Southern Hampshire
PRIMARY CARE ALLIANCE

Managing Incidents in SHPCA

1.4

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1.4	21/07/2022	L Busher	Formatting changes and review

CONTENTS

1. INTRODUCTION AND BACKGROUND

This guide aims to support SHPCA staff in the identification, reporting, investigation and learning from incidents. It has been wholly adopted by SHPCA to reflect that this is best practice and will be updated and revised according to Wessex Wide review. Significant event review has been a key part of learning and improvement activities in primary care for some time now. Its importance is emphasised in regulatory and individual clinician clinical appraisal requirements, and the analysis of significant events encourages a culture of honesty in the team as well as team- based and individual reflection. Applied effectively, the technique provides many opportunities to improve the safety of patient care. SHPCA's Summary Approach to Governance is at Appendix A.

However, there is more to the reporting and management of incidents than significant event analysis alone. The understanding and recognition of serious incidents and never events in general practice is outlined in the NHS England Serious Incident Framework but the use of this framework has been variably applied in GP practices. https://improvement.nhs.uk/resources/serious-incident-framework/

This guidance will provide SHPCA staff with definitions of the key classifications of incidents and provide practical examples to support the identification of incidents and the harm level.

2. DEFINITIONS AND EXAMPLES

Significant event

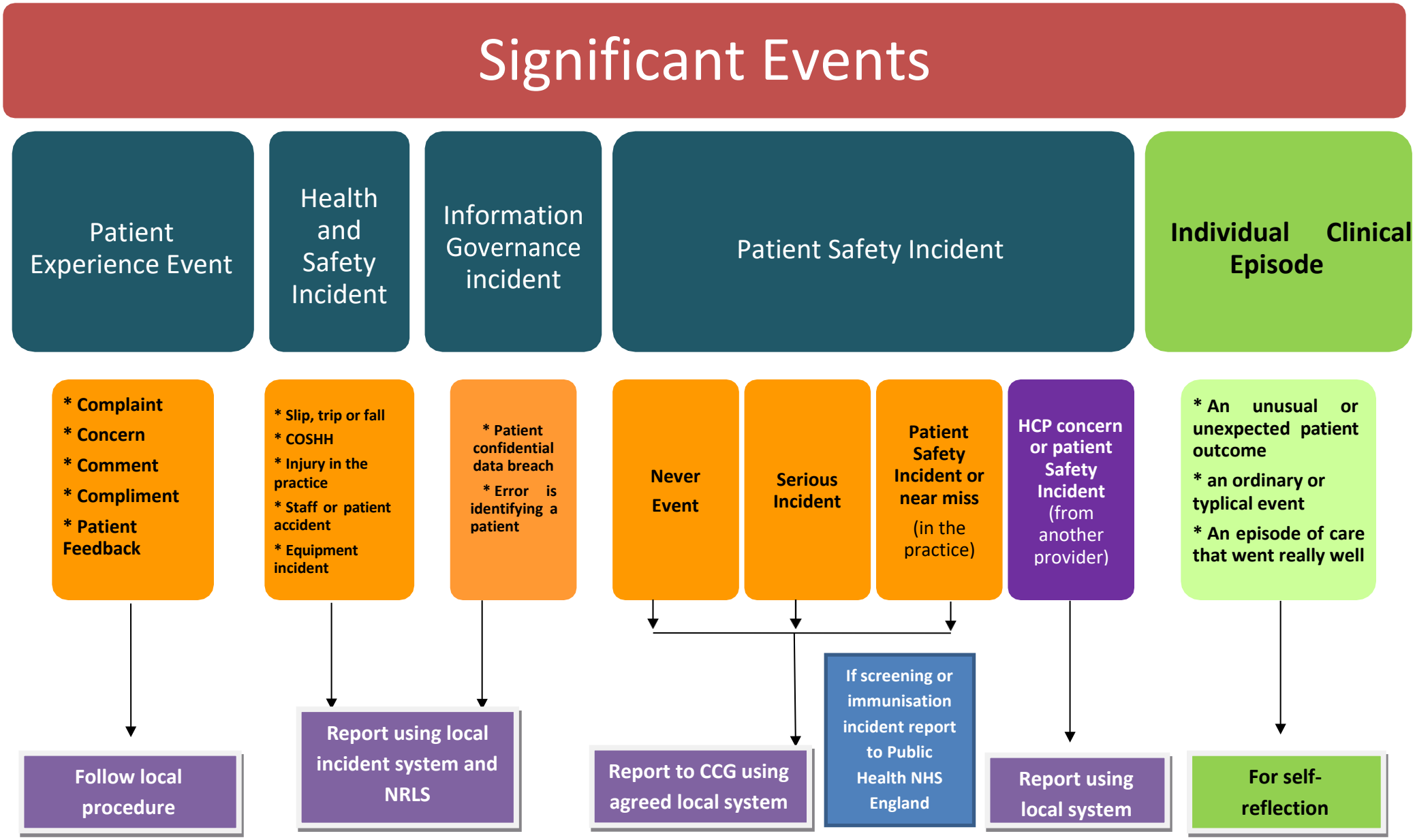
A significant event (SE) is defined as *any episode of care, incident, occurrence or accident, related to clinical or non-clinical care, which has or could have resulted in a positive or negative outcome, or an injury, or near miss to a patient, visitor or member of staff. A significant incident may also be a complaint or piece of patient feedback; it may be related to clinical or non-clinical care or an event resulting from non-compliance with the routine procedures of the practice. The significant event may also result in property or equipment damage, equipment failure, and can include physical aggression or verbal threats to other patients or staff.*

