Briefing Note: Issues, risks and questions regarding the implementation of the Learn from Patient Safety Events (LFPSE) service

This briefing note is informed by discussions at a drop-in session of the Patient Safety Management Network on 8 July 2022, feedback from contributors at a Datix engagement event which took place the week commencing 18 July 2022 and feedback from specialists in patient safety and Trust incident reporting leads. It mainly reflects issues raised in relation to Acute Trusts, recognising that separate discussions will be valuable to better understand the implications for Mental Health, Community and Primary Care service providers.

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Executive Summary

1. LFPSE is a core component of the NHS Patient Safety Strategy. It is a new system to record the details of patient safety events, contributing to a national NHS-wide data source to support learning and improvement, replacing the NRLS and StEIS.

2. This briefing note has been developed by members of the Patient Safety Management Network, Datix user forums and Patient Safety Learning. It highlights serious concerns in the LFPSE's design, development and planned implementation.

3. Significant concerns are being raised by those tasked with leading LFPSE implementation in Trusts and those working in patient safety, risk management, and incident reporting. These concerns have been expressed over many months. Anxiety is now increasing as the test system has now been shared in anticipation of the planned LFPSE implementation date of April 2023.

4. Some Trusts have expressed concerns about the implementation deadline given the tight timescale with software upgrades not being available until the autumn. There will be limited time for the training and communication with the hundreds of thousands of NHS staff who report incidents. However, the biggest concern relates to the design and development of LFPSE and whether the significant changes to the current systems have the potential to add to learning and reinforce rather than undermine a just culture. It has been raised by many that the new dataset does not account for an understanding of how the safety literature has advanced and more modern thinking around learning from events.

5. These concerns are being raised at senior levels in many Trusts. Some Trusts are considering whether to implement LFPSE at all if these concerns are not addressed, and some are escalating these issues with the LPFSE team directly.

6. The concerns are summarised in this report with details included in Appendices. These include comments drawn directly from contributors. A top 30 list of questions is also included where contributors are seeking information and clarification.

7. There is a clear frustration that in forums or webinars attended by NHSE that the scale of collective disappointment and disapproval at the current iteration of LFPSE is not being acknowledged, let alone being addressed.

8. There is a strong view that failure to address these issues will have a significant impact on incident reporting for learning. The failure to learn and act on this learning, will be a failure for patients' safety.

9. The contributors to this briefing note consider there is an urgent need for NHSE to engage with Trusts to:
    a. fully risk assess the implementation of LPFSE
    b. develop effective risk mitigation strategies
    c. give patient safety and organisational leaders the confidence in the beneficial impact of these changes

10. It is proposed that a core group of Patient Safety Managers and Incident Reporting Leads, supported by Patient Safety Learning, meet urgently with NHSE to work through these issues, to improve LFPSE and for it to have a better chance of success.

11. We look forward to NHSE responding positively and urgently to this briefing note.

Background

What is the Patient Safety Management Network?

The Patient Safety Management Network (PSMN) is a network of over 500 members of staff who work in patient safety.[1] They come from a range of different grades and roles, and all have a commitment to engage in conversations about patient safety. This community of like-minded individuals come together to share insights and lessons learned, provide peer support, collaborate on new ideas, solutions and research, introduce new thinking to accelerate patient safety improvements, gain a better, shared understanding of new policies, guidance, directives and regulations that impact their work.

NHS Patient Safety Strategy, NRLS and LFPSE service

The NHS Patient Safety Strategy, published in 2019, sets out a safety vision for the NHS to continuously improve patient safety. To support this, it has three strategic aims to help development a patient safety culture and patient safety system: Insight, Involvement and Improvement.

A key strand of the Insight aim is the creation of a new digital system to support patient safety learning, to replace the existing National Reporting and Learning System (NRLS). The new Learn from Patient Safety Events (LFPSE) service (previously called the Patient Safety Incident Management System (PSIMS) during development) is in now the final stages of development as a central service for the recording and analysis of patient safety events that occur in healthcare. It has now commenced the public beta stage, where some organisations can begin using the system, instead of the NRLS.

LFPSE is replacing the current NRLS and Strategic Executive Information System (STEIS) with the aim of providing better support for staff from all health and care sectors.[2]

Transition from NRLS to LFPSE

Change from NRLS to LFPSE

In 2021, NHS England and NHS Improvement (NHS E/I[3]) announced the creation of a new system to overhaul both the NRLS and the StEIS, to which all declared serious incidents are uploaded.

Details of the latter are still to be finalised, but it is now confirmed that all Trusts should transition from uploading their patient safety incidents to the NRLS to uploading them to the new LFPSE service, and this should be done no later than 31 March 2023.

