

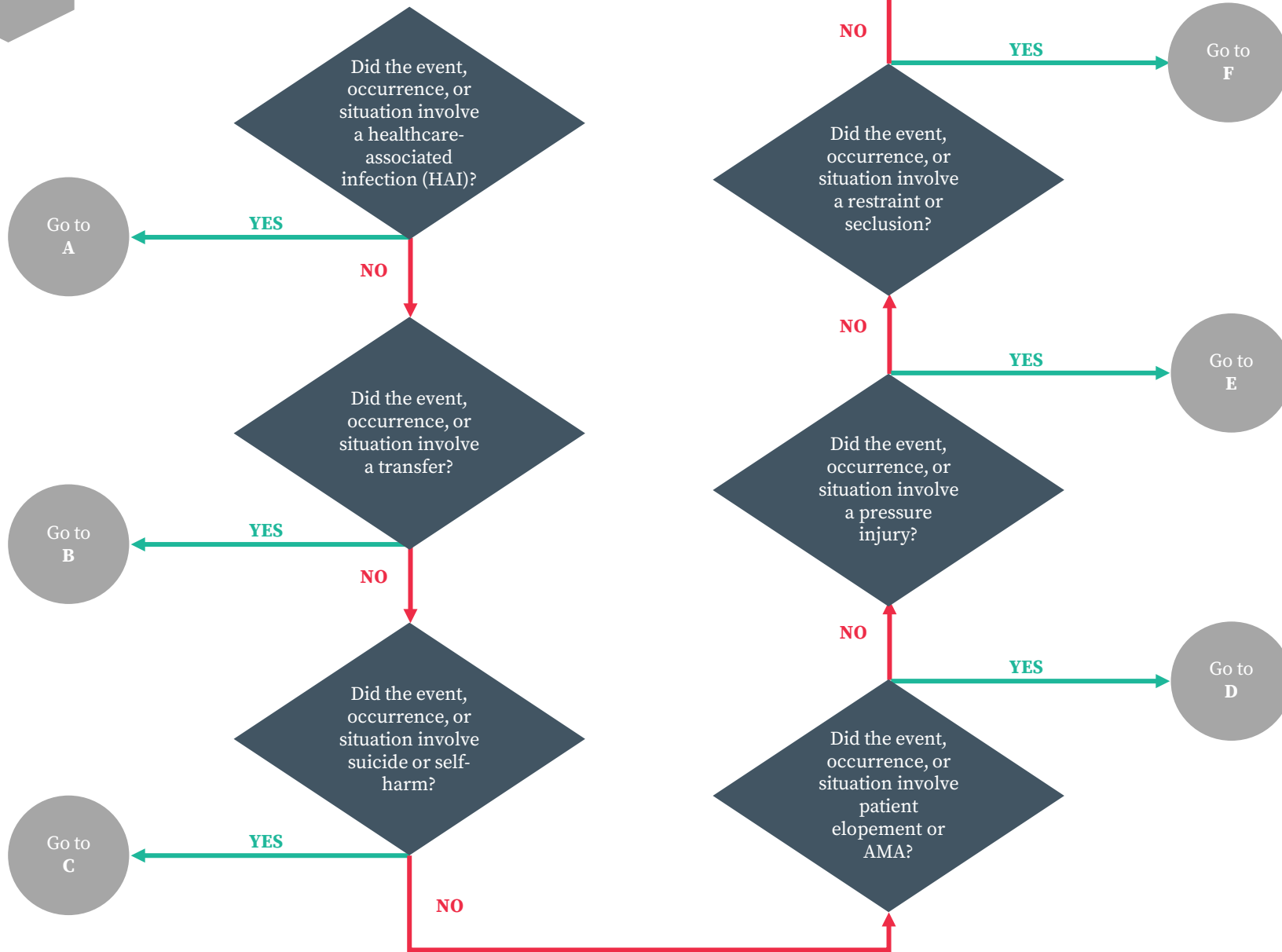
Reporting Decision Tree: Serious Event, Incident, or Infrastructure Failure

