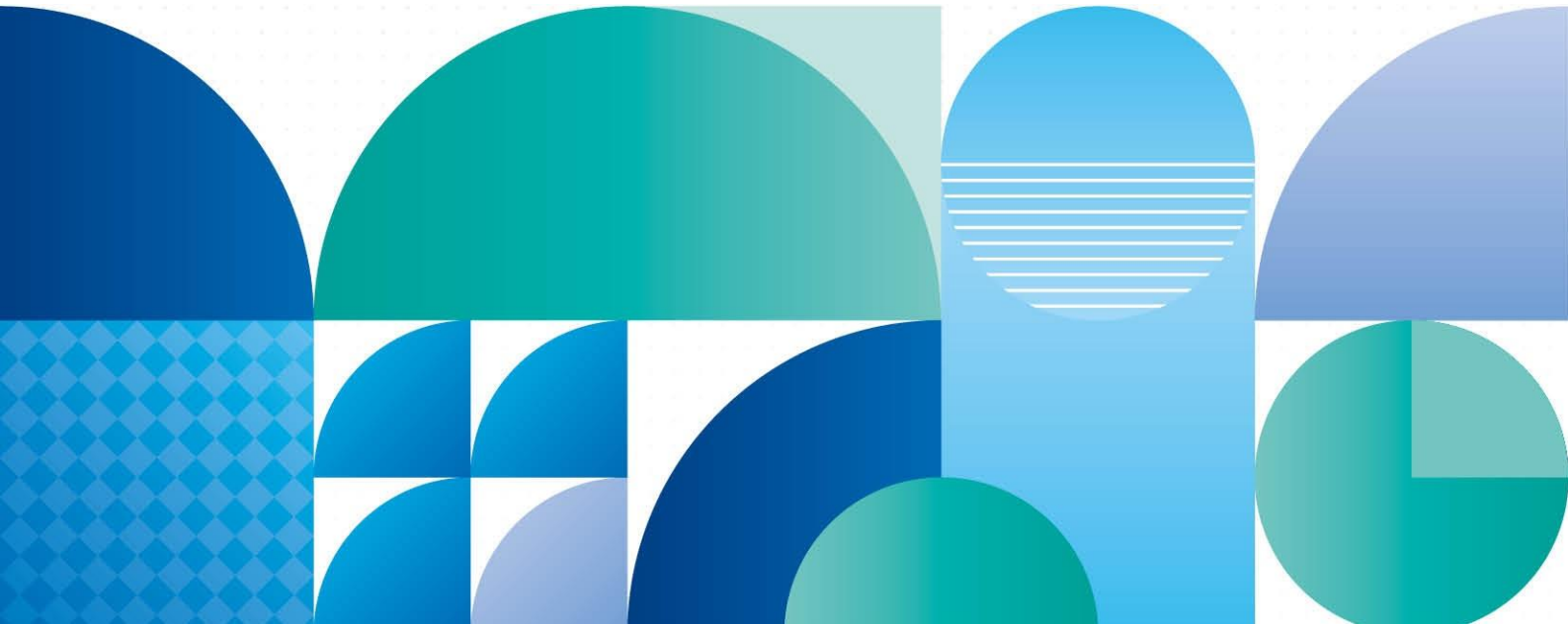
Health Economics Unit

NHS
Midlands and Lancashire
Commissioning Support Unit

Bow tie analysis

A ‘how to’ guide



Health Economics Unit

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1 Background

Risk management has been applied in high-risk industries (e.g., aviation, petrochemical, and mining industries) for several decades and is now an integral part of practice. Risk assessments are intended to answer four simple questions: what can go wrong (hazards); what bad effects could occur (adverse events); how likely the hazard is to lead to harm (risk); and whether there is a need for actions (controls or barriers). Although the findings are unlikely to eliminate risk, they can be helpful in managing any unnecessary risk and minimising adverse events.

The use of risk management strategies has since been adopted by many other sectors. This includes healthcare but, with implementation occurring mainly since the start of the 21st century, familiarity and effectiveness are less advanced than in other sectors.