[1] A key objective of the PSMN is to share knowledge resources that others might use in striving to improve patient safety within their own organisations and to enable its members to influence relevant regional and national policies and add their voices en-masse to campaigns that seek to improve patient safety for all (either directly or indirectly). Each week, the PSMN holds a virtual drop-in session to reflect and discuss on a topical patient safety issue. Patient Safety Learning help support the PSMN with a private space on *the hub* and to write up notes of the drop-in sessions for those unable to attend. Weekly numbers on the drop-in sessions are average 80 to 90 members.

[2] NHS England, Learn from patient safety events (LFPSE) service, Last Accessed 19 July 2022. https://www.england.nhs.uk/patient-safety/learn-from-patient-safety-events-service/

[3] NHSI became part of NHSE in July 2022.

LFPSE will initially provide two main services

1. **Record patient safety events** – organisations, staff and patients will be able to record the details of patient safety events, contributing to a national NHS wide data source to support learning and improvement. Once local systems are made compatible, larger organisations such as NHS trusts will record patient safety events to the national system via a direct upload from their Local Risk Management System (LRMS). Other organisations, such as primary care providers (see the dedicated primary care LFPSE webpage) can record patient safety events directly via the online recording service. A dedicated service for patients and families to use will be developed. In the meantime, patients can continue to record incidents to the NRLS via the existing patient eform.

2. **Access data about recorded patient safety events** – Providers will be able to access data that has been submitted by their teams, in order to better understand their local recording practices and culture, and to support local safety improvement work.

Current NRLS dataset

A small core set of data is taken from Trusts' Local Risk Management Systems (LRMS) and is submitted to the NRLS. All Trusts submit the same fields, and they are integrated seamlessly into their system designs in such a way that front-line staff are not aware these are required for NRLS. These fields are:

- Date of the incident
- Speciality where incident occurred
- Location (Type) where incident occurred
- What Happened? (the description of the incident)
- Action Taken at the time of the incident
- Result (Harm/No Harm/Near Miss)
- Actual Harm (the level of harm)
- Type of Party Affected (these will of course only be *Incidents affecting Patients*)
- Category and Sub-Category
- Medication Stage (if the incident is a medication incident)
- Medication Error (if the incident is a medication incident)
- Product Type (if the incident is a medical devices incident)
- Subtype of staff involved (the designation of the staff member involved in an incident)

Every Trust currently has the flexibility to define its own specialties, location types, results, harm levels, categories, and sub-categories, etc, but in order for the NRLS to analyse a common dataset from each Trust, all Trusts are required to map their values in these fields to pre-set NRLS lists.

Why a change was needed

NHSE noted that the NHS has changed substantially since the NRLS was first implemented, nearly 20 years ago, and there has long been a bone of contention with non-acute Trusts, as the taxonomy, definitions and terminology are all very acute-focused and are seen to have become increasingly outdated. The regular reports are not timely, being compiled several months after the reporting period in question and NHSE assessed that given the weaknesses in the NRLS taxonomy they broadly did not tell Trusts anything that they did not already know.

NHSE identified the following as key drivers for introducing LFPSE:

- Making it easier for staff across all healthcare settings to report safety events
- Reducing the length of time for incidents to be submitted to LFPSE
- The latest technology will be better-utilised, including machine learning, in a way that is not possible with the NRLS
- Collecting information that is better suited to learning for improvement
- Allowing all organisations to access their data on safety events more quickly

Scope and impact of the change

The scope of the changes being brought are a fundamental strategic and operational change, described by one senior Patient Safety Manager to a Trust Patient Safety Committee as:

> *"… a seismic change to the way that all Trusts who use an LRMS report and manage their safety events."*

Key LFPSE changes

What is reported

Trusts will not just be reporting patient safety incidents to the national system as now with the NRLS. LFPSE requires Trusts to record additional types of activity using a new taxonomy, encompassing the following 4 types of safety event:

Event	LFPSE definition
Incident	Something happened, or failed to happen, that could have or did lead to harm
Outcome	A poor outcome but not known if it is a patient safety event (e.g., stillbirth)
Risk	A potential risk to patient safety in the future, including near misses
Good Care	An example of good care that we can learn from

These are significant changes to what is required to be reported by front line staff, effectively removing local flexibility for reporting and ensuring a national wide consistency of reporting.

There are consequences of this approach in terms of:

- The development of a new taxonomy to be used by everyone. Questions are being raised as to the value of some of the questions being asked, how users have been involved in the development and sign-off arrangements and whether the questions reflect latest thinking in patient safety and human factors
- The training required for all staff who report incidents. This will be able to commence when the LRMS is available, sometime after September for the majority of Trusts who use DatixWeb as their LRMS. Several hundreds of thousands of front-line staff will need to be communicated with and trained on this new way of reporting. No training resources are being developed by NHSE, this being seen to be the responsibility of Trusts, including communication with their front-line staff. There is

very little guidance on how fields should be completed in LFPSE, and these factors raise significant data quality concerns.
- The time taken for staff to report events is likely to increase significantly under LPFSE. This is considered likely to have an impact on staff time and commitment to reporting, potentially also on the rate and quality of reporting.

