# APPENDIX 7 - CLINICAL SAFETY HAZARD LOGS

**OurGP #1 personal profile tool -me&myGP - Hazard log draft 0.12**

Description: An online tool to support patients submitting their profile with non medical (predominantly) information which is important to them. Information is securely stored in a cloud using existing security and IG systems/ protocols. Accessibility and other features support risk mitigation.

| Hazard number | Hazard Name | Hazard Description | Potential Clinical Impact | Possible causes | Existing Controls (planned) | Initial Estimated Hazard Risk Assessment | | | Additional Controls | | | | Residual Hazard Risk Assessment | | | Action | Hazard Status |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Severity (table 7) | Likelihood (table 8) | Risk rating (table 9) | Design | Test | Training | Business Process Change | Severity | Likelihood | Risk Rating | Summary | |
| 1 | Potential security breach | Images/information sent to the cloud based tool are at risk of being accessed by someone unauthorised. | Loss of confidence in security of patient held information. | Phone; Theft, unauthorised use, loss resulting in theft, sale/recycle without factory reset, saved passwords in phone. | Cloud based and use of already agreed security protocols for GP practices to maintain secure data including not saving passwords. No plans to keep data on the phone. Images may be stored on the patients own cloud but no additional data will be attached. Images of intimate/identifiable areas of the body would be flagged to patients as a risk. Images are a popular tool for those with smart phones and who use social media. It is assumed that the tool will appeal to those already digitally literate, reducing the risk. Staff will have a permission-given view of the profile in the patients record once the patient has clicked the share with... button. | Significant psychological trauma | Could occur but in the great majority of occasions will not | 2 | Secure cloud storage to prevent access via an unsecured phone. In-tool reminders re security and personal safety. Lock out function for 3 incorrect attempts. | To stress test a range of phones. To agree wording for warnings flagging risks and security requirements for users. Back up contact number to alert unauthorised attempts and recommending change of password. | Staff: to reinforce with patients via website information, the security and easy read guides/terms and conditions. | Patients would need to inform the practice that there was na issue resulting in non use of the tool. Automated feedback form might be useful to capture repeated issues so that the provider can implement improvements. | Minor psychological upset; inconvenience | Negligible or nearly negligible possibility of occurring | 1 | With good use of the tool and well informed patients who are already online and cognisant of the security risks of using digital devices, risks are largely mitigated. Control measures outlined are familiar to most online users. Users control and can remove access to the profile at any time. | Open |
| 2 | Loss of access to the profile to edit it or correct information, add new important information. | The profile author has had a significant change in circumstances that requires an urgent update but the site is unavailable. | Potential impact on communications or access to GP services | Cloud technology issue; change in digital device - compatability issue etc | Default position is to call the practice or use other means such as emial to inform the GP of a significant change. Site down: a message will appear to inform the user and advise direct practice contact until the site is operational. | Minor injury from which recovery is expected in the short term; minor psychological upset; inconvenience; any negligible severity | Could occur but in the great majority of occasions will not | 2 | Clear set up and failure messaging to direct the patient to communicate directly with the practice. | Further user testing. Back up text to the users designated phone number alerting them to an issue and advising to contact the practice. | Practice staff and users guides are clear in the event of a failure to contact the practice directly with any urgent or significant information changes. | Patients would need to inform the practice of the loss/theft/damage to the phone resulting in non use of the tool. A new password could be issued via the webapp/cloud provider. | Minor psychological upset; inconvenience | Could occur but in the great majority of occasions will not | 1 | Failures in the cloud technology are more likely to risk the patients enthusiasm for the tool than add clinical risk as control measures outlined would mitigate this to an acceptable level. | Open |
| 3 | Completed tools are not used by the practice. | Patient experience is impacted negatively in face to face contacts as they realise the staff are not familiar with their profile, risking disengagement. | Patients who are vulnerable, struggle to communicate face to face or are very anxious may disengage from clinical staff where the tool is set up and available but not acknowledge. This could add tot eh patients feels of vulnerability and disempowerment. | Staff are not familiar with the tool. Clinical staff do not wish to use it or feel they do not have time. | The tool will need to be implementable in practices with minimal staff resource (time) to support practices promoting this for patients they may feel would benefit eg: those moving frequently, seeing different staff at each visit, people with minor memory problems who have been assisted to set up a profile, students, people with mental health issues that make GP visits very stressful as an experience. The tool itself will need to work efficiently and be able to be accesses without the practices having to send set up details. Interoperability with GP IT provider platforms is key. [guidance such as that produced by PIF may assist: http://www.pifonline.org.uk/wp-content/uploads/2017/01/PiF-PHR-Guide-2017-V2.pdf ] | Minor psychological upset; inconvenience | Possible | 2 | Patients likely to struggle with non use of the tool would support co-design of training and promotional materials to encourage practice buy-in. | Further user testing will need to focus on ease of use, implementation and surrounding activities to support practice buy in. | Clinical leadership will be essential to the use of the tool in practices. Clusters may provide an opportunity for easier integration inot practice. | Embed in development of digital innovations and developments to support culture change and embedding of the tool for patients who wish to use it. | Minor injury or injuries from which recovery is expected in the short term | Could occur but in the great majority of occasions will not | 2 | This implementation issue is difficult to mitigate from a technology point of view however, efficient operation and ease of use will be key. Implementation needs to be citizen led with co-design activities with practice staff to build confidence in its efficacy. | Open |