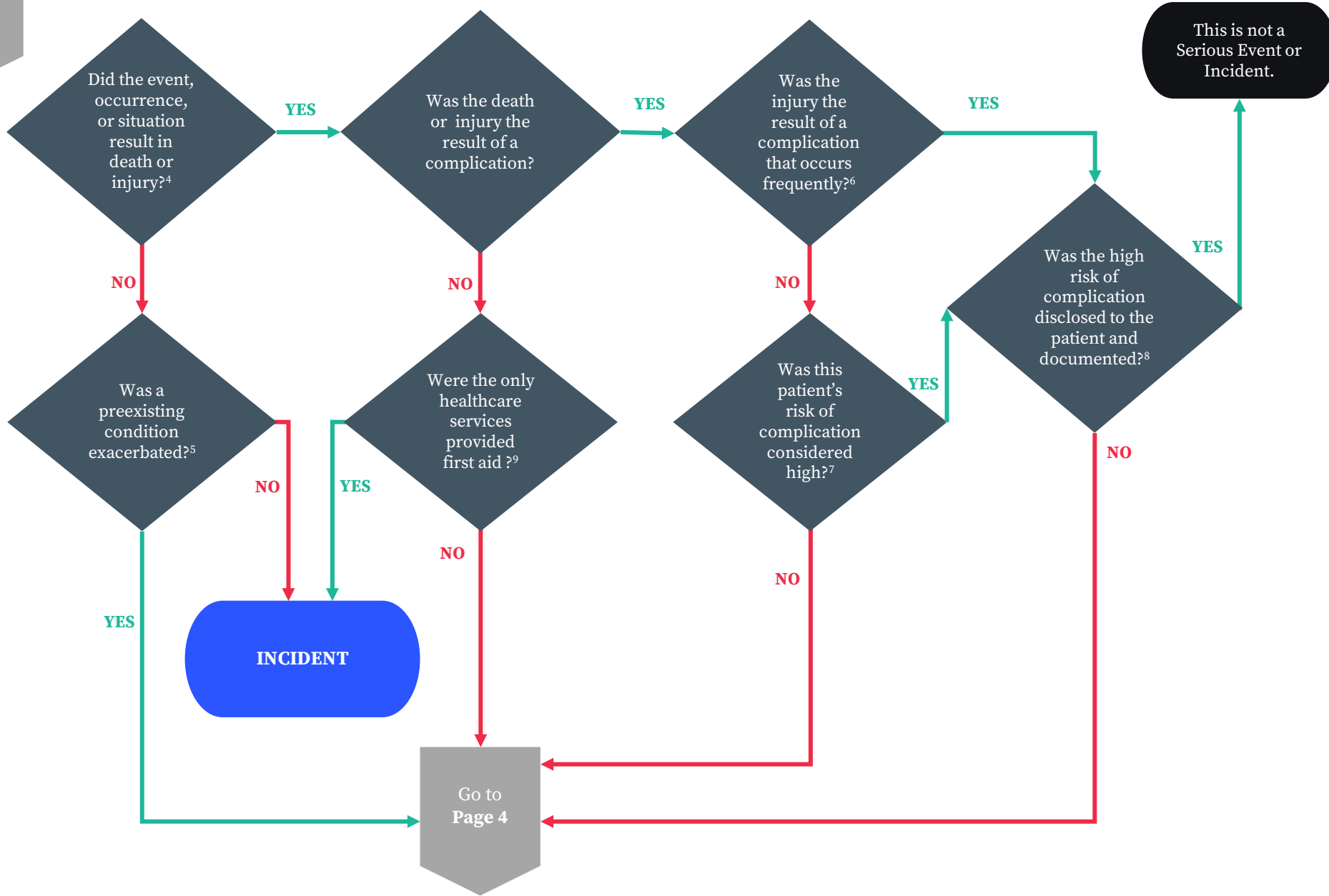
Definitions

- **Serious Event:** An event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient.
- **Incident:** An event, occurrence or situation involving the clinical care of a patient in a medical facility, which could have injured the patient, but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient.
- **Infrastructure Failure:** An undesirable or unintended event, occurrence or situation involving the infrastructure of a medical facility or the discontinuation or significant disruption of a service which could seriously compromise patient safety.