How Trusts report

Organisations will need to make provision for a wide range of questions that LFPSE will require all organisations to complete. These are not included in full in this report, but elements of the new taxonomy/dataset are referred to the appendices.

Who can report?

Most Trusts will continue to use their LRMS, but more organisations are expected to use LFPSE directly to report safety events, including those events that did not occur within their care. For example, GP practices will be able to report events relating to a provider direct to LFPSE and the provider would immediately be notified of this. These are new processes and ways of working will need local discussion as to impact on workflow, the culture of reporting and agreement of responsibility for follow up and action.

When events are sent to the national service

Currently incidents are only sent to the national system after they have been quality assured and fully investigated by a Trust. Under LFPSE, safety events will be sent to the national service as soon as they are submitted by the event reporter without any review by the Trust. NHSE propose that incidents can be re-uploaded after they have been quality-checked. This is a significant revision to business processes and raises data quality questions.

LFPSE preparation planning at Trusts

During 2021, Trusts obtained from their LRMS vendors the dataset of questions that Trusts would be expected to include on their forms when they went live. Many Trusts waited until this year to review it in more depth, partly as further iterations were anticipated and also because without a web-based version it is hard to analyse.

In June 2022 Trusts were given access to the online LFPSE test system to evaluate the question set.

Trusts have attended a number of webinars and engagement events held by NHSE and LRMS vendors and there are ongoing conversations on a number of forums and platforms including FutureNHS Collaboration Platform, PSMN and local networks.

Trusts have been raising concerns since July 2021. The feedback from individual Trusts has not been collated nor responded to their satisfaction. Other Trusts are only now beginning to plan in detail and are frustrated that the issues they are raising are ones that others have previously raised but not resolved.

There is a clear frustration that in the forums or webinars attended by NHSE, the scale of collective disappointment and disapproval at the current iteration of LFPSE is not being acknowledged, let alone being addressed.

LPFSE discussion at a recent PSMN drop-in discussion session

Recent PSMN drop-in sessions have included discussions on topics relating to the NHS Patient Safety Strategy including PSIRF, Patient Safety Partners and LFPSE. These sessions provide the opportunity for colleagues to share their understanding of latest guidance, their experiences of planning and implementing change, to raise any issues of concern and invite advice and support. With invited expert guests, these sessions also provide valuable feedback to colleagues at NHSE on the reality of 'work as done,' the practical issues from the perspectives of those working in patient safety.

Occasionally, PSMN members agree to coordinate on a specific task to highlight issues and provide insights. A recent example has been the development of a Risk Assessment and Risk Management Framework for PSIRF, shared with PSMN members and with NHSE leads. This is planned to be updated when the national guidance is issued, expected shortly.

A recent PSMN drop-in session discussed LFPSE, and the many issues raised by those working in patient safety management through a number of routes: the FutureNHS Collaboration Platform; with software system vendors and directly to NHSE leaders.

PSMN members discussed and shared their worries that:

- There are many issues of significant concern with the design of the LPFSE including the new taxonomy
- Requests for clarification or explanation are not being addressed
- There is insufficient acknowledgement of the significant implementation challenges for the NHS
- Concerns are beginning to be escalated with their senior leadership including to their Quality and Safety Committees and their Boards
- This initiative will require significant resources from Trusts central patient safety and incident reporting teams, but the biggest resource implications will be for the communication, training and support for front line staff who will need to significantly change their way of reporting; likely to be hundreds of thousands of staff
- This change is being required of Trusts whilst they are also preparing for the major PSIRF[4] initiative, outlining how providers should respond to patient safety incidents and how and when a patient safety investigation should be conducted. PSIRF and LPFSE have been developed as separate programmes by NHSE and concerns are being expressed by Trusts on the alignment and inter-relationship between these two substantial organisational change programmes.

PSMN members agreed to summarise and share their concerns with NHSE leaders and invite discussion at a future PSMN drop-in session.

LFPSE concerns

With the support of a core team of PSMN experts, a summary of PSMN members concerns and risks have been collated from the PSMN discussion with significant input from incident reporting leads including those attending a recent Datix users forum, patient safety and human factors experts, reports that have shared with Trust leadership and Patient Safety Learning.

[4] NHS England, Patient Safety Incident Response Framework, Last Accessed 27 July 2022. https://www.england.nhs.uk/patient-safety/incident-response-framework/

These serious concerns relate to a range of issues, collated in detail in separate appendices with unattributable quotes, reflecting the anxiety and frustration of the contributors:

1. Just Culture
2. User and staff engagement and reporting for learning
3. The new LFPSE dataset
4. LFPSE design, development and benefits realisation
5. RLDatix/vendor readiness
6. Implementation

Questions that are being asked

Contributors to this report have also identified questions for NHSE. Response is needed to these questions to enable Trusts to better understand the requirements of the LFPSE dataset, to assist with implementation planning and communication with their Boards, Directors and staff. These are included in a separate Appendix. They included questions relating to:

1. Design and impact assessment of LFPSE
2. Implementation
3. User engagement
4. Guidance required

The questions have been limited to the top 30 questions raised.