Any changeable situation is viable for risk management. In healthcare, some of the most applicable areas of risk management are as follows:

- Clinical/patient safety
- Strategy (goal setting and achievement)
- Compliance (multiple levels, from regulations to treatment adherence)
- Liquidity (meeting financial obligations)
- Operational (maintaining day-to-day running)
- Technology
- Staff (recruitment and retention)
- Opportunity (change leads to positive enhancements).

Low numbers of harmful events can cause leaders to assume that sufficient and effective controls are in place. However, in a study by Mullins and colleagues,[1] after 12 oncology radiotherapy incidents had occurred due to site set up, they found that none of the individual controls in their quality assurance programme would indicate errors with the expected level of robustness. Risk assessments, therefore, when performed regularly, allow an overview of controls and the ability to assess the robustness of control configurations.

The UK Government has published a risk management framework for use by the public sector.[2] This highlights the continual and collaborative nature of risk management assessments (Figure 1). However, it describes only the principles of management without guidance on implementation.

[1] Mullins BT, McGurk R, McLeod RW, Lindsay D, Amos A, Gu D, Chera BS, Marks L, Das S, Mazur L. Human Error Bowtie Analysis to Enhance Patient Safety in Radiation Oncology. Pract Radiat Oncol. 2019 Nov;9(6):465-478. doi: 10.1016/j.prro.2019.06.022.
[2] HM Government. The orange book: management of risk – principles and concepts. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/866117/6.6266_HMT_Orange_Book_Update_v6_WEB.PDF

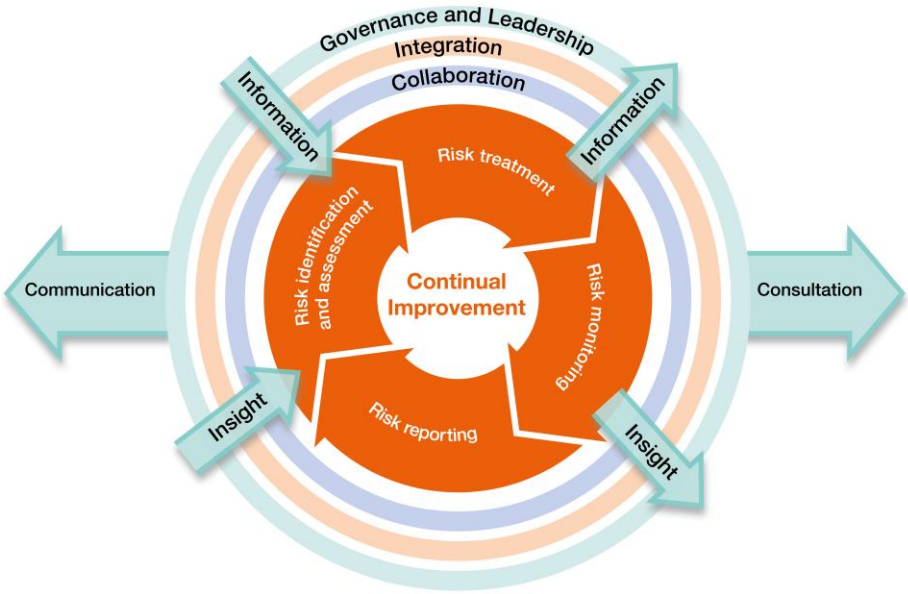

Figure 1: UK Government risk management framework[2]

There are many approaches to risk assessment, such as quality assessments; probability and impact matrices, in which risks are tabulated by type and level of likelihood to group and prioritise them; organising information into a risk register (list of issues, potential solutions, actions, and outcomes); root-cause analysis (deep dive into causes); Delphi technique (forecasting based on anonymised expert opinion); and even just regular meetings and brainstorming.

An increasingly popular method of risk assessment is 'bow tie analysis'. Bow tie analysis makes sources of risk, the effectiveness of controls against harm, the potential outcomes of a specific event, and gaps in risk management strategies easily visualisable to and understandable by a wide range of audiences.

