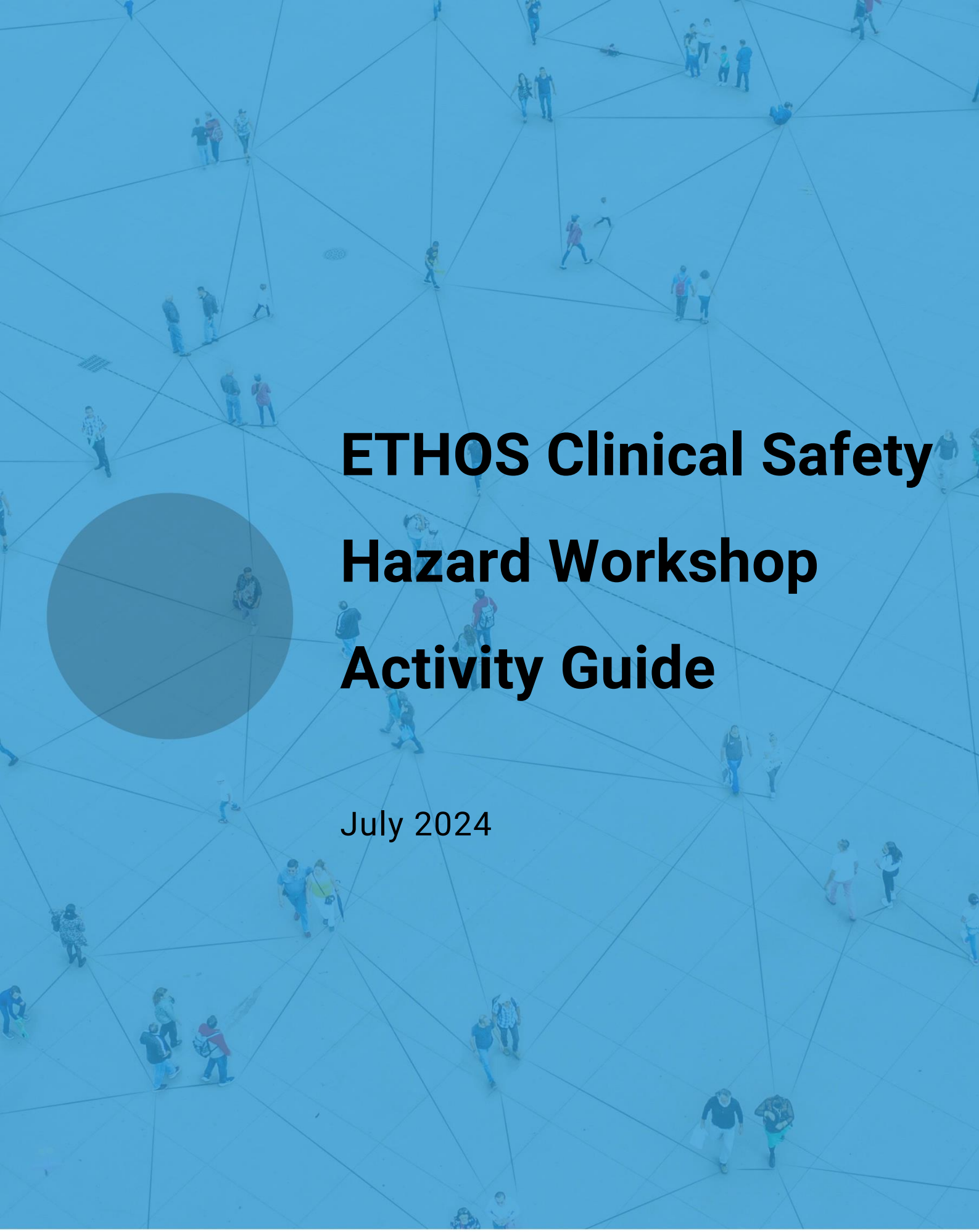

ETHOS Clinical Safety Hazard Workshop Activity Guide

July 2024

ETHOS

ETHOS guide for the Hazard Assessment Workshop

The following are estimates based on ETHOS's own experiences and will vary per product complexity or scale of implementation / deployment.

Preparation Prevents Poor Performance!

