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Policy guidance on recording patient safety events and levels of harm

This guidance is for users of the new Learn from Patient Safety Events (LFPSE) service, to provide context and guidance on selection of appropriate categories when recording incidents. It focuses on which Event Type is appropriate for different circumstances, and how to select the most appropriate options for the Levels of Harm categorisation required within Patient Safety Incidents.

Publication (/publication)

Content

Introduction

This policy guide sets out expectations for the recording of patient safety events and their associated levels of harm when using the ‘Learn from patient safety events’ service. It provides the definitions of the patient safety event types that have been included in the new LFPSE service. This publication supersedes any previous guidance for the NRLS and is the official policy guidance for recording patient safety events to the LFPSE service.

Further contextual information on who should use this service, how to implement it, and other frequently asked questions (FAQs) (https://www.england.nhs.uk/patient-safety/learn-from-patient-safety-events-service/lfpse-faqs-august-2022/) is available online.

Recording the appropriate level of harm associated with a patient safety incident is important so that:

- we have an accurate description of the event and its impact on the patient, based on the best information at the time
- there is consistency and comparability within the organisation's own data
- the national patient safety team (https://www.england.nhs.uk/patient-safety) can use the recorded information to analyse, triage and learn from consistent and high-quality data
- other policies such of Duty of Candour can be enacted appropriately.

Incident recording is mandatory in certain circumstances (see the LFPSE FAQs for further details (https://www.england.nhs.uk/patient-safety/learn-from-patient-safety-events-service/lfpse-faqs-august-2022/#is-use-of-the-lfpse-service-mandatory)) and very much encouraged in all others. If in doubt, it is always better to record a patient safety incident using the available information and best judgement, and LFPSE is designed to support record updates as and when new information becomes available. There are certain mandatory reporting requirements set out in CQC regulations (mailto:https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-18-notification-other-incidents), but ultimately determining when an incident has occurred, the extent to which that incident has caused harm, and the level of harm caused, are all judgements.

To support these judgements, this policy guide sets out the definitions of Incident and Good Care event types, level of harm, and answers some frequently asked questions relating to the recording of incidents.

Definitions – event types

The full definitions of the patient safety event types in this guide are:

Patient Safety Incident – Something unexpected or unintended has happened, or failed to happen, that could have or did lead to patient harm.

What does this mean? – This event type encompasses all patient safety incidents, including "near misses". Select this option if you know that something did not go as intended or expected – whether an act or an omission – and as a direct result the incident could have or did harm one or more patients.

Good Care – An example of good care that can be learned from

What does this mean? – Positive learning opportunities. Select this option if you want to share experiences or learning from things that have gone well whilst delivering care.

Definitions – harm grading

In the NHS, degree of harm recording relates to the actual impact on a patient from the particular incident being reported. Just as in NRLS, LFPSE maintains this principle. Patient safety incident harm definitions should always be applied based on the best information about the actual impact of the incident at the time of recording. The harm grading can be reviewed and updated as more information becomes available, but should not be used to speculate about, for example more severe “potential harm” if that does not appear to have been caused.

The descriptions of the different levels of physical harm in this document are not intended to alter the thresholds of different levels of harm that were described in previous NRLS guidance. They have been developed to provide more clarity and to support more consistent harm grading, but are based on the thresholds that have been used in the NRLS for some time.

A new addition in this policy guide and in relation to patient safety incident data in the LFPSE service relates to specific capture of information on psychological harm. Previously in the NHS, harm grading included psychological harm as well as physical harm within one measure. Following feedback from staff, patients and families, physical and psychological harm have been separated out and each can now be recorded in the LFPSE service.

Where practical, it is good practice to discuss the level of harm with the patient affected and to consider the patient’s perspective on the harm definitions stated below.

Previous harm grades	**New physical harm grades**	**New psychological harm grades**
No Harm	No physical harm	No psychological harm
Low harm	Low physical harm	Low psychological harm
Moderate harm	Moderate physical harm	Moderate psychological harm

Severe harm	Severe physical harm	Severe psychological harm
Death	Fatal	n/a

The full definitions of the harm gradings are as follows:

Physical harm

No physical harm

No physical harm

Low physical harm

Low physical harm is when **all of the following** apply:

- minimal harm occurred – patient(s) required extra observation or minor treatment
- did not or is unlikely to need further healthcare beyond a single GP, community healthcare professional, emergency department or clinic visit
- did not or is unlikely to need further treatment beyond dressing changes or short courses of oral medication
- did not or is unlikely to affect that patient's independence
- did not or is unlikely to affect the success of treatment for existing health conditions.