An increasingly popular method of risk assessment is 'bow tie analysis'. Bow tie analysis makes sources of risk (hazards), the effectiveness of controls (protective barriers) against harm, the potential outcomes (consequences) of a specific event (top event), and gaps in risk management strategies easily visualisable to and understandable by a wide range of audiences. The diagrams are called bow tie because an array of potential hazards is shown on the left of a top event (i.e., the adverse event of interest that is expected to occur if control of the hazards is lost) and the range of possible consequences shown on the right but all centre around one top event (Figure 2). The diagrams are read from left to right to represent the overall changing situation.

The concept is simple, but multiple inputs and outputs can be considered simultaneously, and, therefore, this approach is useful for risk assessment of complex organisations and systems, such as the NHS and healthcare. Risk-barrier assessment adds a layer that is often not included in other types of risk assessment and enhances understanding of the gaps in risk management strategies and what might happen if changes are made. This guide describes how to use bow tie analysis to facilitate risk management in healthcare.

Bow tie analyses consider the full pathway of events from early hazards to ultimate consequences.

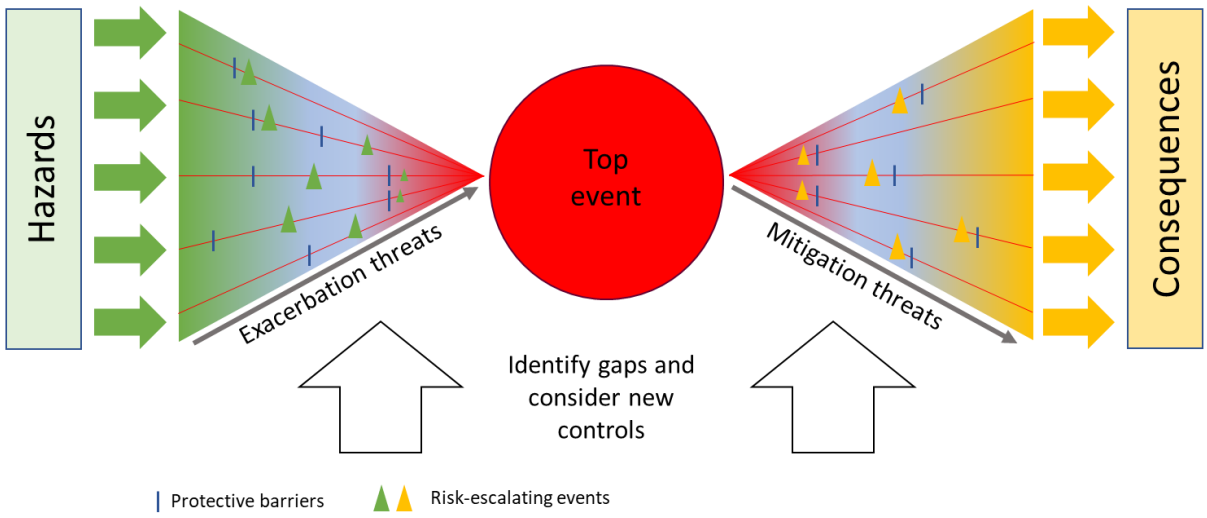

Figure 2: Schematic of bow tie analysis diagram

Bow tie analyses consider the full pathway of events from early hazards to ultimate consequences. Usually, one top event – the event that occurs if control of hazards is lost – is considered per diagram. Each hazard has a pathway along which threats that increase the risk of the top event or a poor ultimate consequence and the barriers intended to protect against them may be represented. The gaps identified in the barriers enable proactive changes to be made to systems and practices.

2 Use of bow tie analysis

Various examples of bow tie analyses in healthcare have been published. We explore these in this section.