Any incident can be a significant event; those involving patient safety should be reported as a patient safety incident via the Alliance's local incident reporting system (e.g. Quasar) well as to the National Reporting and Learning Service (NRLS), regardless of the level of harm. https://report.nrls.nhs.uk/nrlsreporting/

It is really important to capture near misses, where no harm has occurred, as understanding near misses can prevent harm to patients in the future. Some incidents are classified as serious incidents (SI) if the level of harm is serious according to the NHS England Serious Incident Framework.

Please refer to the remainder of this document for explanations on determining *harm.* Figure 1 below shows the various types of incidents and where they should be reported

Figure 1: Types of incidents



3. PATIENT SAFETY INCIDENT (PSI) (INCLUDING SCREENING AND IMMUNISATION INCIDENTS)

A patient safety incident is *any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care.*

A patient safety incident may also be a serious incident, if it involves serious harm to the patient (s).

Screening incidents include any incident where there is harm or risk of harm because one or more persons eligible for screening are not offered screening or the patient does not receive results/adverse results are not acted upon. The characteristics of screening programmes mean that safety concerns/ incidents require special attention and management. This is because:

- There is potential for safety incidents in screening programmes to affect a large number of individuals: seemingly minor local incidents can have a major service and population impact
- poor quality screening can do more harm than good – it can harm individuals and have no benefit to the population
- incidents often affect the whole screening pathway not just the local department or provider organisation in which the problem occurred
- local incidents can affect public confidence in a screening programme beyond the immediate area involved

The Managing Safety Incidents in NHS Screening Programmes guidance should be followed: https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes

4. NEAR MISSES

A near miss is *an unplanned event that did not result in injury, illness, or damage, but had the potential to do so. Only a fortunate break in the chain of events prevented an injury, fatality or damage.*

It may be appropriate for a 'near miss' to be a classed as a patient safety incident or serious incident, depending on the potential severity of harm that could be caused should the incident (or a similar incident) occur again.

Deciding whether or not a 'near miss' should be classified as an incident should be based on an assessment of risk which should consider:

- the likelihood of the incident occurring again if current systems/process remain unchanged or
- the potential for harm to staff, patients, and the practice should the incident occur again.

Every 'near miss' should be reported as where there is a risk of system failure and/or harm, the incident process should be used to understand and mitigate that risk / harm.

5. SERIOUS INCIDENTS

In broad terms, *serious incidents (SIs) are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare*

There is no definitive list of events/incidents that constitute a serious incident, as this can lead to inconsistent or inappropriate management of incidents. Every incident must be considered on a case-by-case basis using the description below. Inevitably, there will be borderline cases that rely on the judgement of the people involved.

Where it is not clear whether or not an incident fulfils the definition of a serious incident SHPCA and the Clinical Commissioning Group (CCG) must engage in an open and honest discussions to agree the appropriate and proportionate response.