Conclusions and proposed next steps

There is a clear frustration that in forums and webinars attended by NHSE, the scale of collective disappointment and disapproval at the current iteration of LFPSE is not being acknowledged, let alone being addressed. These serious concerns are now being raised at senior levels in Trusts with the recognition that a failure to address these issues will have a significant impact on incident reporting for learning. The failure to learn and act on this learning, will be a failure for patients' safety.

The PSMN and the incident reporting management community are highlighting serious concerns regarding the:

- The design of the LPFSE dataset and its inflexibility in implementation
- Lack of confidence that the dataset questions will provide insights for learning
- There is insufficient patient safety and human factors approach to the taxonomy
- Questions as currently phrased may undermine a just culture
- Planned benefits and whether these are likely to be achieved with LFPSE as designed
- Implementation planning being left to local organisations with little resources to help inform Boards, communicate with and train hundreds of thousands of front-line staff
- Damaging impact on the credibility and value of event reporting
- Damaging impact on the workload and morale of front line staff

Comments from Patient Safety Managers and Incident Reporting Leads reflect the strength of concerns of many:

"… most Trusts are now in the invidious position of having to implement a new system (of questionable quality) that will have an adverse impact on their successful, functioning local systems."

"I think this whole LFPSE project should be paused and there should be an independent review, external to NHS England and talking to NHS Trusts, as to whether this is right approach"

"I will not implement the system in its current state. I would not inflict this on staff in the Trust."

"We need to convey just how disappointed and frustrated every single Trust *is by all of this! There has not been one Trust that we have met who have an LRMS and who feels positively about LFPSE. This disappointment is unanimous and uniform! LFPSE is being presented almost as a fait accompli by NHSE, when there are* ***so many*** fundamental *concerns about the entire project that singly would be raising red flags but are not even being acknowledged."*

"Is there the possibility of a phased approach to going live? This would allow for lessons to be learned and acted upon, rather than forcing everyone to go live at the same time? It would certainly reduce anxiety."

We consider there is an urgent need for NHSE to engage with Trusts to: 1. fully risk assess the implementation of LPFSE 2. develop effective risk mitigation strategies 3. give patient safety leaders the confidence in the beneficial impact of these changes.

It is proposed that a core group of Patient Safety Managers and Incident Reporting Leads, supported by Patient Safety Learning, meet with NHSE to work through the issues, to improve LFPSE and for it to have a better chance of success. We look forward to NHSE responding positively and urgently to this briefing note.

Appendices

Comments from contributors are included verbatim in italics

Appendix 1 - Just Culture

Changes in the dataset need to reinforce the Just learning culture that the NHS is aiming to achieve. Some contributors are concerned that the language used in the LFPSE could unintentionally reinforce approaches that are more focused on blame than learning e.g., an emphasis on who did what wrong.

There is also concern that issues raised of this nature have been shared with NHSE at pilot site stage, but these doesn't appear to have been addressed. The risk is that the dataset as proposed undermines the benefits being sought and a psychological safe environment for those working at the front line.

Examples:

People action too much

Something was done too many times/too frequently
Something was done too quickly
Something was done for too long
Something was done too early/soon
Something was done with too much force

People actions

People did too much of something
People did too little of something
People did one thing when they meant to do another
People did not do something they should have
Other
I don't know

How was people's availability involved in what went wrong? (Optional)

Select all that apply.

- [ ] There were too many people involved
- [ ] There were people absent who were required
- [ ] The wrong skill mix was involved
- [ ] Other
- [ ] I don't know

Those "blame" questions MUST be removed. They are not compatible with the standards we operate under. I do not care what your use of the data is, the nurse on the ward is still faced with these questions when they are reporting an incident and that will not make them feel safe, psychological safety applies to staff as well as patients.

Appendix 2 - User and staff engagement and reporting for learning

LFPSE is likely to have a significant adverse impact on:

- The way Trusts report incidents and safety events
- The numbers of events being reported
- The way these are managed and signed off
- The consistency of data across all events (given the large variances between the size and quality of data for patient safety incidents compared with non-patient safety incidents or other types of events)
- The way data can be triangulated for analysis and learning
- The positive culture around incident reporting and the way it is embedded in practice for staff

Some of the changes affect fundamental aspects of how Trusts report incidents. For instance, Trusts currently report patient safety, health and safety and non-clinical incidents in their LRMS, their local incident reporting systems. The small number of core fields from patient safety incidents are then uploaded to NRLS when their investigation has been completed. For LFPSE-submission, a larger dataset is now expected to be completed by safety event reporters and handlers. That is, all staff who reports events (clinicians, risk managers etc) will have to complete a significantly larger set of questions and as they are standardised across the NHS, many of these will not be relevant to the staff member or the service they work within. This is a significant issue for staff and is likely to affect the willingness or capacity of staff to report. Implementing at a time when staff capacity is already significantly stretched is also likely to negatively impact the morale of incident reporters, our front line staff.