2.1 System level

Kerckhoffs et al[3] assessed the performance of protective barriers for patient safety in an intensive care unit after nine events occurred related to intrahospital transportation, unplanned extubation, and communication. Respectively, the analysis revealed 52, 15, and 12 missing but implementable barriers and eight, 22, and seven practical recommendations. Abdi and colleagues[4] also applied bow tie methodology to risk assessment in intensive care. They used the method to investigate incidents related to high-alert medications, ventilator-associated pneumonia, catheter-related bloodstream

[3] Kerckhoffs MC, van der Sluijs AF, Binnekade JM, Dongelmans DA. Improving patient safety in the ICU by prospective identification of missing safety barriers using the bow-tie prospective risk analysis model. J Patient Saf. 2013 Sep;9(3):154-9. doi: 10.1097/PTS.0b013e318288a476.
[4] Abdi Z, Ravaghi H, Abbasi M, Delgoshaei B, Esfandiari S. Application of Bow-tie methodology to improve patient safety. Int J Health Care Qual Assur. 2016 May 9;29(4):425-40. doi: 10.1108/IJHCQA-10-2015-0121.

infections, urinary tract infections, and unwanted extubation. The causal factors were identified for 48 potential adverse events and new protective barriers or those aimed at improving existing barriers were assessed, leading to practical recommendations that would eliminate or control the hazards.

Culwick and colleagues[5] used bow tie analysis in anaesthesiology and found that it improved understanding of anaesthesia hazards and risks, pre-emptive identification of absent or inadequate hazard controls, investigation of clinical incidents, teaching anaesthesia risk management, and demonstrating risk management strategies to third parties when required. They conclude “Bowtie diagrams have an advantage over existing methods to analyse and understand critical incidents as they combine possible causes and methods to prevent similar events in the future, with management strategies and learning from outcomes. In this way, all the aspects of a critical incident are combined into a single diagram, which can be used as an educational tool, as an analysis summary or a document to assist with safety and quality improvement.”

2.2 Treatment level

Wieregna and colleagues[6] aimed to assess risk within the hospital medication prescribing process. They set their hazards as applicability, comprehensibility, creation of awareness in and motivation of participants, and the capability related to working conditions. Initially, a high number of medication safety risks were identified, meaning that it was challenging to set barriers that would create sufficient awareness and motivation to address them. The method was adjusted to perform in-depth assessments of a small number of safety issues, which substantially improved the applicability and helped with selection and prioritisation of protective barriers.

2.3 Disease level

De Oliveira et al[7] studied risks and consequences associated with sepsis (Figure 3). They used NHS Hospital Episode Statistics data in England to investigate coded disorders in the 2 years before and 1 year after cases of sepsis. The software used to create the bow tie diagram in this study (Tableau) allowed illustration of not only the types of hazards for sepsis but also the contributions they made to different pathways in time-ordered sequence and by accumulating numbers of patients they affected.

[5] Culwick MD, Merry AF, Clarke DM, Taraporewalla KJ, Gibbs NM. Bow-tie diagrams for risk management in anaesthesia. Anaesth Intensive Care. 2016 Nov;44(6):712-718. doi: 10.1177/0310057X1604400615.
[6] Wierenga PC, Lie-A-Huen L, de Rooij SE, Klazinga NS, Guchelaar HJ, Smorenburg SM. Application of the Bow-Tie model in medication safety risk analysis: consecutive experience in two hospitals in the Netherlands. Drug Saf. 2009;32(8):663-73. doi: 10.2165/00002018-200932080-00005.
[7] De Oliveira H, Prodel M, Lamarsalle L, Inada-Kim M, Ajayi K, Wilkins J, Sekelj S, Beecroft S, Snow S, Slater R, Orlowski A. "Bow-tie" optimal pathway discovery analysis of sepsis hospital admissions using the Hospital Episode Statistics database in England. JAMIA Open. 2020 Sep 20;3(3):439-448. doi: 10.1093/jamiaopen/ooaa039.