Moderate physical harm

Moderate harm is when **at least one** of the following apply:

- has needed or is likely to need healthcare beyond a single GP, community healthcare professional, emergency department or clinic visit, and beyond dressing changes or short courses of medication, but less than 2 weeks additional inpatient care and/or less than 6 months of further treatment, and did not need immediate life-saving intervention
- has limited or is likely to limit the patient's independence, but for less than 6 months
- has affected or is likely to affect the success of treatment, but without meeting the criteria for reduced life expectancy or accelerated disability described under severe harm.

Severe physical harm

Severe harm is when **at least one** of the following apply:

- permanent harm/permanent alteration of the physiology
- needed immediate life-saving clinical intervention
- is likely to have reduced the patient's life expectancy
- needed or is likely to need additional inpatient care of more than 2 weeks and/or more than 6 months of further treatment
- has, or is likely to have, exacerbated or hastened permanent or long term (greater than 6 months) disability, of their existing health conditions
- has limited or is likely to limit the patient's independence for 6 months or more.

Fatal (previously documented as 'Death' in NRLS)

You should select this option if, at the time of reporting, the patient has died and the incident that you are recording may have contributed to the death, including stillbirth or pregnancy loss. You will have the option later to estimate to what extent it is considered a patient safety incident contributed to the death.

Psychological harm

Please note that when recording psychological harm, you are not required to make a formal diagnosis; your answer should be an assessment based on the information you have at the point of recording and can be changed if further information becomes available.

No psychological harm

Being involved in any patient safety incident is not pleasant, but please select 'no harm' if you are not aware of any specific psychological harm that meets the description of 'low psychological harm' or worse. Pain should be recorded under physical harm rather than psychological harm.

Low psychological harm

Low psychological harm is when **at least one** of the following apply:

- distress that did not or is unlikely to need extra treatment beyond a single GP, community healthcare professional, emergency department or clinic visit
- distress that did not or is unlikely to affect the patient's normal activities for more than a few days
- distress that did not or is unlikely to result in a new mental health diagnosis or a significant deterioration in an existing mental health condition

Moderate psychological harm

Moderate psychological harm is when **at least one** of the following apply:

- distress that did or is likely to need a course of treatment that extends for less than six months
- distress that did or is likely to affect the patient's normal activities for more than a few days but is unlikely to affect the patient's ability to live independently for more than six months
- distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, but where recovery is expected within six months

Severe psychological harm

Severe psychological harm is when **at least one** of the following apply:

- distress that did or is likely to need a course of treatment that continues for more than six months
- distress that did or is likely to affect the patient's normal activities or ability to live independently for more than six months
- distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, and recovery is not expected within six months

When are harm grading fields mandatory?

If an incident has happened where a person(s) is directly involved (regardless of impact/harm) then recording levels of physical and psychological harm is mandatory in the LFPSE system.

Below are detailed examples of patient safety incident events and where the recording of harm is required or not:

- Incident where a **patient was harmed**: for example, patient given a medication to which they have a known allergy
    - Harm grading required: yes
    - Details for LFPSE recording: Select the appropriate level of actual physical and/or psychological harm, within the categorical fields and provide further details in the "Describe what happened" free text section, including how the issue was identified.
- Incident where the **patient sustained no harm**: for example, patient given incorrect medication, but to no ill-effect, physically or psychologically
    - Harm grading required: yes

    - Details for LFPSE recording: These should be recorded with no physical/no psychological harm within the categorical fields and provide further details in the “Describe what happened” free text section, including how the issue was identified.
- Incident where a **patient was involved, but harm to the patient was prevented:** for example, medication stored at the incorrect temperature was selected, but not administered to the patient because temperature control issues were identified in time; or, patient invited for the wrong procedure, but the invited patient queried the procedure prior to attending
    - Harm grading required: yes
    - Details for LFPSE recording: LFPSE also records “near miss” or ‘prevented incidents’ in which specific patients are identifiable, but the incident resulted in no harm due to a timely intervention. These should be recorded with no physical/no psychological harm, within the categorical fields, and further details provided in the “Describe what happened” free text section, including how the issue was identified, and how the intervention protected the patient(s).
- Incident where **no patients were involved:** for example, medicine storage issues identified before medicines are selected to be administered to any patients; or, oxygen supply disruption in patient areas but patients were not present at the time; or, temporary power issues in a computer which holds a ward’s falls assessment templates, though no patients were admitted during the time the system was off-line
    - Harm grading required: no
    - Details for LFPSE recording: This should be recorded with 0 patients within LFPSE as no specific patient can be identified as having been involved, and so no patient information need be recorded. You will however be asked if the incident creates an imminent risk (within 2 weeks) of severe harm or death, and if so, if there are any specific patient populations who might be at most risk. This information is used to triage such risks for review at the national level. Answers are understood to be subjective and speculative.
- Incident where **multiple patients were involved:** for example, an overrunning outpatient clinic requiring multiple patients to be rebooked for their follow up appointments; or, infection control – outbreak in ward area; or, faulty CT scanner preventing multiple patients from having their scans
    - Harm grading required: yes
    - Details for LFPSE recording: LFPSE allows you to record the details for up to 10 individual patients affected by one incident; the harm fields must be completed for each of these. This field can be updated as more information becomes available. If a patient safety incident affects more than 10 patients, you need only record one patient’s details with the most serious single harm, physical or psychological, in the