6. EXAMPLES OF INCIDENTS IN PRIMARY CARE

Incidents in primary care can generally be allocated into six groups, these are set out in the table below. The examples included below alongside the definitions provided and the harm ratings are intended to support practices to determine whether the incident is a near miss, a SE or a SI. Please note the examples included in the figure 2 below are not an exhaustive list; they are intended to provide guidance only, to help you determine if an incident requires further investigation under the near miss, SE or SI framework.

Figure 2: Examples of Incidents which may occur in primary care services

Patient Safety Incidents	
• Delayed or missed diagnosis • Medication errors • Wrong drug prescribed • Wrong drug dose • Drug interaction • Inadequate drug monitoring • Wrong drug / dose dispensed • Important message not acted on • Result miss-filed • Result not acted on • Investigation request not sent • Fridge/cold chain failures affecting vaccines • Wrong vaccine/dose administered	• Misinterpretation of a handwritten prescription • immunisation incident • Delayed or missed diagnosis • unexpected / avoidable death within 48 hours of contact with the practice • Failure to offer or refer to screening • Delay in performing screening or reporting results • Medication errors resulting in severe/catastrophic harm i.e. admission to acute or death • Communication failures • Urgent referral not done • Complications related to procedures undertaken on the premises (e.g. infection resulting from minor surgery, retained instrument etc.)

Information Governance breach	Health & Safety Incident	Adverse Media/ Reputational	Business Continuity	Safeguarding
• Appointment letter sent to wrong address • Wrong information given over telephone • Equipment failure • Computer data loss • Loss of Personal Identifiable Data • Wrong address of patient • Information shared with the wrong person • e.g. parent or patient with the same name and/or date of birth	• Accidents on premises (Inc. sharps/splash injury, patient falls etc.) • Damage to premises	• Poor CQC rating • Poor patient feedback following surveys, complaints, concerns • Litigation	• Staffing / resource issues such as registrar on alone, limited GP /nurse/admin cover, • Disruption of services • IT failure /disruption	• Patient expelled from practice • Termination of pregnancy request • Domestic abuse issues • Angry or upset • Violence /aggression towards staff or patients • Allegations, or incidents, of physical abuse and sexual assault or abuse • Child protection concerns • Accusation of physical misconduct or harm

7. MEASUREMENT OF HARM

The main methods used to measure harm in primary care include:

- incidents reported by staff
- review of individual patient records
- Structured or planned audits
- automated review of electronic records
- examination of registries or databases
- patient interviews and surveys
- staff surveys and interviews
- Direct observation.

Incidents are firstly assessed on the **probability** (likelihood of the incident happening) and secondly on what would happen i.e. the **consequence** or **impact**.

When assessing how likely it is that an incident will occur, the current environment should be taken into account. Consideration must be given to the adequacy and effectiveness of the controls (e.g. policies and procedures; staff training) already in place within the environment, which could address the causes of the incident and therefore the likelihood of the risk being realised.

When assessing what the impact of the incident, consideration should be given to what the impact of the incident would be in most circumstances within the environment and what is reasonably foreseeable.

8. HOW TO SCORE AN INCIDENT

Consequence score (C): choose the most appropriate domain for the identified incident / risk from the left hand side of the below matrix. Then work along the columns in the same row to assess the severity of the risk on a scale of 1 to 5 to determine the consequence score, which is the number given at the top of the column.

Likelihood score (L): what is the likelihood of the consequence occurring? The frequency-based score is appropriate in most circumstances and is easier to identify. It should be used whenever it is possible to identify a frequency.

Likelihood →	1	2	3	4	5
Consequence score ↓	Rare	Unlikely	Possible	Likely	Almost certain
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

For grading risk, the scores obtained from the risk matrix are assigned grades as follows