| Field | Description |
|---|---|
| Hazard number | A unique number for the hazard |
| Hazard name | A short descriptive name for the hazard |
| Hazard description | A short description for the hazard |
| Potential Clinical Impact | Description of effect of hazard in the care setting and potential impact on the patient |
| Possible Causes | Possible cause(s) that may result in the hazard.These may be technical, human error, etc. Note: a hazard have multiple causes |
| Existing Controls | Identification of existing controls or measures that are currently in place and will remain in place post implementation that provide mitigation against hazard, i.e. used as part of initial Hazard Risk Assessment |
| **Initial Hazard Risk Assessment** | |
| Severity | The severity of the hazard as defined in Table 7 |
| Likelihood | The likelihood of the hazard as defined in Table 8 |
| Risk Rating | The derived risk rating from the combination of likelihood and severity according to Table 9 |
| **Additional Controls** | |
| Design | Identification of design features or configurations implemented in the Health IT System in order to provide mitigation against the hazard. |
| Test | Identification of testing to be completed in order to provide mitigation against the hazard |
| Training | Identification of training to be implemented in order to provide mitigation against the hazard |
| Business Process Change | Identification of any Business Process Changes implemented in order to mitigate against the hazard |
| **Residual Hazard Risk Assessment** | |
| Severity | The severuty of the mitigated hazard as defined by Table 7 |
| Likelihood | The likelihood of the mitigated hazard as defined in Table 8 |
| Risk Rating | The delivered mitigated risk rating from the combination of likelihood and severity according to Table 9 |
| **Actions** | |
| Summary | Summary of the action being taken with regard to mitigation of the hazard or individual causes |
| Owner | The owner of the action |
| **Hazard Status** | The status of the hazard:<br>- 'Open' not all clinical risk management actions, owned by the Manufacturer, in respect of this hazard, have been completed.<br>- 'Transferred' all clinical risk management actions owned by the Manufacturer, in respect of this hazard, have been completed but not all actions, owned by the deploying Health Organisation, have been completed.<br>- 'Closed' all clinical risk management actions in respect of this hazard have been completed. |

## Table 7 Example Severity Classification

| 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 or injuries 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 severity | Single |

**Table 8 Example Likelihood Classification**

| 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 |

**Table 9 Example Clinical 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** | | | | |

pocketGP #2 Info and Advice Tool - Hazard log draft 0.2

Description: An online tool to support patients in remembering advice given to them in a GP consultation by audio recording and by personalised information sent to them at agreed intervals, to support knowledge/understanding and behaviour change. Information is stored in a cloud using existing security and IG systems/protocols. Accessibility is a key feature along with high levels of personalisation.