categorical fields and can outline the other impacts within the “describe what happened” free text field including the number of patients involved.

Recording guidance questions and answers

The questions and answers presented below represent questions or issues that frequently arise in relation to patient safety event recording. If you have a question that is not covered below please send it to england.patientsafetyhelpdesk@nhs.net (mailto:england.patientsafetyhelpdesk@nhs.net).

1. Do we only record patient safety incidents that we know have occurred in our organisation?

No. You should record patient safety incidents whether they occurred during an episode of care at your organisation or occurred during care provided by another healthcare provider if you are the first provider to become aware of them.

For example, if a pressure ulcer was present on hand over to your organisation from a previous provider, it should still be recorded as a patient safety incident, stating ‘No’ to the question “Did the incident occur whilst the patient was under your organisation’s care?” and documenting the organisation where the care was provided previously.

NB: this record will then become visible to, and “owned by” that provider. Depending on the provider type and location, your organisation may or may not maintain visibility of that record.

If a patient presents to your organisation with a pressure ulcer and has not been under the care of a health care provider (see FAQs (https://www.england.nhs.uk/patient-safety/learn-from-patient-safety-events-service/lfpse-faqs-august-2022/#who-is-the-lfpse-service-for) for details on which services this includes) prior to presentation, then this does not align with the definition of a patient safety incident and does not need to be recorded to LFPSE. However, if the pressure ulcer were then to deteriorate further during the healthcare episode, an incident should be recorded.

This documentation supersedes previous NRLS documentation (Implementing the pressure ulcer framework in local reporting systems and reporting to NRLS 2019 (https://www.england.nhs.uk/wp-content/uploads/2021/09/Guidance-for-reporting-pressure-ulcers.pdf)) specifically in relation to:

- *Recommendation 11* – ‘The definition of a new pressure ulcer within a setting is that it is first observed within the current episode of care.’
- *Recommendation 15* – ‘Reporting of all pressure ulcers grade 2 and above on admission (POA) (which is observed in the skin assessment on admission to that service) should be incorporated into local monitoring systems.

2. Can category of pressure ulcer be matched to a LFPSE degree of harm?

No, the degree of harm depends on the actual impact for this patient as a result of the patient safety incident and does not corelate with the category of pressure ulcer. For example, a patient with a category 3 pressure ulcer could fall into moderate harm because they needed additional healthcare for 3 months.

However, if the same ulcer was on the heel and expected to affect mobility even after healing, then that would be graded as severe harm. Each pressure ulcer must be assessed for degree of harm, using category of pressure ulcer only as a guide and the reason for the level of harm selected should be demonstrated in the free text description of the incident.

If a patient has multiple pressure ulcers that developed by the same mechanism, then only one incident need be recorded. The harm associated with this incident would be the actual level of harm to the patient (i.e., the highest level of harm the patient has incurred from any or all of the pressure ulcers).

If a patient has multiple pressure ulcers which developed due to different mechanisms (i.e, one develops due to a monitoring device, and the other is related to profiling bed equipment), two distinct incidents have occurred and should be recorded as such.

3. How are suicides, self-harm and deaths from drugs and alcohol recorded as patient safety incidents?

The following summarises the guidance for organisations providing specialist mental health services. Further detailed guidance for mental health service providers (including self-harm and restrictive practice) will be published shortly:

Scenario	Location of patient	Patient safety incident?	Reportable to LFPSE	Help notes

Apparent/actual suicide	Former patient	PSI indicated	Yes	
		PSI not indicated	No	
		Circumstances suggest PSI possible, requires fact finding to confirm	Yes	If fact finding is required to confirm a PSI has occurred, organisations can report with full details of why they are reporting as an incident including the reason PSI is suspected as a possibility.
	Current patient	N/A	Yes	

Self-harm not resulting in death	Former patient	PSI indicated	Yes	
		PSI not indicated	No	
	Current patient	PSI indicated	Yes	
		PSI not indicated	No	
		Circumstances suggest PSI possible, requires fact finding to confirm	Yes	If fact finding is required to confirm a PSI has occurred, organisations can report with full details of why they are reporting as an incident including the reason PSI is suspected as a possibility.