1 - 3	Low risk
4 - 6	Moderate risk
8 - 12	High risk
15 - 25	Extreme risk

9. LEVELS OF HARM & EXAMPLES IN PRIMARY CARE

Term	Definition	Clinical example
No harm	Any patient safety incident that did not result in harm or injury or that had the potential to cause harm but was prevented, resulting in no harm (near miss)	A GP prescribes the twice the recommended dose of a new drug, which the local community pharmacist picks up when dispensing the prescription.
Low harm	Any patient safety incident that required extra observation or minor treatment	A patient's home visit is missed; the patient has cellulitis of the right leg; this was picked up the following day resulting in the GP deciding to prescribe I.V. rather than oral antibiotics which need to be delivered by community frailty team.
Moderate harm	Any patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm	Continuing treatment with warfarin without monitoring INR for 6 weeks. The patient had an upper GI bleed and was admitted to hospital for 5 days for monitoring and follow-up. It was noted on admission that the INR was 7.
Severe harm	Any patient safety incident that appears to have resulted in permanent harm.	A patient who is a heavy smoker with a persistent cough is noted to have a suspicious lesion on a chest x-ray. The GP messages the practice reception to arrange an urgent appointment with the patient, although there is no answer on the patient's home telephone as he is on holiday. The message to follow up is missed. Two months later the patient presents with shortness of breath and haemoptysis. He is admitted to hospital via MAU and is diagnosed with lung cancer.
Death	Any patient safety incident that directly resulted in death	A patient is on a repeat prescription for morphine sulphate 10mg twice a day for chronic pain. The patient requests a prescription and, in error, a prescription is issued for morphine sulphate 100mg twice a day. The medication is dispensed and the patient's wife, who looks after his medicines, gives her husband 100mg tablets of morphine sulphate. He takes 2 doses over the next day and then his wife is unable to rouse him in the morning. He is admitted to hospital where he has a cardiac arrest and dies.

Duty of Candour

Duty of Candour is a legal duty to inform and apologise to patients if there have been mistakes in their care that have led to significant harm.

All NHS provider bodies registered with the Care Quality Commission (CQC) have to comply with a Statutory Duty of Candour. http://www.cqc.org.uk/guidance-providers/regulations- enforcement/regulation-20-duty-candour

Your CCG can help and provide support on how to share information with patients when things go wrong both in principle and in practice.

10.REPORTING OF INCIDENTS

The majority of incidents in primary care result in no or low harm levels which will be investigated via significant event analysis at organisational level. All incidents should be recorded using the Incident Reporting Form (Embedded in Appendix B) and submitted as soon as possible after an incident has occurred to the shpca.complaintsincidents@nhs.net email address. This must be within 24 hours of the event.

Internally, incidents will be logged on SHPCA Quasar, and all incidents will be discussed with the Lead Clinical Director for Governance and Lead Clinical Directors for specific services or roles as appropriate (e.g. CAS 111, IPCAS, , safety, safeguarding, IG etc)

Currently, reporting to the NRLS system of patient safety incidents can be undertaken directly by SHPCA onto the NRLS form or via the CCG for those incidents that they have been made aware of.

Incidents that meet the definition for reporting as a serious incident will be raised per locally agreed processes as serious incidents and the CCG should be informed within 24 working hours of the incident occurring. This will be to the Quality Team at FGSEH CCGs and to the Appropriate contractual Lead Commissioner. The CCG in turn will enter these incidents onto the national serious incident reporting system - STEIS (Strategic Executive Information System). If SHPCA are not sure if the incident meets the criteria, we will contact the CCG Quality Team tosupport decision making.

SHPCA Governance Lead will liaise with the CCG if support is required with the coordination of an investigation and SHPCA recognise this may also be for incidents where significant harm has, or may have occurred but which does not meet the threshold for a SI.

11.REPORTING OF INFORMATION GOVERNANCE (IG) BREACHES

GDPR or DPA 2018 personal data breach

A personal data breach is a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data.

If you experience a personal data breach you need to consider whether this poses a risk to people. You need to consider the likelihood and severity of the risk to people's rights and freedoms, following the breach. When you've made this assessment, if it's likely there will be a risk then you must notify the ICO; if it's unlikely then you don't have to report. You do not need to report every breach to the ICO.

Use the self assessment tool in the first instance to aid decision making: Self-assessment for data breaches | ICO

IG breaches that meet the threshold for a serious incident must be referred to the information commissioner's office: https://ico.org.uk/for-organisations/health/

Refer to the SHPCA IG Team (SIRO, DPO, Caldicott Guardian, IG Lead) for advice and support about how to report an IG breach:

12.REPORTING OF SCREENING INCIDENTS

Screening incidents (either suspected or confirmed) must be reported and investigated in accordance with the guidance on Managing Incidents in NHS Screening Programmes.

https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening- programmes

This means they must all be notified within 24 hours to the Screening and Immunisation Team (SIT) embedded within the NHS England Public Health Commissioning Team via england.wessexph@nhs.net. For screening incidents, the SIT may advise that Public Health England's Screening Incident Assessment Framework (SIAF) form should be completed.