Many Trusts have made stringent efforts to keep their incident reporting forms as concise as possible to encourage reporting. The feedback from a Trust that has already gone live with LFPSE is that front-line staff struggled with the volume and wording of the new question set required for LFPSE. They reflected that the sheer length of the new dataset means the Trusts' incident reporting forms will become more cluttered and take longer to complete.

There is also risk of either a reduction in the number of incidents reported, or a reduction in the number of patient safety incidents specifically, as reporters are discouraged by the new dataset. The reduced rate of reporting may compromise Trusts' ability to learn from incidents of unsafe care or good practice, thereby reducing the Trusts' abilities to make patient safety improvements and reduce avoidable harm.

With Trusts only being given access to the test LFPSE system in June this year, it has become apparent that the fears being expressed by patient safety managers and incident reporting leads have now been realised. Amongst the comments from several highly experienced patient safety managers and incident reporting leads are:

We could finally see what the questions looked like online (rather than staring in bewilderment at spreadsheets). I have spoken with at least 10 Trusts individually and am part of other networks containing many more Trusts, and we are all of the same mind. LFPSE has not been properly thought-through, and it will be a disaster.

This is going to have a huge impact on staff ease of reporting. They have already had to take on the huge impact in data capture the MH Act of force has caused, and I think it will impact on staff's ability to report incidents.

LFPSE will lead to a decline in incident reporting, and one manager highlighted that incidents would likely be reported as risks or outcomes as staff would realise these require far fewer fields to be completed

It does all seem very back to front to what we are used to. Surely it is still best to verify the data, harm levels etc before submitting, as opposed to submitting raw, almost meaningless data that will need many updates to it over the following weeks?

The real concern is that all the comments here have been made at every LFPSE call I have been on for the past 9 months; and are sadly ignored and/or not addressed. This only increases the concern and anxiety.

For me the concerns are the potential damage to the reporting culture we have built up, the lack of clarity in what we are expected to do and the timescales for implementation.

Both today and on the Q&A session with NHSE the feedback about LFPSE has been overwhelmingly negative and people have raised many concerns. Does that give the LFPSE team any pause for thought at all that this is the right approach, being implemented in the right way. If not, why not?

My concern is that if the data integrity is important nationally and if this is going to provide better information than NRLS then we need EVERYONE in the NHS to be reporting in the same way, apples with apples, without deviation, we need the NHSEI definitions within our policies and procedures. And for each HCP, Team, and Trusts to follow the same definitions or we will not be able to depend on the benchmarking data.

Can someone please explain to them (the LFPSE team) that we will be using our Datix Systems to generate our reports/data. We will not be using LFPSE to generate our reports - why on earth would we do that? The Datix system has live data/dashboards which we have been using for years. The reporting to NHSE is just something else we have to do; it is a very minor point of the purpose of the Datix systems we have. The sooner the LFPSE understand this material point the better.

Doing the uploads to NRLS currently is a pain for administrators, a small team. NHSE have replaced this with a system which is a pain for all reporters, so instead of a small inconvenience for 3-4 people for a large Trust, you are now inconveniencing 10,000 staff members.

Appendix 3 - The new LFPSE dataset

Trusts will need to ensure that the new LFPSE dataset is used for incident reporting with the dataset built into their existing Local Risk Management System (LRMS) dataset.

Some patient safety managers and incident reporting system leads have expressed their shock at the quality of the dataset on the LFPSE test system, stating that the questions are often worded simplistically, in a long-winded way or not reflecting a human-factors informed approach. The content of so many fields is considered to be disappointing, and some have gone as far to say this violates many basic principles of data quality.

Patient safety managers and incident reporting system leads are being asked to raise questions individually through the NHS Futures Platform helpdesk. Concern has been expressed that this doesn't allow for a collation of issues and discussion with users. There needs be an active discussion between NHSE and users and the development of shared understanding of the concerns and how they can be addressed. Concern has also been expressed that Trusts will be jettisoning their own fields to replace them with a standardised LFPSE dataset that is poor.

There are a large number of specific concerns, too detailed to be included in this briefing note, but some examples are shared below:

- There are inconsistencies in which fields are used in which modules that will make data collection more difficult. e.g. Patient Ethnicity or the Speciality IS mandatory in an Incident but IS NOT in an Outcome.

- There are over 25 questions where reporters can choose: "I don't know". The fact that records containing these "I don't knows" will be sent directly to LFPSE upon submission is a cause for concern.

- The lack of design customisation means that the adaptability, flexibility and scope for local innovation, which has always been one of the advantages of using a LRMS such as Datix, will not be available. There will be no option to relabel the new LFPSE-required fields or edit the dropdown options in those fields or any accompanying help guidance. There is therefore a risk that staff will not understand what is expected of them when reporting a safety event even assuming there is sufficient guidance and time to train and brief all clinical staff that could/should be reporting under LFPSE.