Death from drugs or alcohol	Former patient	PSI indicated	Yes	
		PSI not indicated	No	
	Current patient	PSI or suicide indicated	Yes	
		PSI or suicide not indicated	No	
		Circumstances suggest PSI possible, requires fact finding to confirm	Yes	If fact finding is required to confirm a PSI has occurred, organisations can report with full details of why they are reporting as an incident including the reason PSI is suspected as a possibility.

NOTE: ‘Former patient’ is defined as any patient who has been discharged from the Trust’s services or who does not have a current open episode for inpatient or community care.

As a general guide, if a patient dies from actual or apparent suicide within 6 months of discharge, or during a further referral to Mental Health (MH) services, a judgement needs to be made as to whether a patient safety incident may have

occurred. That incident could be something such as inappropriate discharge or failure in communication. If it is determined that an incident has occurred, the incident should be recorded locally and to the LFPSE service.

It is less likely that death of a former patient more than 6 months after discharge will indicate a patient safety incident has occurred. However, judgment can still be applied to determine if a patient safety incident should be recorded.

The free text incident description should demonstrate how the incident meets the reporting criteria i.e. whether patient is former or current, details of the act or omission that indicates it is or might be a patient safety incident, clearly indicating the actual injuries, or stating that death occurred.

Whilst MH services rightly are mindful that determining if a death is suicide is the role of the coroner, all contextual information that would suggest the likelihood of fatal self-harm needs to be included in the initial incident record.

It is accepted that sometimes toxicology or wider information-gathering is needed to determine if a death is from self-harm, accidental or natural causes. MH services may have to initially record the event on the basis that they suspect rather than can confirm self-harm, but they should not routinely report all unexpected deaths solely because the possibility of self-harm cannot yet be excluded. The CQC accepts recording at a later date in circumstances where self-harm did not initially appear a likely cause of death.

4. Can I change the level of harm of an incident recorded to the LFPSE service after initial record submission?

Yes. As new information becomes available, the incident harm grades (and any other relevant information) can be amended to reflect the update. Please complete the free text description to explain any changes made to the harm grades.

5. How do we select the degree of harm when the ultimate clinical impact of a patient safety incident is not known?

A best assessment at the time of the incident should be carried out and if, at a later date, more information is received, the incident degree of harm and other details about the incident can be amended.

6. Can I still record an incident's level of psychological harm if I am not a trained mental health professional?

Yes, all staff users should be able to make an initial selection of levels of harm on both the physical and psychological scales as it is understood to be a snapshot of limited information at this stage. A formal diagnosis is not required – only the recorder's clinical judgement. To support this, we have:

- Worked with users to provide clarified definitions and examples for each, to help guide decision-making.
- Mirrored the language used in the physical and psychological scales, to make it simpler for recorders.
- Provided the ability to amend all fields including these, should further information become available at any point. This can be done by the original recorder, or by designated users with enhanced permissions at the review stage.

It is important that all records for incidents are submitted with this data, even if it is an initial best-guess, to enable local and national prioritisation and response.

7. What if a death is considered to be due to the natural disease process but a patient safety incident occurred during the provision of care that did not lead to the death?

Based on what is known at the time of recording, a judgement would be needed by the reporter as to the actual impact on the patient from the incident they are reporting. Where it is considered that the incident could have resulted in the death of the patient, rather than the progression of their natural disease, this should be recorded as an incident with a degree of harm selected as fatal. Where the impact is not considered to have resulted in the fatality, a lower level of harm can be recorded.

The supplementary question "how much did the incident contribute to the outcome for the patient?" allows the reporter to indicate their best assessment of the extent of association between incident and outcome.

8. Can we re-classify incidents recorded as fatal if it is later found the death was due to natural causes and not the incident that occurred?

Yes. If it is considered, after review of the circumstances, it is unlikely the incident was associated with the death, the harm level can be downgraded to reflect more accurately the actual harm the incident likely led to, and a rationale in the free text field for why this has been done should be included.