Reporting Decision Tree: Serious Event or Incident¹

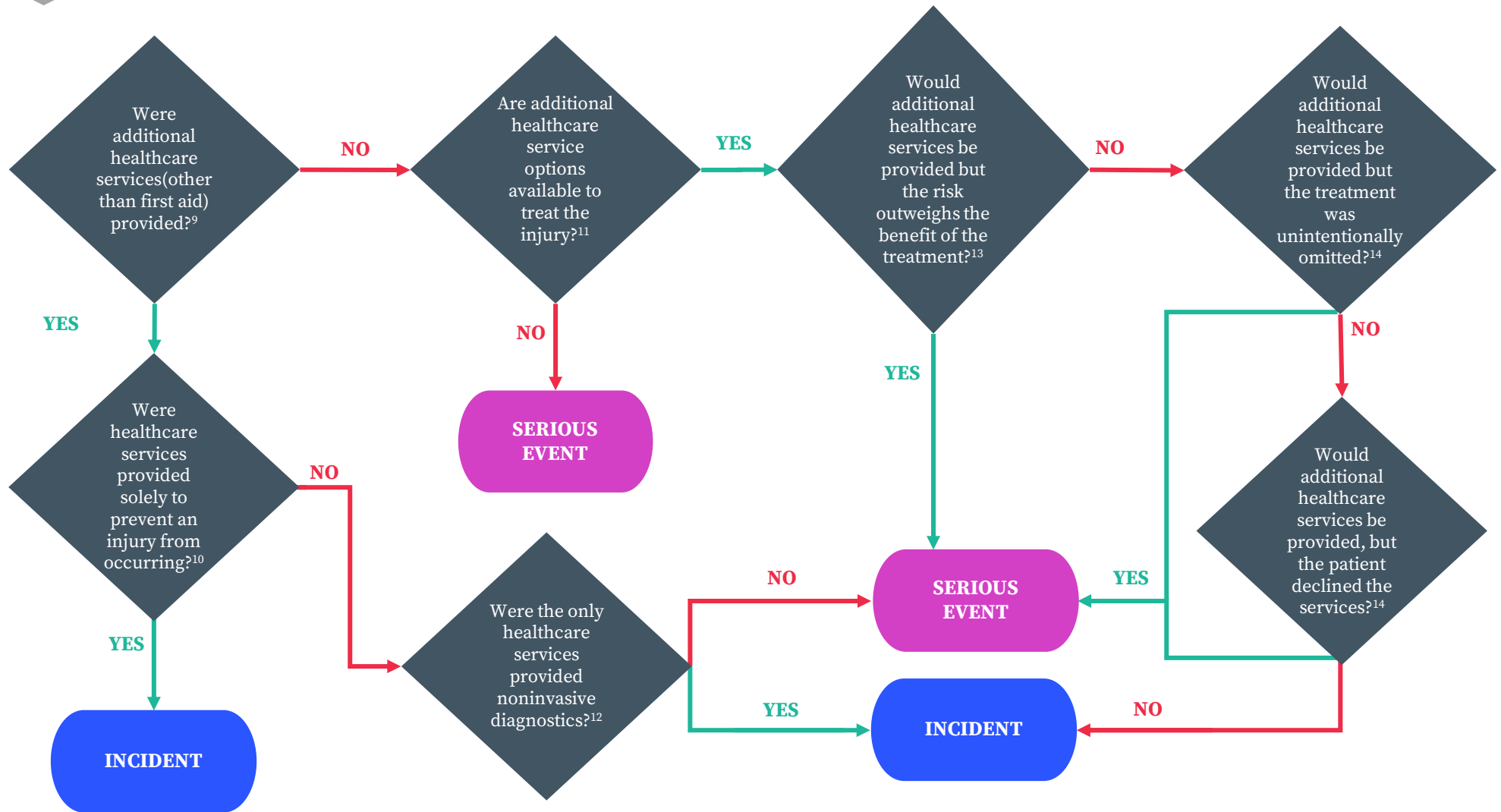




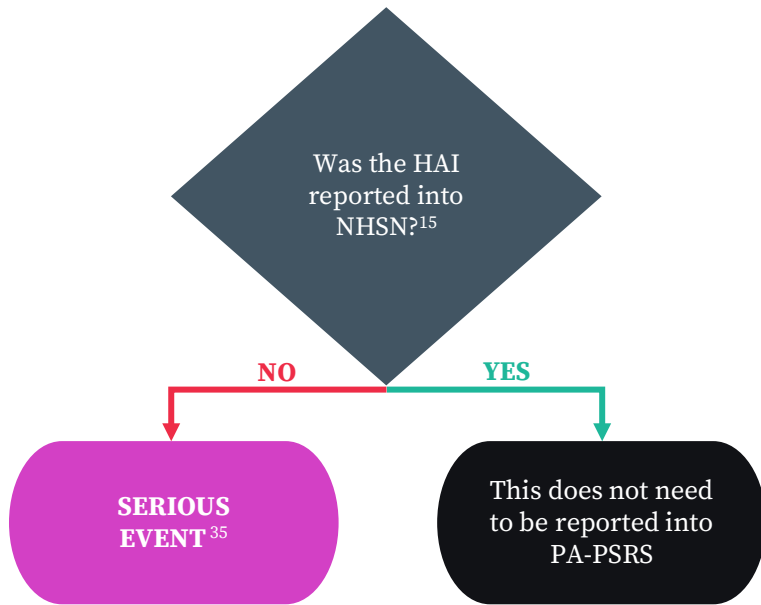


Healthcare Services – (services that must be provided or ordered by a healthcare professional)⁹