For all product clinical safety reviews, plan for one 2-hour workshop (use additional 2-hour sessions if needed). Representation at this is usually 8 to 15 people and roles are generally required as follows for quorum:

- Clinical subject matter expert(s) preferably with clinical safety awareness or understanding of the clinical risk management processes
- Representative users of the system – administrative / clerical, health care professionals or patients
- Technical / product specialists as required – deployment lead, expert user, trainer, service support lead, and project management
- Technical support for product related queries and application functional expertise – preferably manufacturer representation or a suitable equivalent
- Clinical Safety Officer and Safety Engineer – knowledgeable in the clinical risk management process.

Run the workshop, document the discussion and provide a summary report to record the event.
The event may also be recorded as this is useful for anyone who can't attend (if held online or utilising appropriate tools). The Hazard Workshop Agenda will usually be as follows:

1. Representation - Quorum - Capture details of suitably qualified persons in attendance.

2. Presentation of safety requirements and the hazard workshop process - Provide a slide deck presentation and cover the following:
    a. Explanation of the clinical safety standard and requirements for compliance
    b. How the hazard log was established
    c. How the hazard workshop will be conducted.

3. Objective review of the Hazard Log - Discussion and agreement of hazard areas, hazard potential causes, clinical impact and the mitigations provided. Mitigations will generally take two forms:
    a. Those directly related to the 'product' / existing support processes for the product
    b. Those related to the introduction and ongoing use of the use of the service.

4. Key Safety Assets / Evidence - This will be based on the summary table of hazards. Ideally there should be a representative version of the application available to use to demonstrate potential hazard scenarios and mitigation controls for the product. This can be completed as part of a separate evaluation exercise and results fed into the hazard workshop if necessary. As a minimum, we must establish how the product will be used through some form of demonstration, in whatever format is available for the best results.
    Clinical workflows that the product will be integrating into (digital health intervention) are also essential. It is good to work with a clinical workflow (or patient pathway) with the Hazard Workshop attendees and discuss potential areas of risk and how they are mitigated technically, by training and process. The NHS Clinical Safety process and risk matrix is commonly used for the hazard assessments unless there is a specific client requirement.

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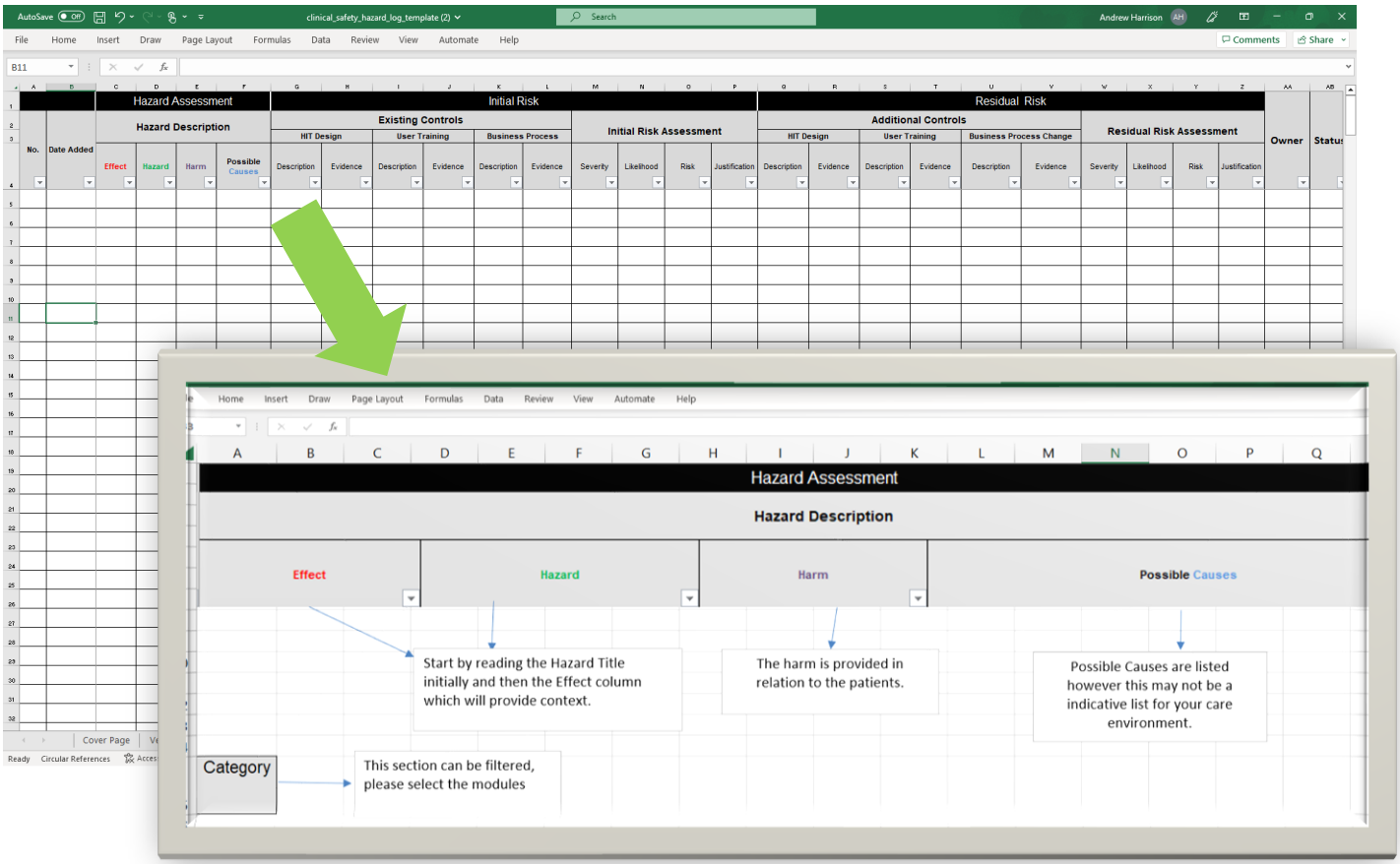
Typically, the Hazard Log would have the following features:

Hazard Log



Sourced from NHS England - [Clinical Safety Documentation]

The risk matrix used for scoring hazard risk ratings is shown overleaf.

Risk Matrix

Likelihood						
	Very High	3	4	4	5	5
	High	2	3	3	4	5
	Medium	2	2	3	3	4
	Low	1	2	2	3	4
	Very Low	1	1	2	2	3
		Minor	Significant	Considerable	Major	Catastrophic
		Severity				

Likelihood Category	Interpretation
Very high	Certain or almost certain; highly likely to occur
High	Not certain but very possible; reasonably expected to occur in the majority of cases
Medium	Possible
Low	Could occur but in the great majority of occasions will not
Very low	Negligible or nearly negligible possibility of occurring

5	Unacceptable level of risk
4	Mandatory elimination of hazard or addition of control measure to reduce risk to an acceptable level
3	Undesirable level of risk. Attempts should be made to eliminate the hazard or implement control measures to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical
2	Acceptable where cost of further reduction outweighs benefits gained or where further risk reduction is impractical
1	Acceptable, no further action required

Severity Classification	Interpretation	Number of Patients Affected
Catastrophic	Death	Multiple
	Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term	Multiple
Major	Death	Single
	Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term	Single
	Severe injury or severe incapacity from which recovery is expected in the short term	Multiple
	Severe psychological trauma	Multiple
Considerable	Severe injury or severe incapacity from which recovery is expected in the short term	Single
	Severe psychological trauma	Single
	Minor injury or injuries from which recovery is not expected in the short term	Multiple
	Significant psychological trauma	Multiple
Significant	Minor injury or injuries from which recovery is not expected in the short term	Single
	Significant psychological trauma	Single
	Minor injury from which recovery is expected in the short term	Multiple
	Minor psychological upset; inconvenience	Multiple
Minor	Minor injury from which recovery is expected in the short term; minor psychological upset; inconvenience; any negligible consequence	Single

Running the workshop (ETHOS guide)

The following is a general guide on the 'flow' of the workshop.

1. **Hazard Workshop Introduction**
    a. Capture attendee name and role for audit trail (use online meeting tools if available)
    b. Housekeeping, break to help keep focus, and convene for 2 hours maximum. Ask if we can record the session too?

2. **Brief background**
    a. Pre-reading (if provided) done?
    b. Clinical Safety standard(s) – brief explanation
    c. Assessment method, Preliminary Hazard Assessment

3. **Assessment**
    a. Start point:
        - Introduce concept of Hazard Themes – provenance, experience etc
        - Overview of Clinical workflow – use a process model or diagram and explain the broad process for use of the product
        - Explain the link at key points in the process to themes
        - First workflow linked theme – fully explain with an example of risk and how patient harm could occur
        - Further workflow points – ask for possible hazards and harm
        - Clinical risk – ask "what is the risk to the patient?", If none, record & move on

4. **Capturing information**
    a. Attendance and role are important to show the workshop had quorum
    b. Record if possible (but ask first)
    c. Write up immediately after the workshop
    d. Use transcripts for detail if available
    e. Capture actions in the meeting notes

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