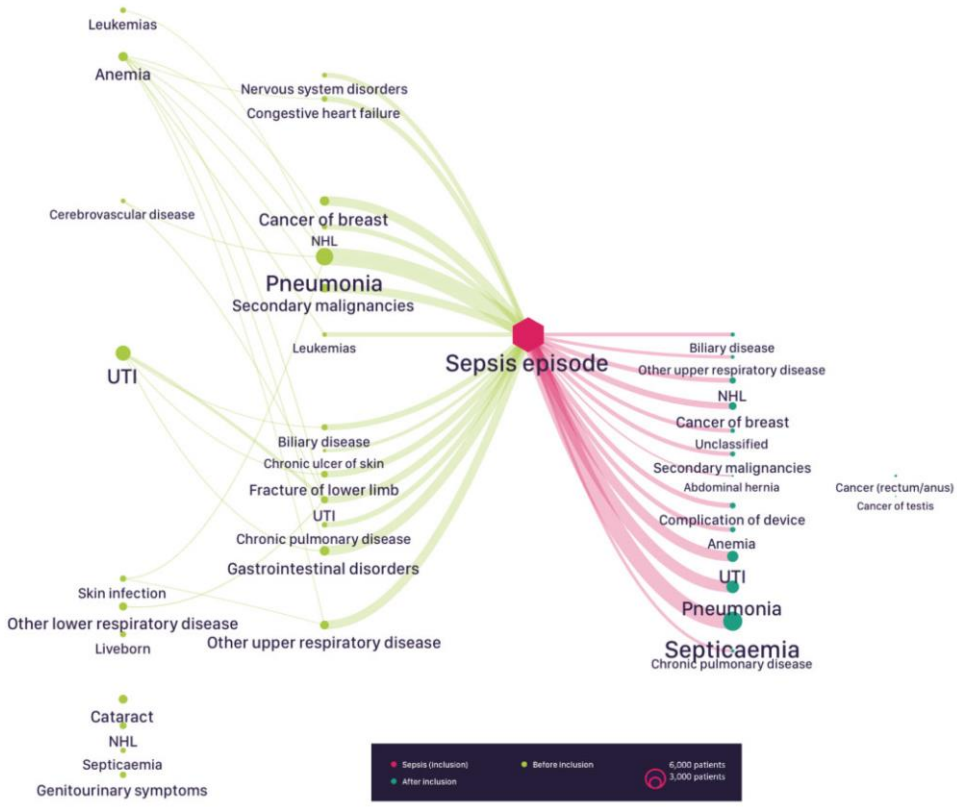

Figure 3: Node and edge bow tie representation of risks and consequences associated with sepsis [7]

Circles (nodes) indicate events that occurred in the 2 years before and 1 year after cases of sepsis, and the lines (edges) show the pathways affected. The thickness of lines increases with rising number of patients.
NHL=non-Hodgkin lymphoma; UTI=urinary tract infection.

Bow tie analysis was used by Rayner Brown and colleagues[8] to investigate potential factors in the degradation of barriers against spread of SARS-CoV-2 in Nova Scotia, Canada. Degradation factors are not expected to cause a barrier to fail but could contribute to its failure. In the case of SARS-CoV-2, these could have been poor hand hygiene or not adhering to social distancing rules, and so on. The virus was used as the hazard and the top event was an individual at high risk of infection (e.g., nurse, care home resident, immunocompromised patient). Threats and consequences were risk of catching the virus and the effects of that, barriers were public health measures, and degradation factors were non-adherence to these measures. The outputs of the bow tie analysis were complex and emphasised the importance of identifying degradation factors and safeguards against them to ensure barrier reliability and effectiveness.

[8] Brown KR, VanBerkel P, Khan FI, Amyotte PR. Application of bow tie analysis and inherently safer design to the novel coronavirus hazard. Process Saf Environ Prot. 2021 Aug;152:701-718. doi: 10.1016/j.psep.2021.06.046.

3 Creation of bow tie diagrams

3.1 Process

Bow tie analysis might be initiated due to a concern about risk or as part of a regular review of risk barriers. McLeod and Bowie[9] have suggested a process that can facilitate analysis (**Figure 5**). They note that it is important to define the top event, hazards, and consequences clearly, which might mean that terminology needs to be agreed before analysis begins. The hazards and consequences (harm, loss, or damage) must be credible, and where multiple hazards or consequences are likely to share all controls, they should be grouped into one.

Bow tie analysis might be initiated due to a concern about risk or as part of a regular review of risk barriers.