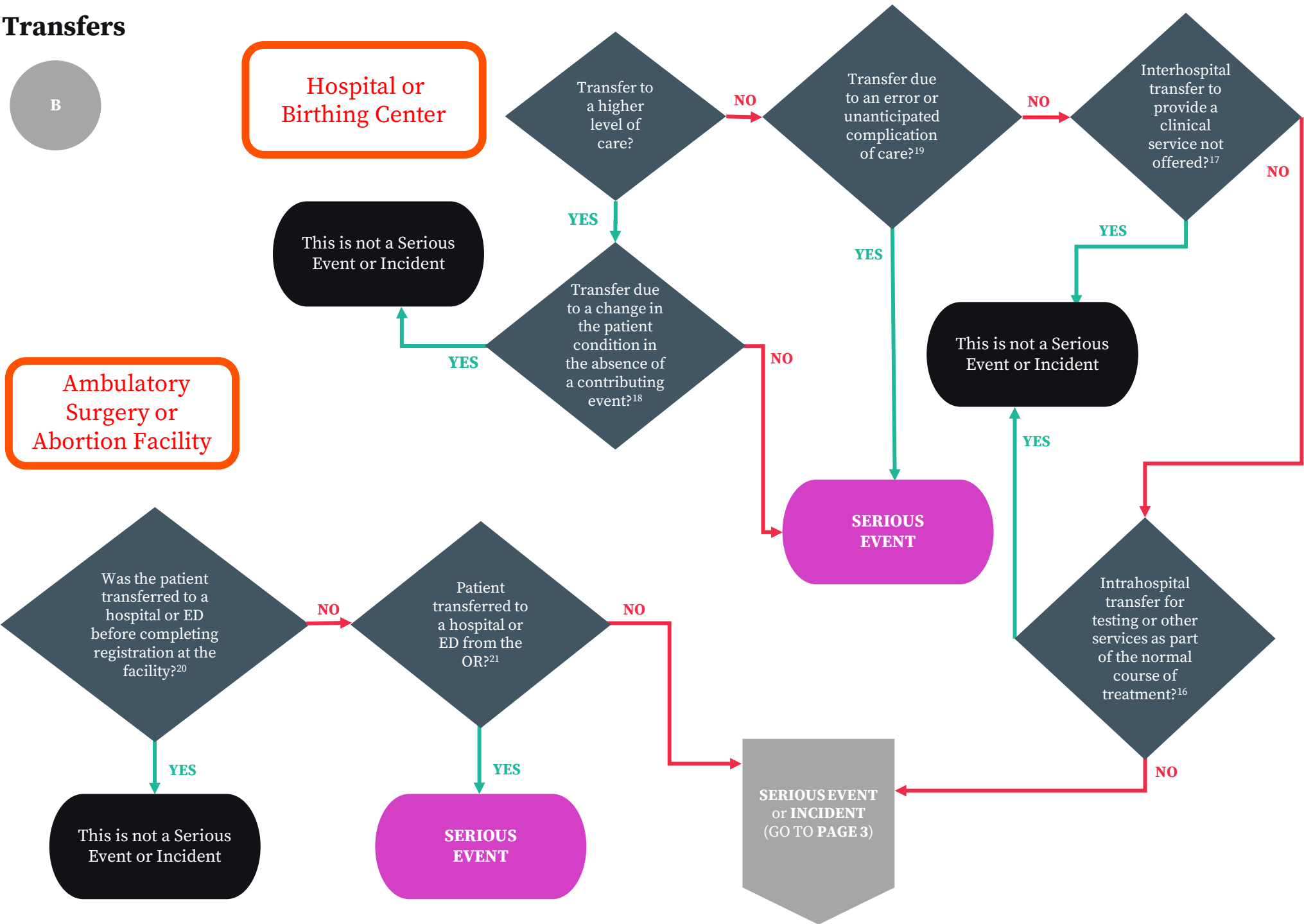
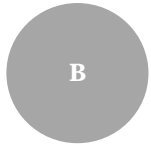
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Page 3



Healthcare-Associated Infections (HAIs)