| Hazard number | Hazard Name | Hazard Description | Potential Clinical Impact | Possible causes | Existing Controls (planned) | Initial Estimated Hazard Risk Assessment | | | Additional Controls | | | | Residual Hazard Risk Assessment | | | Action | Hazard Status |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Severity (table 7) | Likelihood (table 8) | Risk rating | Design | Test | Training | Business Process Change | Severity | Likelihood | Risk Rating | Summary | |
| 1 | Potential security breach | Information sent to the cloud based tool are at risk of being accessed by someone unauthorised. | Personal information which could identify a health condition (and thus vulnerability) is accessed by unauthorised sources and shared without their knowledge leading to psychological harm. | Phone; Theft, unauthorised use, loss resulting in theft, sale/ recycle without factory reset, saved passwords in phone. | Cloud based and use of already agreed security protocols for GP practices to maintain secure data including not saving passwords. Data/audio stored within the tool not on the phone. Info from trusted sources (white list) will be able to be stored in the tool reducing risk of unknown websites/spamming etc. Access can be via the easiest route for the patient - PIN, voice, password etc increasing the degree of difficulty needed to breach security. It is assumed that the tool will appeal to those already digitally literate, reducing the risk. The patient is in control of audio content and the speech to text function in the tool. | Significant psychological trauma | Could occur but in the great majority of occasions will not | 2 | Secure cloud storage and in-tool information flow to prevent access to it via unsecured phone. In-tool reminders re security and personal safety. Lock out function for 3 incorrect attempts. | To stress test a range of phones. To agree wording for warnings flagging risks and security requirements for users. Back up contact number to alert unauthorised attempts and recommending change of password. | Staff: to reinforce with patients. In-tool messages to support security and easy read guides. Clinical activation (prescription) is key. | Patients would need to inform the practice of the loss/theft/damage to the phone resulting in non use of the tool. | Minor psychological upset; inconvenience | Negligible or nearly negligible possibility of occurring | 1 | With correct use of the tool, supported by clinician activation, well informed patients who are already online are likely to be cognisant of the security risks of using digital devices, mitigating risks in the event of a breach hazard. Control measures outlined are familiar to most online users. | Open |
| 2 | No access to information | The patient has lost access to review the information or listen to audio. | Lack of memory triggers for important treatment related interventions or advice. | Phone; Theft, unauthorised use, loss, sale without factory reset, saved passwords in phone. Cloud technology issue. | Patients will be asked to contact the practice to obtain support with a treatment regime or intervention they were confused about. NB. Patients cannot message the GP directly through the tool. | Minor injury or injuries from which recovery is expected in the short term | Could occur but in the great majority of occasions will not | 2 | Text sent to carer/ supporter to flag the lack of access and new security is set up. Tool content is backed up and not lost. Possible print function for materials and off line access. Back up text to the users designated phone number alerting them to an issue and advising to contact the practice or 111. | Extensive fail testing to explore options for patients to whom this might apply. | Safety online course links via practice websites and with the tool to support staff and patient digital literacy. Carer training in the support of patients using the tool. | Patients would need to inform the practice of the loss/theft/damage to the phone resulting in non use of the tool. | Minor psychological upset; inconvenience | Could occur but in the great majority of occasions will not | 1 | Clinical activation to the use of the tool is key to informed use and realisation of potential benefits to patients. With the features included the risks are significantly mitigated. | Open |
| 3 | Accessibility impact | Accessibility issues impact on accuracy or appropriate information use | Patient becomes confused about advice given due to translation issues or sensory impairment, learning difficulties or literacy issues. | Settings are not sufficiently diverse. English is not first language (including BSL users) or unable to read own language (any). | The tool is designed with an accessibility tool such as Browse Aloud which will meet many of the requirements for those with accessibility issues but not all. Information fro the GP can include links to information which had full accessibility for example via NHS Inform or RNIB, etc. These will be links included on the white list of web links (trusted sources).Tagged/surfaced information will be sent from the practice to the cloud and then to the patient. Audio can be recorded into the tool either by the GP for the patient to support memory or by the patient to reinforce learning during the appointment. Speech to text functions included. Clinical activation is vital so that it can be a collaborative tool. | Minor injury or injuries from which recovery is expected in the short term | Possible | 2 | Options for printing transcribed audio in the tool as well as infoscripts sent at different intervals. Use offline. | Target co-design with a range of accessibility issues and complex requirements to establish innovative solutions and potential new technologies. | Training for staff and patients in the use of existing device functions and the in tool accessibility tools. Feedback to patient groups to facilitate ongoing engagement. | Practices embed the use of the tool in usual business to support improved adherence to prescribed interventions. | Minor psychological upset; inconvenience | Negligible or nearly negligible possibility of occurring | 1 | Improvements in accessibility which the patient has control over will improve their use of advice and information in the context of their own care. Technologies are increasingly available to support this therefore this risk is likely to reduce further. | Open |
| 4 | Audio editing of speech to text | Following audio storage, patient edits the word to text changing the meaning | The patient adheres to the narrative rather than the audio and does not comply with agreed treatment or other regime. | Patient edits the text to make more sense to them and does not realise the impact it may have on wellbeing | The tool will be designed to flag this risk and support high quality speech to text software to optimise the quality of narrative. As the tool is clinically activated, it would be a clinical judgement re what might be useful for the patient to remember/better uderstand and therfore further controls would need to be related to training and quality of interaction between clinician and patient. | Content dependent therefore assumed to be mitiagated by clinician: Minor injury from which recovery is expected | Possible | 2 | Robust design of the speech to text and clear user instructions. | Extensive fail testing to explore options for patients to whom this might apply. | Staff training and support for clinical activation and use.In tool user warning box prior to changes in the text asking if the person still wishes to alter the text. | No change anticipated | Minor injury from which recovery is expected in the short term; minor psychological upset; inconvenience; any negligible severity | Could occur but in the great majority of occasions will not | 1 | This risk requires clear clinical activation and initiation for safe and effective patient use. Further robust testing would be needed. | open |