Identification of barriers should be thorough and include multiple sources of information. Consider that these might be local, regional, and/or national and contact organisations and consult guidance as appropriate. Additionally, relevant stakeholders should be consulted to obtain further information, including real-world experience. This could be achieved by meetings, interviews, surveys, and so on. A mix of individual and group discussions/responses would be helpful provided that people are comfortable discussing risk in those situations. It is important to clarify that information sought at this stage is about expected barriers and will be documented without pre-judgement of credibility; methods that allow anonymised responses might help people to provide details.

Identification of barriers should be thorough and include multiple sources of information.

Judging the credibility of suggested barriers relies on several factors. Barriers may be active or passive. The former enable detection of, decisions about, and actions against harm, and the latter prevent harm just by their presence (e.g., checklists).[10] McLeod and Bowie[9] suggest a set of criteria against which to assess the quality of barriers:

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. If it does, what is expected and if every other barrier failed, could it prevent the top event and/or consequences?
6. Can it be audited to confirm it is in place and working as expected?

[9] McLeod & Bowie. Guidance on customising bowtie analysis for use in healthcare. In: Charles R, Golightly D, eds. Contemporary ergonomics and human factors. Wootton Wawen: Chartered Institute of Ergonomics and Human Factors, 2020. https://publications.ergonomics.org.uk/uploads/Guidance-on-customising-Bowtie-Analysis-for-use-in-healthcare.pdf

[10] McLeod RW, Bowie P. Bowtie analysis as a prospective risk assessment technique in primary healthcare. Policy Pract Health Saf 2018;16:177-193. doi: 10.1080/14773996.2018.1466460.

They note that complexity of health means that not all barriers can be absolute and suggest that if criterion 5 is not met, a barrier should be judged on whether it has a key role in the pathway to the top event. This type of barrier is referred to as a safeguard (Figure 4) and is defined as something that is intended to prevent exacerbating threats from interfering with the functioning of the barrier.[10] McLeod and Bowie highlight that gaining clarity about what acts as a true barrier versus a safeguard is an important output of bow tie analysis.

As in the example study by Rayner Brown and colleagues,[8] this process includes identification of degradation factors. These are often issues that are fundamental to good clinical practice, such as cleanliness, communication and reporting, and professional standards. As the potential number of degradation factors could be high, key factors need to be identified and prioritised. McLeod and Bowie recommend asking the following question as a guide: “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?”

Finally, as relevant to healthcare as any other industry is that if gaps are identified that lead to the recommendation for additional barriers, it should be considered whether there were barriers in place that degraded or failed because of their original designs or whether they were missing. If degradation led to failure, the same fate might be met by any new barrier unless the reason for the degradation is understood. Further assessment might be warranted in structural, maintenance, awareness, and testing before a new barrier is added.[11]

Gaining clarity about what acts as a true barrier versus a safeguard is an important output of bow tie analysis.

[11] Manton M. Johnson M, Pitblado R et al. Standardisation of bow tie methodology and terminology via a CCPS/EI book. Symposium series no 162. Rugby: IChemE, 2017. https://www.icheme.org/media/15543/poster-09.pdf