Immunisation incidents should also be notified to NHS England, as the responsible commissioner, via the SIT email address england.wessexph@nhs.net

In both cases, the SIT will oversee the investigation and will advise on the process to be followed.

13.COMPLETION OF INCIDENT INVESTIGATION

Investigation of internal incidents should be undertaken using an established significant event analysis process. Additional guidance can be found www.npsa.nhs.uk/nrls/gp

If the Alliance has determined that an incident is to be reported as an SI a full root cause analysis will be conducted supported by the quality team at your CCG. Further information on the completion of a root cause analysis can be found here: http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/

The CCG are able to provide support in the coordination of root cause analysis which includes investigation tools, templates, guidance and staff support. This technique enables the practice to identify contributory factors that led to the incident. Importantly it provides the learning to improve patient safety. It is recognised that investigating an incident can be challenging and the CCG can provide a forum for support and learning.

The Screening and Immunisation Team (NHS England) will advise on and oversee the investigation of screening and immunisation incidents.

14.SHARING LEARNING FROM INCIDENTS

The purpose of reporting and investigating incidents is to ensure learning is identified, recurrence is limited by identification of actions and to ensure that learning is shared with other practices.

It is recommended that as well as sharing the learning with your team, with increased locality working you may want to consider sharing your key learning points with other providers, member practices and through the SHCPA Board, Combined Assurance Group and team meetings.

SHPCA Governance Lead maintains a Learning Log for all events, including incidents. The learning from these is shared at CAS.

SHPCA will summarise Learning from Events in the Learning Log and share key themes and learning with all staff via newsletters, on intranet, using EMIS Message Boards.

SHPCA Governance Leads will liaise with CCG to support the sharing of learning at a local level via forums, meetings, educational sessions and newsletters.

SHPCA Governance Summary Policy:

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ce%20Policy%201.1%2

15.ROLE OF THE CCG, NHS ENGLAND AND SHPCA IN THE MANAGEMENT OF INCIDENTS IN PRIMARY MEDICAL CARE.

Clinical Commissioning Groups	NHS England	Southern Hampshire Primary Care Alliance
Train/guide practices to use locally agreed system for reporting incidents Provide advice and guidance in decision making for classification for serious incidents Support practices to undertake investigations into serious incidents Share learning from incidents	NHS England is responsible for maintaining an oversight of serious incident management in Clinical Commissioning Group (CCG) commissioned care. NHS England's embedded Screening and Immunisation Team is responsible for oversight of incidents in screening programmes. NHS England remains the responsible commissioner for immunisations and screening carried out in general practice. Sharing themes and trends from NRLS	To have systems and processes in place that supports staff to report incidents. To encourage a culture of reporting and learning. Ensure there are processes for sharing of learning as a result of significant events, incidents and near misses To inform the appropriate commissioner (CCG/NHS England) of any serious incident that requires an investigation

Appendix A: SHPCA Summary Approach to Quality & Governance

Patients are entitled to care that is safe, clinically effective and patient experiences of care are listened to as measure of success or need for improvement.

Our Leadership approach and our organisational Culture support this at every level.

A Model for Quality – SHPCA Approach

- **Quality is 'everybody's business'** regardless of role or position.
- **Quality means we are safe** for patients, carers and staff.
- We are a **'learning organisation',** our services are **open and transparent**, and we are honest when things do not go as planned and putting things right for those affected.
- **We operate a 'Just Culture' We seek first to understand, not to blame. Individual incidents** can be **a symptom of** a **system issue** that has not been recognised, **a process that is lacking or can be improved.**