| Field | Description |
|---|---|
| Hazard number | A unique number for the hazard |
| Hazard name | A short descriptive name for the hazard |
| Hazard description | A short description for the hazard |
| Potential Clinical Impact | Description of effect of hazard in the care setting and potential impact on the patient |
| Possible Causes | Possible cause(s) that may result in the hazard.These may be technical, human error, etc. Note: a hazard have multiple causes |
| Existing Controls | Identification of existing controls or measures that are currently in place and will remain in place post implementation that provide mitigation against hazard, i.e. used as part of initial Hazard Risk Assessment |
| **Initial Hazard Risk Assessment** | |
| Severity | The severity of the hazard as defined in Table 7 |
| Likelihood | The likelihood of the hazard as defined in Table 8 |
| Risk Rating | The derived risk rating from the combination of likelihood and severity according to Table 9 |
| **Additional Controls** | |
| Design | Identification of design features or configurations implemented in the Health IT System in order to provide mitigation against the hazard. |
| Test | Identification of testing to be completed in order to provide mitigation against the hazard |
| Training | Identification of training to be implemented in order to provide mitigation against the hazard |
| Business Process Change | Identification of any Business Process Changes implemented in order to mitigate against the hazard |
| **Residual Hazard Risk Assessment** | |
| Severity | The severuty of the mitigated hazard as defined by Table 7 |
| Likelihood | The likelihood of the mitigated hazard as defined in Table 8 |
| Risk Rating | The delivered mitigated risk rating from the combination of likelihood and severity according to Table 9 |
| **Actions** | |
| Summary | Summary of the action being taken with regard to mitigation of the hazard or individual causes |
| Owner | The owner of the action |
| **Hazard Status** | The status of the hazard:<br>- 'Open' not all clinical risk management actions, owned by the Manufacturer, in respect of this hazard, have been completed.<br>- 'Transferred' all clinical risk management actions owned by the Manufacturer, in respect of this hazard, have been completed but not all actions, owned by the deploying Health Organisation, have been completed.<br>- 'Closed' all clinical risk management actions in respect of this hazard have been completed. |