9. Additional observations are taken after an inpatient fall, so does this make all falls low harm?

Levels of harm should be selected based on the information available about the presentation of the patient at the time: observations may help to establish this, but taking them to ascertain the presence or absence of neurological harm does not in and of itself equate to harm level. Should any initial observations be abnormal and necessitate an extended observation period, and/or treatment, this may indicate a higher degree of harm has been caused.

Each incident should be judged individually, based on the LFPSE definitions and examples, and please note that all of the statements in the definition of low harm must apply for the level of physical harm selected to be “low”.

10. Are falls resulting in fractured hips classed as severe harm?

A patient who has fractured a hip from an inpatient fall is unlikely to regain the levels of mobility and independence they had prior to the fall, in which case the degree of harm is severe. However, in a few cases the patient could recover after an extended hospital stay (moderate) or die (fatal). Each incident should be judged individually, based on the LFPSE definitions and examples.

11. What if no problems in care preceded the incident? How is harm graded? For example, a patient falls in hospital and fractures their neck of femur, but the ensuing information-gathering or review highlights no lapses in care or treatment.

If a patient falls and suffers a fractured hip, that would more often than not result in severe harm. Review of the circumstances might be unable to identify problems in care, but something unexpected or unintended still happened that resulted in harm to the patient and so the definition of a patient safety incident is met. As noted earlier, it may not always be clear if an incident has occurred or the extent to which an incident was associated with harm, but it is always preferable to err on the side of caution and report, not least as the circumstances of the fall could still represent important intelligence locally or nationally.

12. Are falls resulting in sub-dural haematoma classed as severe harm?

A patient who has a sub-dural haematoma from an inpatient fall is unlikely to regain the levels of mobility and independence they had prior to the fall; but in a few cases the patient could recover after an extended hospital stay (moderate) or

die (fatal). Each incident should be judged individually, based on the LFPSE definitions and examples.

13. Does discharge from hospital indicate full recovery after a patient safety incident during hospital admission?

No, discharge from hospital does not in itself indicate full recovery. A patient may be discharged after a patient safety incident with any level of non-fatal harm: after a full recovery, or with a permanent disability. Levels of harm should be judged individually, based on the LFPSE definitions and examples, and updated accordingly if further information emerges.

14. Do the NHSE Clinical Reviewers amend the harm grading if they appear incorrect?

No, The National Patient Safety Team Clinical Reviewers do not alter any data submitted. They may identify data quality concerns and flag these to the Patient Safety Reporting Leads (RLs), who may contact the reporting organisation to offer support, advice and guidance.

15. If recording incidents that have occurred in another organisation, what should the degree of harm be?

You should record the harm level of an incident in another organisation as you would for an incident that occurred in your organisation. The harm should not be downgraded because it occurred elsewhere. The nature of typical patient pathways that cross primary, secondary and tertiary care means that effective recording and learning frequently relies on one organisation identifying and recording incidents that occurred earlier in the care pathway.

16. Does Duty of Candour apply to both the LFPSE physical and psychological scales?

Yes, any incident which is graded as having resulted in moderate or higher harm on either or both scale triggers the Duty of Candour. A severe psychological harm with low physical harm, for example, would qualify.

17. What can be recorded as a Good Care event?

A Good Care event is a positive learning opportunity from care events that have gone well whilst delivering care to and for patients.

A trust provided a recent example: "*pioneering the adoption of elastomeric devices to facilitate early discharge of patients on antibiotics. Since their introduction at the beginning of the year, these devices have saved 1750 bed days for a total of 120 patients, with no increase to the number of readmissions in comparison to the baseline. Further evaluation on satisfaction and outcomes is being carried out and the evidence will be shared with the ICB*".

18. How does recording patient safety events to LFPSE relate to the new Patient Safety Incident Response Framework (PSIRF)?

Events recorded to LFPSE can form one source of data for deciding on your local priorities to be included in your Patient safety incident response plan (PSIRP). These should be considered alongside other potential issues, such as complaints, claims, Section 28 letters, and other data sources. The PSIRF module will allow users to annotate existing records with details of whether a safety response was taken forward for that issue, and any relevant findings or safety actions agreed as a result.

It may not always be the case that issues being explored under PSIRF (or according to a provider's PSIRP more specifically) are recorded as individual incidents on LFPSE. This is because providers may choose to explore broader issues including those spanning care pathways for example. These therefore do not need to be entered into LFPSE if they do not meet the definition of a patient safety incident.

Developed by the NHS England National Patient Safety Team. For any enquiries, please contact england.patientsafetyhelpdesk@nhs.net (mailto:england.patientsafetyhelpdesk@nhs.net)

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