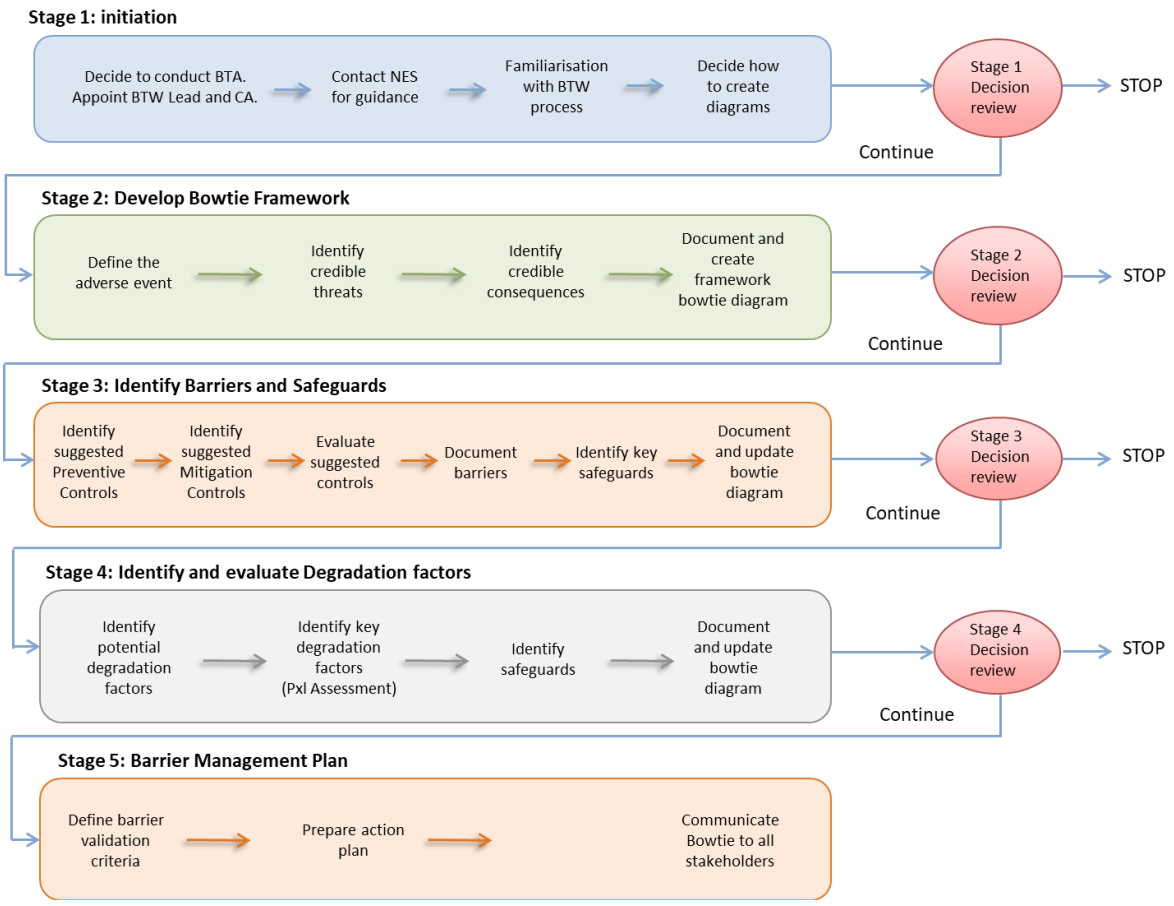

Figure 4: NHS Education Scotland guide to the bow tie analysis process[9]

3.1.1 Software

Various risk assessment software packages are available that can build bow tie diagrams. Tableau has already been mentioned. Other options are BowTieXP. Microsoft Visio, Bowtie Master, and so on. Templates, plug-ins, and macros are also available for Excel online.

3.2 After analysis

Bow tie analysis should be part of an ongoing risk management process and, once the analysis is complete, a plan needs to be put in place to manage required barrier changes. The plan should encompass prioritisation of barrier and safeguard changes, ensuring that needs in terms of effort and resources may be met, and implementation. Objectives might include the following:[9]

- Identify who needs to be aware of and will take responsibility for barriers and safeguards
- Define how awareness is to be achieved and responsibilities and roles managed
- Identify implementation and performance review activities and by whom and how these will be performed
- Plan how the results will be assessed.

As part of the raising awareness and assigning responsibility, it is important to make clear that barriers degrade continuously and at different rates for different reasons and,

therefore, the timing of status reviews will vary. Information on local, regional, and national updates should be discussed and not just shared. Where responsibility or the ability to influence or assure barriers or safeguards is outside the control of the local organisation, the relevant stakeholders must be included in planning.

4 Resources and further reading

NHS Commissioning Support Units can provide business intelligence support.

The Association of Professional Healthcare Analysts has numerous experts who can help with preparation, analysis, and visualisation of data.

The UK Government has published a risk management framework for use by the public sector: The orange book: management of risk – principles and concepts.

NHS Education for Scotland published a technical report on Bowtie Analysis as a Prospective Risk Assessment Technique in Primary Healthcare.

Preliminary case report study of training and support needed to conduct bowtie analysis in healthcare published in the BMJ Open Quality journal.