## Table 7 Example Severity Classification

| 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 or injuries 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 severity | Single |

**Table 8 Example Likelihood Classification**

| 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 |

**Table 9 Example Clinical 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** | | | | |

**PhotoGP #3 Digital Image Triage Tool - Hazard log draft 0.16**

Description: An online tool to support patients submitting their images of a minor skin condition/injury for a clinician in the practice to triage, pre appointment booking. Information is stored in a cloud using existing security and IG systems/protocols. Accessibility and other features support risk mitigation.

| Hazard number | Hazard Name | Hazard Description | Potential Clinical Impact | Possible causes | Existing Controls (planned) | Initial Estimated Hazard I | | | Additional Controls | | | | Residual Hazard Risk Assessment | | | Action | Hazard Status |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Severity (table 7) | Likelihood | Risk rating | Design | Test | Training | Business Process | Severity | Likelihood | Risk Rati | Summary | |
| 1 | Potential security breach | Images sent to the cloud based tool are at risk of being accessed by someone unauthorised. | Images of a personal nature are accessed by unauthorised sources and shared without knowledge of the patient leading to psychological harm. | Phone; Theft, unauthorised use, loss resulting in theft, sale/ recycle without factory reset, saved passwords in phone. | Cloud based and use of already agreed security protocols for GP practices to maintain secure data including not saving passwords. No plans to keep data on the phone. Images may be stored on the patients own cloud but no additional data will be attached. Images of intimate/identifiable areas of the body would be flagged to patients as a risk. Images are a popular tool for those with smart phones and who use social media. It is assumed that the tool will appeal to those already digitally literate, reducing the risk. Staff will have the option to save data into the patients record from the cloud and add any alerts or other actions they may wish to implement. | Significant psychological trauma | Could occur but in the great majority of occasions will not | 2 | Secure cloud storage and in-tool messaging to prevent access via an unsecured phone. In-tool reminders re security and personal safety. Lock out function for 3 incorrect attempts. | To stress test a range of phones. To agree wording for warnings flagging risks and security requirements for users. Back up contact number to alert unauthorised attempts and recommending change of password. | Staff: to reinforce with patients. In-tool messages to support security and easy read guides. | Patients would need to inform the practice of the loss/ theft/ damage to the phone resulting in non use of the tool. A new secure access could be issued if needed. | Minor psychological upset; inconvenience | Negligible or nearly negligible possibility of occurring | 1 | With correct use of the tool, supported by clinician activation, well informed patients who are already online are likely to be cognisant of the security risks of using digital devices, mitigating risks in the event of a breach hazard. Control measures outlined are familiar to most online users. | Open |
| 2 | No access to messages or responses to triage request. | An image has been submitted and the patient has lost access to review the response from the practice. | Delay in getting advice that could exacerbate the problem. | Phone; Theft, unauthorised use, loss, sale without factory reset, saved passwords in phone. Cloud technology issue. | Patients will be asked to contact the practice if they require a more immediate response to an issue. The home screen would remind patients the tool is not for urgent or serious concerns. This would also include being unable to access the tool after the allotted timescale has passed to retrieve messages. Default position is to call the practice. | Minor injury or injuries from which recovery is expected in the short | Could occur but in the great majority of occasions will not | 2 | Secure cloud storage and in-tool messaging/ image controls so data is not lost or corrupted by phone | User testing notifications, reminders etc. Back up text to the users designated phone number alerting them | Safety online course links via practice websites and with the tool to support staff and patient digital literacy. | No response to a request to attend for a face to face appointment would be responded to within 48 hours via | Minor psychological upset; inconvenience | Could occur but in the great majority of occasions will not | 1 | Clinical activation to the use of the tool, either directly or indirectly, is key to informed use and realisation of potential benefits to patients. With the features included in hazard 1 above, the risks are | Open |
| 3 | Potentially inappropriate use for an urgent issue. | Patient tries to use the tool for serious symptoms despite the home screen warnings and in-site guides/ information. | The patient does not seek help immediately. | Patient stress results in warnings not being read/ understood. English is not first language or patient cannot read. Lack of clarity re purpose of the tool to support management of minor injury or skin problems. Clinicians not involved in | The tool will have accessibility functions to support read out loud and easy read text. Text will be kept to a minimum and commonly used symbols will be used. Default advice in the tool is to contact 111 or call the practice. Key, high risk conditions such as Meningitis and Septicaemia could be specifically flagged as requiring urgent intervention on the home page and again pre-submission. In tool questions will also provide support to patients in making appropriate decisions re seeking help. Initially it is anticipated the target group could be adults with existing conditions, activated to the tool by the GP/Practice Nurse who will screen out high risk patients. Future developments could include carers and parents, clinicians such as District | Minor injury or injuries from which recovery is not expected in the short term | Possible | 3 | Features to reinforce the minor injury and non urgent function of the tool could be designed. Patients likely to struggle with the tool would support co-design of these features. Additional reminders could be added to receipt | Clinical leadership of the information will be required and user testing of the wording and approach, images and symbols used will be required in future prototyping. | Patient activation by a clinician is essential to reduce this risk. Embedding the use of the tool in campaigns to support early identification of the two conditions highlighted would reinforce appropriate use. | Initial time taken by clinicians to activate patients to the appropriate use of the tool may require resource. However, it is anticipated this would reduce as staff became more use to advising patients | Minor injury or injuries from which recovery is expected in the short term | Could occur but in the great majority of occasions will not | 2 | If used with the controls outlined here, the risks are also significantly mitigated by the use of existing accessibility tools and building in high quality, clinically led but easily understood information for patients which diverts those needing more urgent advice towards the appropriate services. The default message in the tool is to contact 111 if the patient is in doubt. | Open |