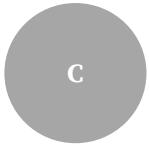
Transfers



Hospital or Birthing Center

Ambulatory Surgery or Abortion Facility

Self-Harm/Suicide



Patient-Intended
Suicide



NO

INFRASTRUCTURE
FAILURE

YES

SERIOUS
EVENT

YES

Patient-Intended
Self-Harm

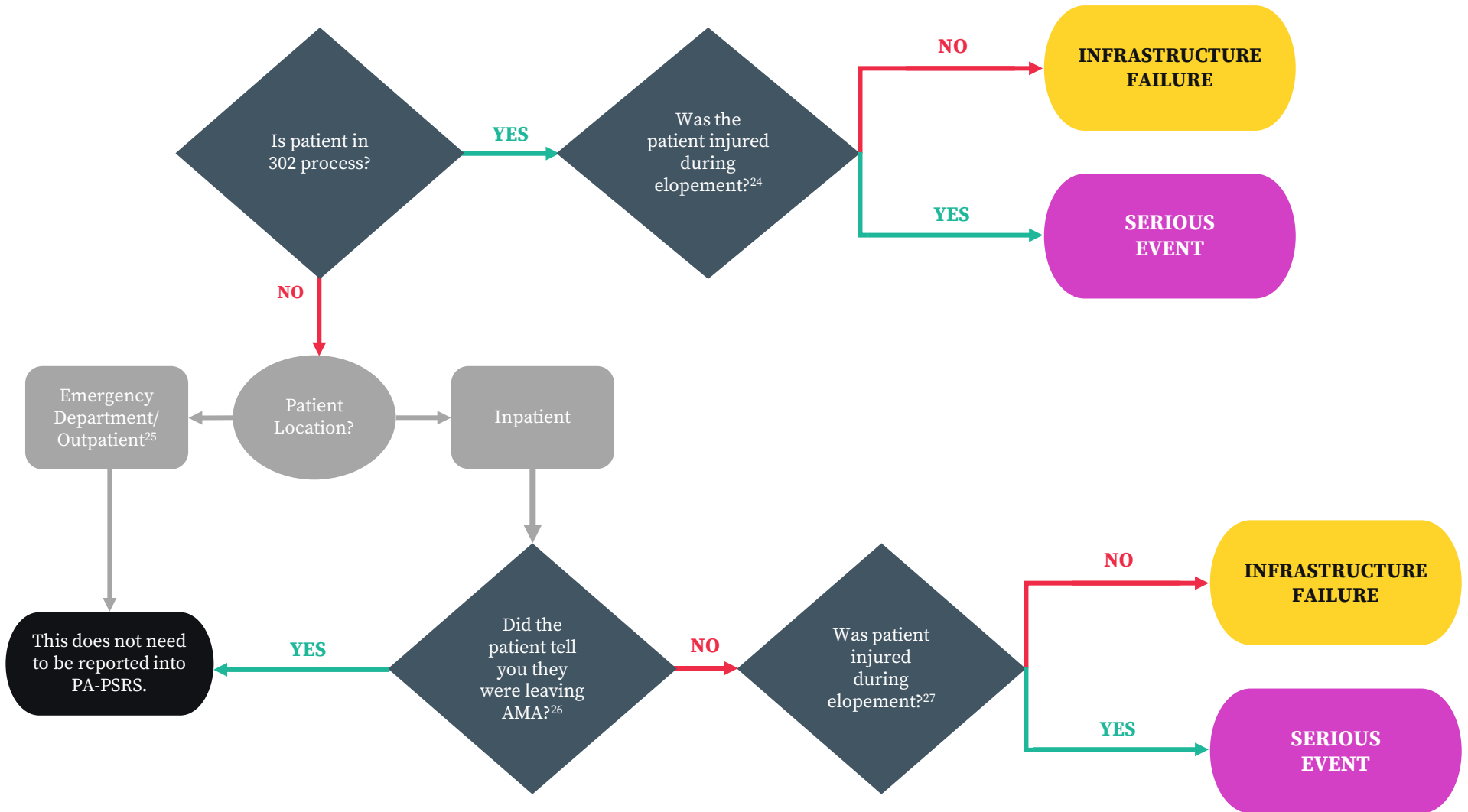


NO

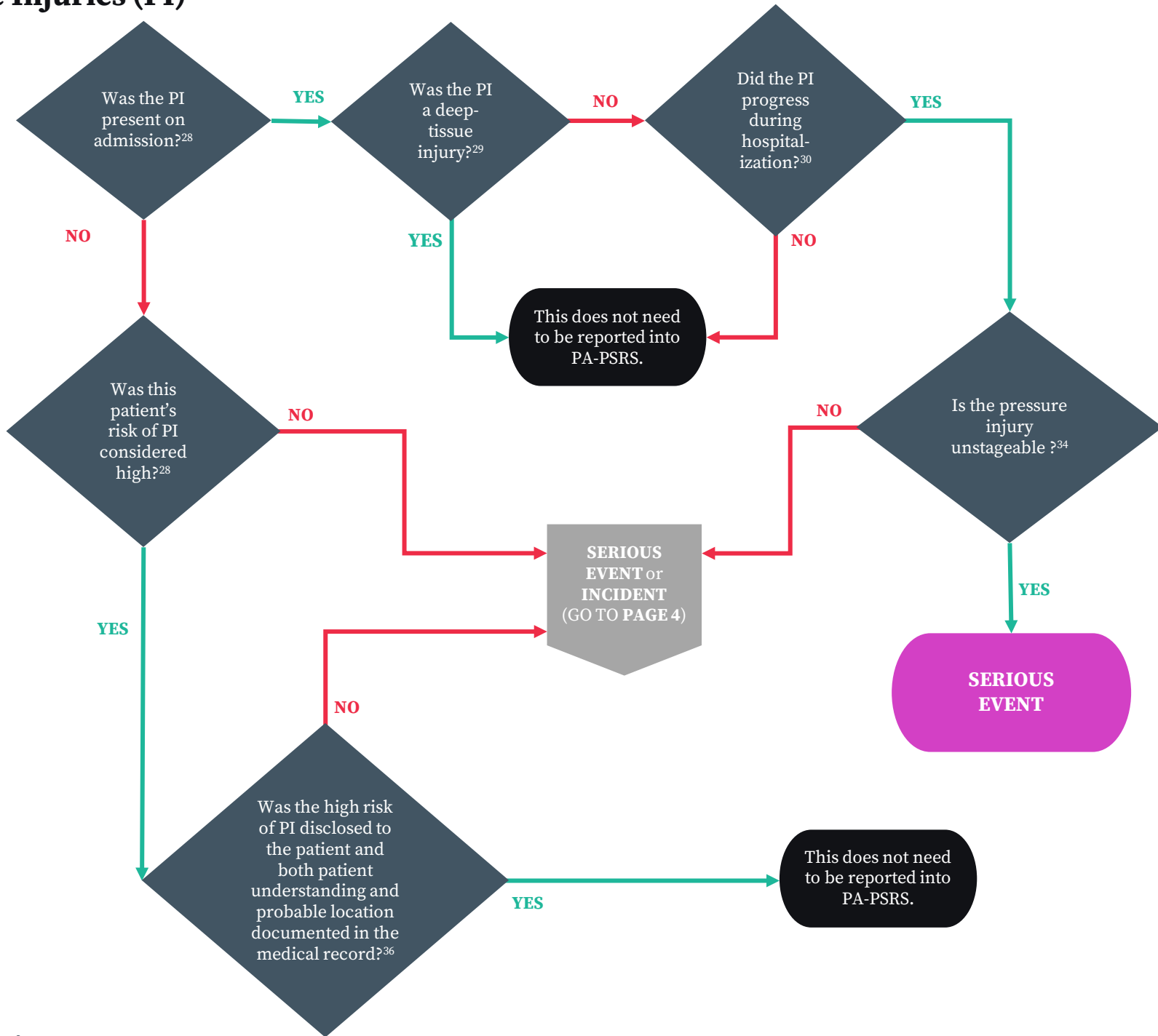
INCIDENT

Elopement/Against Medical Advice (AMA)

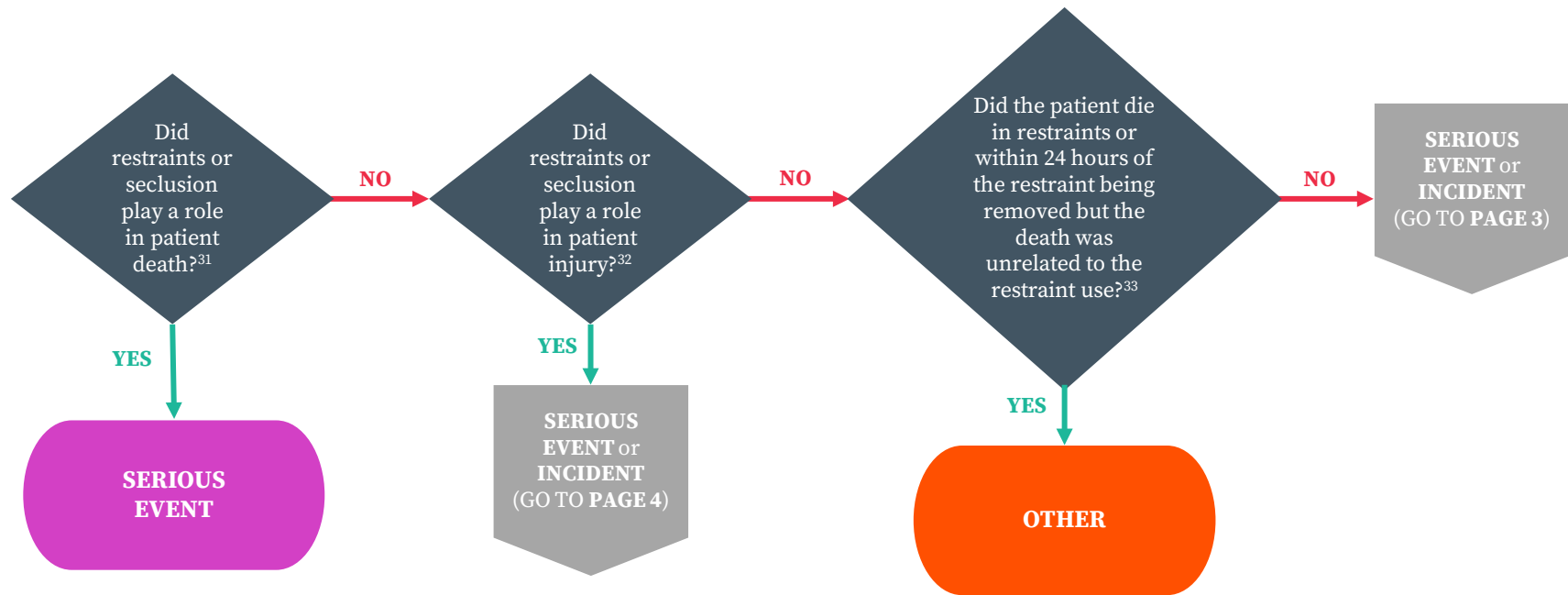
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Pressure Injuries (PI)