- Without detailed guidance and training, there is a significant risk that staff will have a range of interpretations, in particular, the new fields of outcomes and risks. Also, events such as unplanned admissions or readmissions, returns to theatre, post-partum haemorrhages and stillbirths are currently reported as incidents but will now expected to be reported as outcomes. Risks – whether clinical or non-clinical – are usually recorded in separate modules to incidents (e.g the Risk Register module in Datix). Under the new service, Trusts are expected to record patient safety risks in the Incidents module, not the Risk Register.

- The impact of staff recording incidents relating to other organisations needs to be considered and developed into clear system and processes. Cross organisational and care pathway reporting is new, and Trust and ICS input is needed to design new ways of working.

- Unclear how the dataset will inform learning as the information requested is often unspecific and subjective e.g. ‘people did too much of something’ or ‘there were too many people involved.’ See Appendix 1 for these examples

Definition of incident, outcome and risk

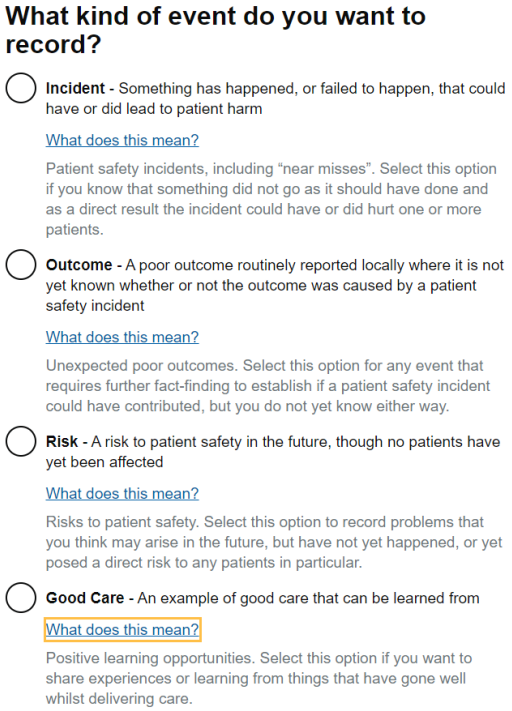
If nothing happened, it is a NEAR MISS not a RISK. Risks belongs in the risk register not in the incident reporting module. This has been expressed consistently by many Trusts, that the word ‘risk’ must be removed from the types of incidents.

Patient safety and risk leads can't understand the distinction that is being made in LPFSE and they are concerned that staff reporting incidents will not understand what is expected of them and they will presume they should now record risks in the incident module.

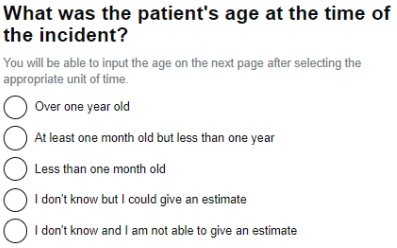
For staff on the ground, I think choosing between incident, Risk, outcome etc. will cause a huge amount of confusion.

Understand the need re risk recording, but what is the expectation on Trusts in responding to risks? Especially when this is creating a separate risk framework outside our respective Trust risk management frameworks.

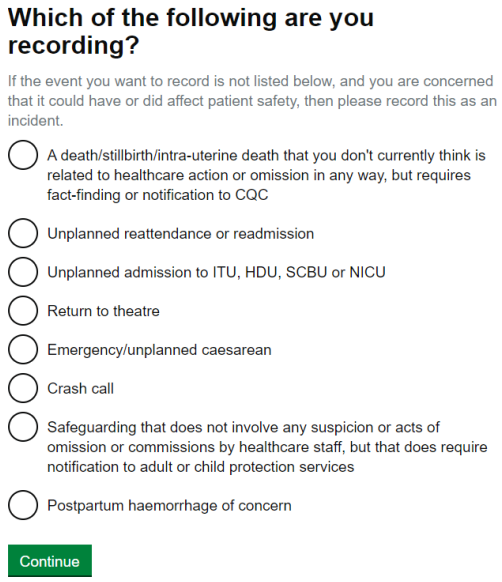
There is a potential loss of learning by merging all types of safety events together. There are differences in the value of exploring contributory factors and controls/recoveries in the different types. Near misses with other incidents will mean no focus on wanting to understand what interventions worked to make it a near miss or not…we have to assume incidents will always happen, but we want to build controls in the system.



Why not just ask for date of birth?



When reporting Outcomes, reporters are presented with a defined list of these 8 outcomes only, when there are likely to be other types of incidents that Trusts currently report which would fit under the definition of an 'outcome'.



Staff reporting will have to select from a standard list of service areas and specialties as well as the Trust's own specialties:

This list does not include options for clinics, health centres, schools, and other locations where community staff may report incidents

Also, currently in LRMSs, locations can be displayed based on the incident occurring in different divisions, specialities or settings (e.g. acute or community setting). This conditional design is not possible in LFPSE, making reporting across specialties and locations more time-consuming.