| Field | Description |
|---|---|
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| Possible Causes | Possible cause(s) that may result in the hazard.These may be technical, human error, etc. Note: a hazard have multiple causes |
| Existing Controls | Identification of existing controls or measures that are currently in place and will remain in place post implementation that provide mitigation against hazard, i.e. used as part of initial Hazard Risk Assessment |
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| Severity | The severity of the hazard as defined in Table 7 |
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| **Additional Controls** | |
| Design | Identification of design features or configurations implemented in the Health IT System in order to provide mitigation against the hazard. |
| Test | Identification of testing to be completed in order to provide mitigation against the hazard |
| Training | Identification of training to be implemented in order to provide mitigation against the hazard |
| Business Process Change | Identification of any Business Process Changes implemented in order to mitigate against the hazard |
| **Residual Hazard Risk Assessment** | |
| Severity | The severuty of the mitigated hazard as defined by Table 7 |
| Likelihood | The likelihood of the mitigated hazard as defined in Table 8 |
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| **Actions** | |
| Summary | Summary of the action being taken with regard to mitigation of the hazard or individual causes |
| Owner | The owner of the action |
| **Hazard Status** | The status of the hazard:<br>- 'Open' not all clinical risk management actions, owned by the Manufacturer, in respect of this hazard, have been completed.<br>- 'Transferred' all clinical risk management actions owned by the Manufacturer, in respect of this hazard, have been completed but not all actions, owned by the deploying Health Organisation, have been completed.<br>- 'Closed' all clinical risk management actions in respect of this hazard have been completed. |

## Table 7 Example Severity Classification

| Severity Classification | Interpretation | Number of Patients Affected |
|---|---|---|
| Catastrophic | Death | Multiple |
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| 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 or injuries 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 severity | Single |

**Table 8 Example Likelihood Classification**

| 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 |
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| Very low | Negligible or nearly negligible possibility of occurring |

**Table 9 Example Clinical 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** | | | | |