Restraints/Seclusion

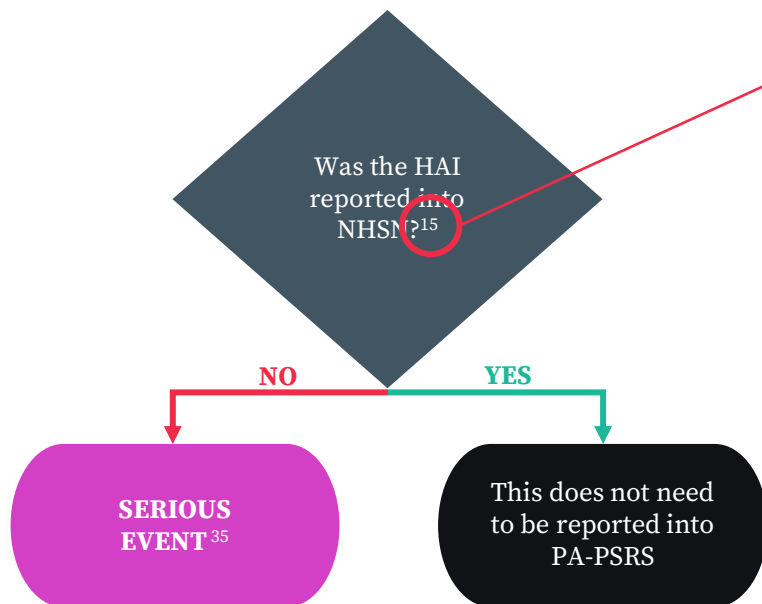


Additional Information

References

- A. Act 13 of 2002: Medical Care Availability And Reduction Of Error (MCARE) Act. Also available: <https://www.legis.state.pa.us/cfdocs/legis/li/uconsCheck.cfm?yr=2002&sessInd=0&act=13>
- B. Act 52 of 2007: MCARE Act. Also available: <https://www.legis.state.pa.us/cfdocs/legis/li/uconsCheck.cfm?yr=2007&sessInd=0&act=52>
- C. (FG) 44 Pa. Bull. 6178 (Sept. 27, 2014). Final guidance for acute healthcare facility determinations of reporting requirements under the MCARE Act. Also available: <http://www.pabulletin.com/secure/data/vol44/44-39/2041.html>
- D. (PI) 47 Pa. Bull. 2163 (April 8, 2017). Final guidance for acute healthcare facility determinations of reporting requirements for pressure injuries under the MCARE Act. Also available: <http://www.pacodeandbulletin.gov/Display/pabull?file=/secure/pabulletin/data/vol47/47-14/599.html>

How to Interpret the Notes Section



15. Healthcare-Associated Infections that meet Centers for Disease Control and Prevention (CDC) definitions/criteria and which a hospital reports into NHSN should not also be reported into PA-PSRS. (FG26)

(FG26) refers to Final Guidance (reference C above) #26.

Notes

1. This includes only select Infrastructure Failures.
2. The concepts of human error and preventability do not appear in the Serious Event definition. It is not necessary for an error to be involved, nor for the harm to be preventable, for a death or unanticipated injury to constitute a Serious Event. (FG1) Deaths or injuries resulting from the patient's disease, in the absence of a contributing event, occurrence or situation, are not Serious Events. (FG10)
3. It is not necessary to report a Serious Event that occurred in another healthcare setting. If the facility discovers a Serious Event that occurred in another facility, the facility is strongly encouraged to notify the other facility. (FG11)
4. Any unnecessary invasive procedure or invasive procedure performed in error that carries risk for the patient constitutes an injury and performance of the correct or intended procedure then constitutes additional healthcare services. These occurrences are Serious Events. (FG8) A mid-procedure change in the plan of care in response to new information discovered during the procedure does not constitute an injury. (FG12)
5. A Serious Event can include an unanticipated event, occurrence or situation that: exacerbates a preexisting condition requiring additional healthcare services (FG6b).
6. A Serious Event that is within statistical norms or within benchmarks available in the clinical literature must still be reported. There is nothing in the law that allows for reporting Serious Events only when they exceed a statistical norm or benchmark. (FG5) The unanticipated nature of the injury is from the perspective of a reasonably prudent patient. While every provider anticipates some rate of complications from the procedures they perform, infrequent complications are rarely anticipated by the patient unless the patient is somehow at increased risk. While the Authority does not specify an exact threshold for the frequency of complications that makes a complication transition from unanticipated to anticipated, complications that occur rarely would be unanticipated by most reasonably prudent patients. (FG2)
7. The disclosure of a potential complication on a patient consent form does not constitute anticipation of the complication by the patient. Informing the patient of a risk does not mean the patient or the provider anticipates that the untoward outcome will occur. (FG3)
8. Complications may be considered anticipated when they occur frequently, or the risk of the complication is considered high for the patient and the high probability of this complication was disclosed to the patient in the informed consent discussion and documented either on the consent form or medical record. (FG4)
9. Services that could be provided by someone other than a licensed healthcare practitioner outside the clinical setting—essentially, first aid care—do not constitute additional healthcare services. (FG13b)
10. Healthcare services provided to prevent an injury from occurring are excluded from this term for the purpose of Serious Event determinations. (FG13a)
11. If a patient sustains an unanticipated injury for which no additional healthcare services are possible, but treatment would be provided if options were available, this is considered a Serious Event. (FG9a)
12. Noninvasive diagnostic services provided to rule out an injury do not constitute additional healthcare services for purposes of the Serious Event determination. (FG13c)
13. If a patient sustains an unanticipated injury and additional healthcare services are possible, but the risk of those services outweighs the negative consequences of the injury, this is considered a Serious Event. (FG9b)
14. If additional healthcare services are required to treat an unanticipated injury and these additional healthcare services are not provided either because of unintentional omission or because the patient declines treatment, the occurrence is still a Serious Event. (FG9c)
15. Healthcare-Associated Infections that meet Centers for Disease Control and Prevention (CDC) definitions/criteria and which a hospital reports into NHSN should not also be reported into PA-PSRS. (FG26)
16. Routine intrahospital transfers between nearby buildings for specialized testing or other services in the normal course of treatment are not reportable. (FG16b)
17. Inpatient transfers from a specialty hospital to an acute care hospital or from one acute hospital to another acute hospital, due to the patient requiring a clinical service not offered in the transferring hospital are not reportable. (FG16d)