Where did the incident happen?

- ◯ Public place
- ◯ Private home
- ◯ Care home
- ◯ Hospital
- ◯ Mental health unit
- ◯ General practice building
- ◯ Community pharmacy
- ◯ Another sort of healthcare building
- ◯ Ambulance or other healthcare vehicle
- ◯ Prison
- ◯ No specific location
- ◯ I don't know

The way some options are listed is obtuse. Given most incidents tend to involve one patient, why are the LFPSE options as below?

How many patients were involved in this incident?

- ◯ None
- ◉ Between 1 and 9
- ◯ 10 or more

Has this been developed with advice from EDI professionals? What does 'other' refer to?

What is the patient's sex?

- ◉ Female
- ◯ Male
- ◯ Withheld, not specified or other
- ◯ I don't know

One colleague raised the following issues, seeking NHSE advice on what the definition of sex is for the purposes of LFPSE either:

1. *Sex Assigned at Birth*
2. *Sex as per Medical Records – although there will be some variation for some patients (for example a trans man may have F on their local gynaecology record, but M on the PAS record at the same Trust / a trans woman may have M on their Urology record, but F on their PAS record)*
3. *Gender (Self-Described)*

Also - what does "Other" mean in relation to Sex, is this the same as "Indeterminate"?

Similarly, as the same question is posed (due to the use of the contacts module) for Staff – are NHS Trusts expected to record Sex of Staff (rather than gender), which could lead to disclosure of protected information for Staff who have a GRC or are undergoing gender reassignment.

Appendix 4 - LFPSE design, development, and benefits realisation

The planned benefits of LFPSE as described by NHSE:

- The concept of a system from which Trusts can effectively derive meaningful data and analysis to help them improve and to learn (both on a national and local level) was the original intention of the NRLS
- Long overdue is the concept in LFPSE of learning from examples of good care, which will help balance the tone of the conversations around patient safety
- Allowing staff to identify risks at an early stage may be considered a more effective way to capture events that are yet to occur
- LFPSE also makes a clear distinction between physical and psychological harm whereas NRLS definitions were more focused on physical harm.

However, serious concerns have been expressed about the design and development of LFPSE and whether these benefits are likely to be realised.

A change of this magnitude needs to be manged carefully to ensure that the changes in the dataset deliver the planned benefits.

There is concern to the extent that some patient safety managers and incident reporting leads are questioning whether users have been involved in the design at all.

For me the concerns are the potential damage to the reporting culture we have built up, the lack of clarity in what we are expected to do and the timescales for implementation.

I don't think anyone is arguing against changes; however, we need that to be change for the better. LFPSE seems like a backward step and the timescales for implementation don't seem realistic.

Are we not the experts, with a voice that should be valued on how this new process will impact on our organisations reporting culture and the data we would like to extract locally, let alone nationally?

This feels a step backwards and does not add anything that the NRLS didn't already do; the questions do not account for an understanding of how the safety literature has advanced and the more modern thinking around learning from events; it remains too sharp end focussed and doesn't encourage a just culture. I would be keen to know the safety experience of those designing the system as this does not feel apparent in the system.

Ultimately it doesn't feel that it has the potential to add any new learning. There is so much that could be learnt from other databases in other industries and the secondary coding of data in a way that is useful.

My xxx is a GP and it makes me think how primary care will also be supported to use this…they don't engage with the NRLS, they won't engage with this.

Appendix 5 - RLDatix/vendor readiness

Organisations who use an LRMS will have to wait for compatible releases. LFPSE-compatible versions of the following software are now available:

- Datix Cloud IQ (RL Datix Ltd)
- Incident Oversight (InPhase Ltd)
- Radar Healthcare (Smartgate Solutions Ltd)
- Ulysses (Ulysses 2000 Ltd)

However, it is understood that over 75% of Trusts use RLDatix's DatixWeb product suite. Users have been advised that a compatible-release version will only be available in September 2022 at the earliest (barely 6 months before the April 2023 go-live date).

This release will be supplied to Trusts free of charge, although Trusts will need to pay to have RLDatix Support team to install the software (the standard practice for many Trusts).

There is concern that RLDatix won't have the support capacity to support all the Trusts to meet this Sept 2022 deadline and this will significantly affect Trusts' ability to respond and work with their IT departments to make changes in readiness for the end March 2023 deadline.

There is also concern that the LFPSE help desk will not have sufficient capacity to review and sign off Trusts' upload of LFPSE into their LRMS, delaying the project significantly and restricting the time available for staff communication, engagement, and training.

Appendix 6 - Implementation

Trusts are expected to go live with these changes on 31 March 2023 which doesn't give Trusts much time to prepare systems and arrange suitable training and communications.

