of the management plan is to ensure:

- That a process is in place for ensuring that the identified barriers and safeguards are implemented and protected against degradation.
- That local management understands what is needed in terms of effort and resource to implement the plan.

Specific objectives are:

- To identify who needs to be aware of the barriers, key safeguards and safeguards identified as being relied on to protect against the adverse event, including their roles and responsibilities.
- To define how that awareness is to be achieved (for example management meetings, distribution of the BTA diagram, training, etc.) and how confirmation that the roles and responsibilities are understood and accepted is to be assured.
- To identify what activities will be carried out to review the implementation and performance of each of the identified barriers and key safeguards, including what evidence or records will be needed in each case.
- To create a plan identifying when the various awareness and review activities will be conducted and how the results will be assured.

In addition, where responsibility or the ability to influence or assure barriers or safeguards is outside the control of the local organisation (for example where equipment or services are procured or controlled at a national level) the barrier management plan should ensure an action is in place to discuss the implications with the responsible stakeholders.

# Analysis tables

An important learning from the original NES primary care workshop, as well as observation from innumerable BTAs performed across different industries, is that the information generated and used frequently lacks rigour, precision and clarity. This occurs largely because of the highly graphical nature of the method – which, indeed, is an important reason why it is so popular. There is a very powerful temptation to start creating diagrams from the very outset of an analysis. And the need to keep 2-D diagrams as simple as possible frequently leads to great over-simplification of the understanding of the risks and how they are controlled.

To encourage BTA analysts to think more deeply and critically about the nature of the risks and controls involved, and to try to prevent them from jumping into creating diagrams too early, the NES guide includes five tables to help structure and review the information generated. Table 1 summarises the five tables recommended in the guide. Table 2 shows an example of the table

intended to help decide if suggested controls could be considered as being or contributing to full barriers or key safeguards.

Table	Stage	Purpose		
A1: Bowtie	2	Document the hazard, adverse		
framework summary		event, threats and consequences		
A2: Barrier	3	Evaluate suggested controls to		
identification		identify those that can be		
summary sheet		considered barriers and key		
		safeguards		
A3: Summary of	3	Document identified barriers,		
barriers, elements and		their elements involved and key		
key safeguards		safeguards		
A4: Degradation	4	Document degradation factors,		
factor and safeguard		their safeguards and who is likely		
summary sheet		to be responsible for		
		implementation and assurance of		
		the safeguards		
A5: Practicality x	5	Prioritise safeguards to identify		
impact assessment		where the greatest return on effort		
summary form		would be achieved		

Table 1: Summary of tables recommended in NES BTA Guidance

Table 2: Summary of barriers, elements and key safeguards

Title of the control	What has to happen for the control to be effective?	<ul> <li>Which of the functions of an active barrier does the control perform?</li> <li>Detects the threat?</li> <li>Decides what to do?</li> <li>Takes action?</li> </ul>			Is the control a full barrier?	Is the control a barrier element?	Is it a key safeguard?
		Detect	Decide	Act	-		

# **Evaluation study**

An invitation was sent out to interested parties across NHS Scotland to attend a one-day BTA training session, after which they were invited to carry out a BTA of their own using the NES guide as their principal support. Specifically, the study set out to test the following hypothesis:

Drawing on a practitioners guide, healthcare professionals in Scotland will be able to facilitate a Bowtie Analysis of a significant adverse healthcare event to an acceptable quality standard with no more than six hours face-to-face training and no more than four hours one-to-one support from a specialist.

Seventeen individuals drawn from across a variety of Scottish health boards, representing both primary and secondary care, as well as functions such as mental health, the ambulance service and medical physics attended the training. Following the training, eleven groups planned to carry out an analysis. However, for a combination of reasons, mainly to do with organisational change, resourcing or urgent priorities, only three case analyses were taken to the point of being considered complete:

- 1) Management of the risks associated with misadministration of gentamicin in a hospital environment.
- 2) Unknown development of acute kidney injury arising from an external infection, conducted in a primary care setting.
- 3) Disposal of medical devices containing patient identifiable information.

The first study was led by a medical consultant in a hospital environment; the second was led by a business manager in a GP surgery; and the third was led by a technical manager in the medical physics department of an NHS Trust in Scotland. Initial conclusions indicate that:

- 1) All of the individuals who acted as BTA leads felt they had been able to perform the role successfully to a degree (note that the ongoing analysis is assessing the quality of the analyses produced). There was a general feeling, however, that it may be more appropriate to target effort acquiring competence in BTA at those in NHS Scotland who have an existing responsibility for safety or risk management.
- 2) Although some of the concepts and terminology in BTA were relatively new to the participants, in most cases they had little difficulty understanding and using them.
- 3) All three studies initially set out with a poorly defined adverse event. This led to confusion and difficulty in conducting the analysis. When the definition and location (relative horizontal location on the Bowtie) of the adverse events were challenged and clarified during the progress review however, the analyses became much easier. (Note that the descriptions of the case analyses at the top of this page are the final definitions of the adverse events studied.)
- 4) Despite the emphasis given in the training and in the written guide about taking time to think and use the tables provided to structure the analysis before starting to draw diagrams, all three studies jumped into drawing diagrams from day one. This inhibited clarity and quality of thinking about the nature of the risks and controls involved. After the six-week review, all three studies used the tables provided to document, organise and assess the information gathered. This made the analyses significantly easier and of better quality.

The draft NES guide is being updated based on these and other feedback and learnings from the study.

# Conclusions

Based on both an initial workshop-based study in a primary care context, as well as feedback from training and a series of case studies conducted across primary and secondary care and supporting health functions, BTA has been found to have significant potential as an approach to identifying and managing risk in healthcare. It seems realistic to expect that existing healthcare professionals should be able to conduct BTAs to a reasonable quality standard making use of an NES guidance document, together with a relatively small amount of training and support.

#### References

- CIEHF. (2017). Human factors in barrier management. Chartered Institute of Ergonomics and Human Factors. Available at: https://www.ergonomics.org.uk.
- CCPS. (2018). Bowties in risk management. Wiley.
- McLeod, R. W., Bowie, P. (2018). Bowtie analysis as a prospective risk assessment technique in primary healthcare. Policy and Practice in Health and Safety. May.
- McLeod, R. W. (2018). Conducting bowtie analysis in healthcare: A guide for practitioners. Working paper prepared by Ron McLeod Ltd.
- NHS. (2007). Healthcare risk assessment made easy. National Patient Safety Agency.
- Panagioti, M,. Khan, K., Keers, R., Abuzour, A., Phipps, D., Bower, P., Avery, T., Ashcroft, D. (2017). Preventable patient harm across healthcare services: A systematic review and metaanalysis. Report for the General Medical Council. https://www.gmc-uk.org/-/media/documents/preventable-patient-harm-across-health-care-services\_pdf-73538295.pdf