Sign up to SAFETY
LISTEN LEARN ACT

The NHS Patient Safety Strategy

Safer culture, safer systems, safer patients

July 2019

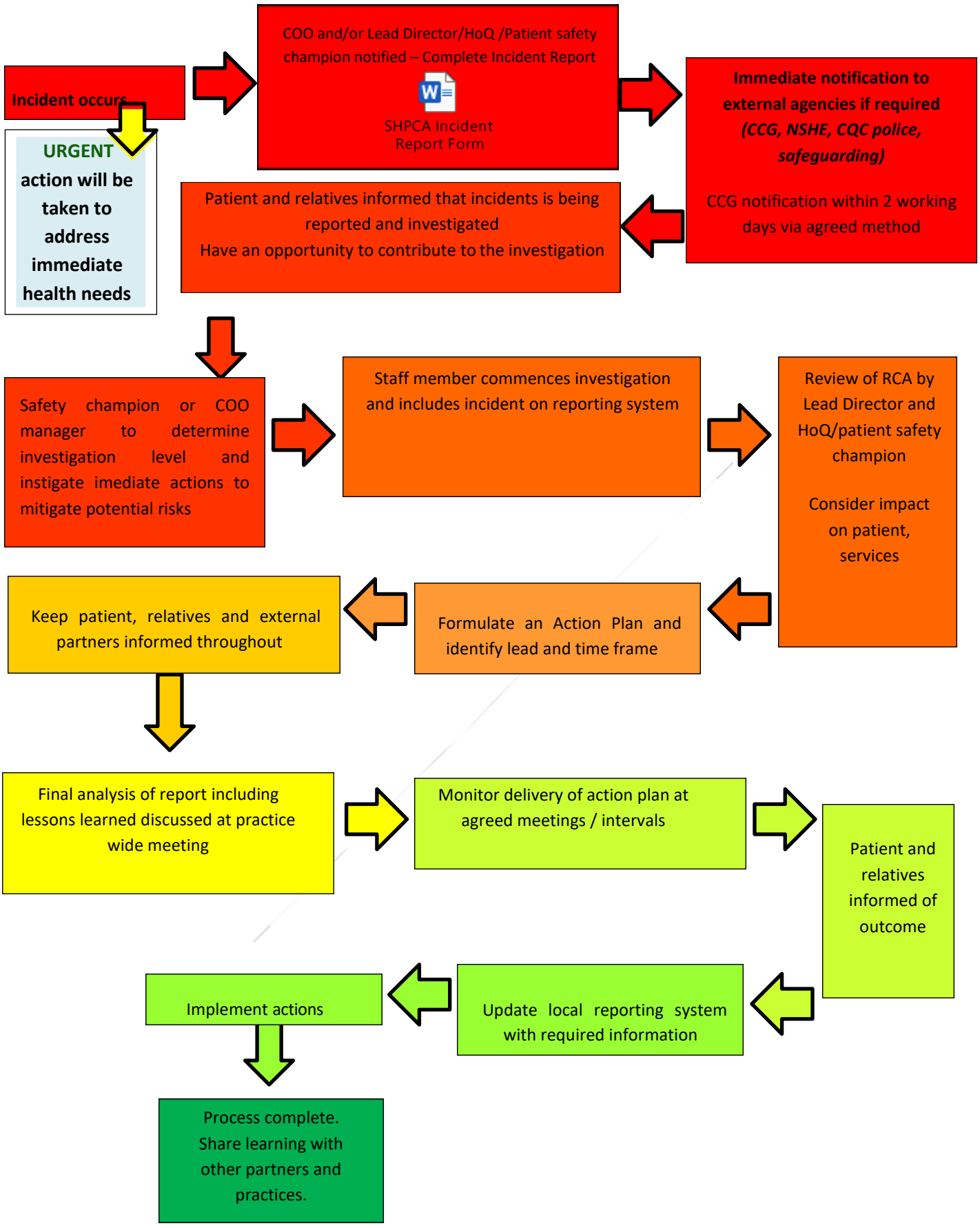
NHS

A just culture guide

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

Appendix B: Incident reporting pathway

INCIDENT REPORTING PATHWAY



Appendix C: Definition of a just culture.

What is a JUST CULTURE?

- If you make an error, you are **cared for** and **supported**
- If you behave in a risky manner by not adhering to policies, you are **asked why first** before being judged
- If you recklessly and intentionally put your patients or yourself at risk, you are **accountable** for your actions

Embedding these principles into your policies and leading by example will help all staff feel able to speak out and will make sure they are supported when they do so

To learn more about Just Culture, google *"Patient Safety and the Just Culture: A Primer For Health Care Executives"* or scan the QR code to the right

Sign up to Safety is here to help NHS staff and organisations achieve their patient safety aspirations and care for their patients in the safest way possible

Find out more www.signuptosafety.nhs.uk

Sign up to SAFETY

Links to guidance

https://improvement.nhs.uk/resources/serious-incident-framework/

https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes

https://report.nrls.nhs.uk/nrlsreporting/