Many Trusts avoid making changes to their systems mid-year in order to maintain the integrity of regular quarterly and annual reporting requirements. We therefore understand that many Trusts intend to go live – if they do so at all – on 31st March 2023.

Trusts are also identifying that they wish to learn from the implementations at other Trusts, and to avoid impacting the integrity of quarterly and annual reports by making changes mid-period.

Implementation planning appears to be the sole responsibility of Trusts, to coordinate with vendors and NHSE Helpdesk. There does not appear to be an implementation framework with communication and other resources to brief Board and leadership, patient safety teams and all the staff that will be encouraged to report events in a significantly new way. It would be useful to have insights and resources from Early Adopters to help with risk assessment, risk mitigation and implementation plans.

We are all screaming at our computers, we are raising these issues again and again and we might as well scream them out of the window for all the difference they make. I did suggest that a whole day event with LFPSE and Datix to resolve some of these issues was necessary, but LFPSE felt they are doing enough consultation apparently. I think there is plenty of evidence on here to suggest this is not the case. I will not talk to them if my comments are dismissed again and again.

I will not be implementing this system in its current state. I would not inflict this on the staff in the Trust. At the end of the day, it is me that is responsible for the system and me they will moan at. As it is I cannot defend this system and I will not put my name to this. I will leave it to my employer to decide what they will do about that.

Appendix 7 - Questions (Top 30)

Design and impact assessment of LFPSE

1. What workload assessment has been undertaken of the transition for users to the new dataset, to assess the reporting burden and impact on reporting rates etc?

2. What review and sign-off of the dataset was undertaken from a quality perspective including patient safety managers, incident reporting leads, human factors experts etc?

3. What are the success criteria that will be used to assess whether the LFPSE benefits have been realised?

4. How have the questions in the dataset been assessed to ensure that they reinforce a systems approach to safety and not unintentionally focus on blaming staff?

5. How have the questions been developed and assessed by human factors experts to ensure a systems focused approach?

6. What is the outcome of testing with early adopters e.g., the impact on staff time and the rate and quality of reported incidents following implementation?

7. How much has been spent on the development of the LFPSE, nationally and locally?

8. How will the LPFSE improve learning through its national analysis and sharing of data?

9. Is there a LFPSE risk or issues log and does this include all the concerns being raised by users?

Implementation

10. What guidance is available and under development to support Trust implementation and staff training?

11. In user testing, how has it been assessed what knowledge and training users will need to complete the necessary mandatory fields?

12. In user testing, how have the process flows been assessed to ensure that Trusts staff are able to update a report following quality review and that this doesn't lead to any double counting?

13. What assurance have NHSE sought or received that vendors are prioritising the changes they need to make and will have completed these for all Trusts by end Jan 2023?

14. Is there scope to pause the requirement for all Trusts to transition to LFPSE by end March 2023 if vendors are struggling to get all Trusts upgraded in time?

15. What have the experiences been as to how staff will need to be briefed as to the changes and what guidance and briefing notes are available to assist Trusts in their implementation planning and staff communication?

16. What assessment has been made on the impact of a standardised reporting on staff understanding or willingness to report? How can this inform Trusts' implementation planning and staff communication and training?

17. What assessment has been made of the training requirement for staff, an overall capacity assessment given the hundreds of thousands of staff that will need to be trained and during the winter months?

User engagement

18. Are there proposed to be user forums that invite all interested parties from Trusts and primary care to collectively raise concerns and develop a shared agreement of ways forward for subsequent dissemination?

19. What user testing was undertaken with patient safety managers/specialists and incident reporting leads and what were the sign off arrangements?

20. Some of the new terminology does not relate at to what most trusts use. What consultation has been undertaken?

21. The feedback about LFPSE has been overwhelmingly negative and people have raised many concerns. Does that give the LFPSE team any pause for thought at all that this is the right approach, being implemented in the right way? If not, why not?

22. Given the workforce and wellbeing crisis in the NHS, what assessment has been made of the impact of this change in terms of staff morale?

Guidance required

23. How are staff to report 'near misses?' There is much debate about the definitions of near misses, what guidance is available and training of staff to ensure consistency in reporting and effective learning?

24. What the definition of 'sex' is for the purposes of LFPSE. Have the options in the Patient's Sex field had any oversight from an EDI perspective e.g., inclusion of 'other?'

25. What resources have been developed and shared with Trusts and primary care to enable them to brief and engage their staff in this fundamental and large-scale change in how incidents, near misses, outcomes and good practice are to be reported?

26. How will the dataset reflect the new PSIRF reporting requirements?

27. How does this link into Use of Force Act, mortality learning and the MH minimum dataset?

28. Will it be possible to hide questions that are totally irrelevant to Trusts' services?

29. How has the information governance risk been assessed e.g., staff unintentionally uploading personal identifiable info (PII) nationally (even if there is a warning response)? Trusts currently check incidents for PII before NRLS upload.

30. Will the NRLS continue to exist for Wales after 31/03/2023? If so, could the implementation deadline for England not be longer?