Notes (cont.)

18. Routine intrahospital transfers to higher levels of care due to changes in the patient's condition—in the absence of a precipitating event that would meet the definition of a Serious Event, Incident or Infrastructure Failure—are not reportable. (FG16a)
19. Unanticipated intrahospital transfers to higher levels of care due to an error or unanticipated complication of care are reportable as a Serious Event. (FG16c)
20. Transfers and Cancellations from Ambulatory Surgery Facilities: Cancellations prior to completing registration are not reportable. (FG17aii)
21. Intra-operative transfer from an ASF to a hospital is reportable as a Serious Event. (FG17b)
22. Suicide attempts that result in death or injury requiring additional healthcare services are reportable as Serious Events. Suicide attempts not resulting in injury requiring additional healthcare services are reportable as Infrastructure Failures. (FG15a)
23. Other forms of intentional self-harm that result in injury requiring additional healthcare services are reportable as Serious Events. Other forms of intentional self-harm not resulting in injury requiring additional healthcare services may be reportable as Incidents. (FG15b)
24. Elopement of a patient who has been involuntarily committed or is in the process of being involuntarily committed is reportable as an Infrastructure Failure. If the patient is injured during the elopement, this is reportable as a Serious Event. (FG18b)
25. Patients leaving the ED waiting room or treatment area without being seen are not reportable unless they are in the 302 process. (FG18a)
26. Events in which a patient leaves against medical advice (AMA), whether they sign a waiver, are not reportable. (FG20)
27. Inpatient elopements are reportable as Infrastructure Failures. If an eloped patient is injured during an elopement, this is reportable as a Serious Event. (FG19)
28. Incidents: All unanticipated hospital-acquired pressure injuries that do not require additional health care services (PI1b1)
Serious Events: All unanticipated hospital-acquired pressure injuries that require additional health care services (PI1c1)
29. Not reportable: Deep tissue injuries present on admission (PI1a1)
30. Not reportable: All pressure injuries present on admission that remain stable (that is, unchanged) or improve during hospitalization (PI1a2)
Incidents: All pressure injuries present on admission that progress during the hospitalization but do not require additional healthcare services (PI1b2)
Serious Events: All pressure injuries present on admission that progress or worsen during the hospitalization and require additional healthcare services (PI1c2). Report changes (i.e., worsening) in pressure injuries. Whether a pressure injury was present on admission or was hospital-acquired, if the injury progresses or worsens during hospitalization, acute healthcare facilities should report a Serious Event or Incident based on the deepest stage of any pressure injuries that progress (PI3).
31. Restraint-related or seclusion-related death or injury are reportable as Serious Events. (FG14a)
32. Restraints or seclusion may be involved in Incidents in which there is no death or injury requiring additional healthcare services. (FG14b)
33. Any death in restraints or in which restraints were used within 24 hours of death (other than soft wrist restraints) in which the restraints are not suspected of playing a role are reportable as "Other." (FG14c)
34. An unstageable pressure injury that develops or progresses during admission is reportable as a Serious Event (PIResponse14)
35. The occurrence of a healthcare-associated infection in a healthcare facility shall be deemed a Serious Event [Act 52, Section 405(a)]
36. Complications and injuries from clinical care may be considered anticipated (that is, not reportable as a Serious Event) when they occur frequently or the risk of the complication is considered high for a particular patient and the high probability of this complication was: (1) disclosed to the patient or the patient's representative, or both; and (2) documented in the medical record, including the patient's understanding and the probable location of the pressure injury that is expected to develop if preventive measures are not implemented (PIResponse7).