

Adverse Event Reporting – Quick Reference Sheet

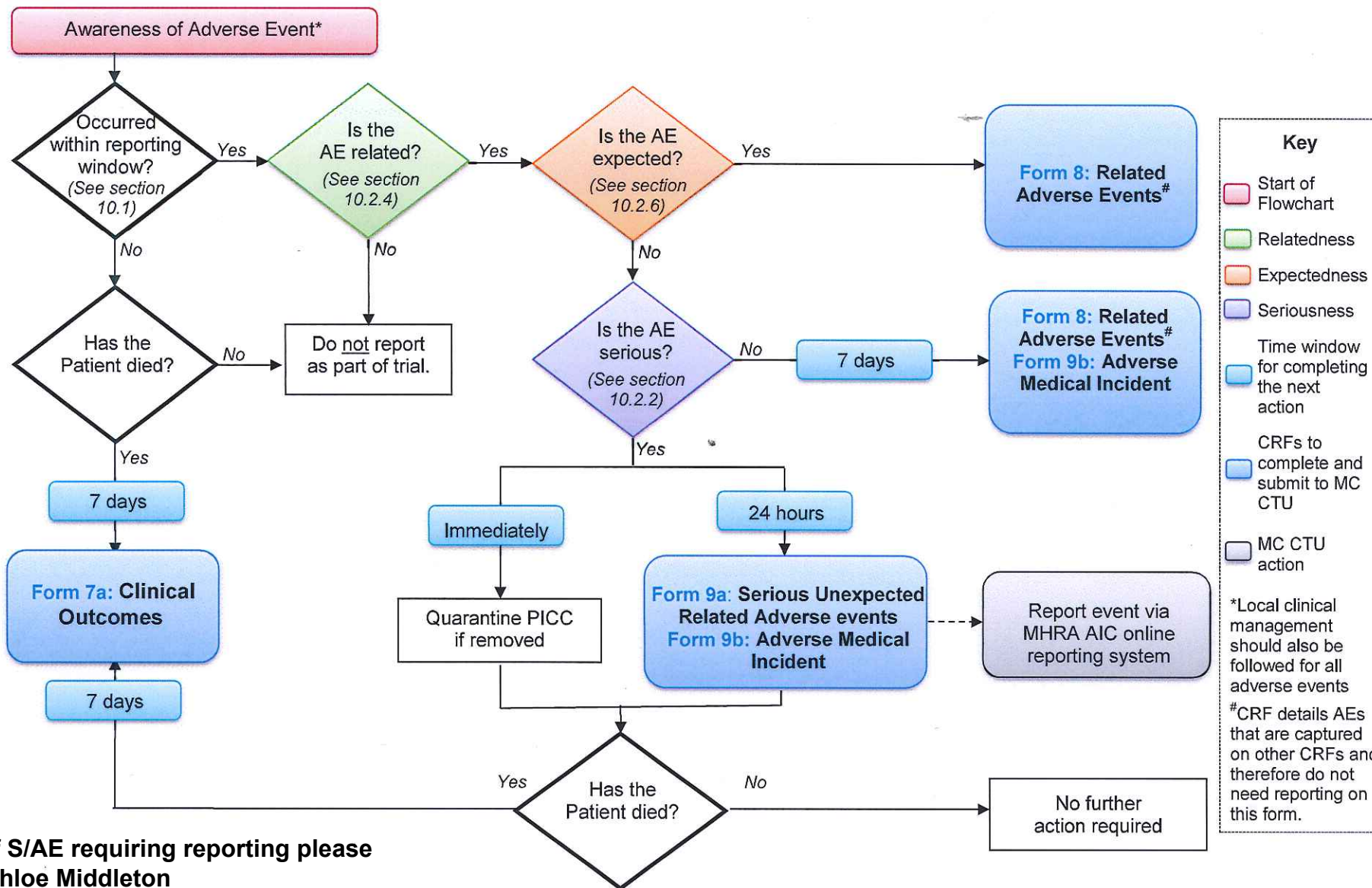
Event	Relatedness	Expectedness	Seriousness	Reporting to MC CTU required within	Forms to complete
	<i>For definition see section 10.2.4 of Protocol</i>	<i>For definition see section 10.2.6 of Protocol</i>	<i>For definition see section 10.2.2 of Protocol</i>		
	Related	Not-expected	Serious ¹	24 hours	Form 9a: Serious Unexpected Related Adverse Events Form 9b: Medical Device Adverse Incident Report ²
	Related	Expected	Serious ¹	7 days	Form 8: Related Adverse events
	Related	Not-expected	Not Serious	7 days	Form 8: Related Adverse events
	Related	Expected	Not Serious	7 days	Form 8: Related Adverse events
	Not related	N/A	N/A ¹	None	None

¹ If outcome of event is death, this should also be recorded on Form 7a: Clinical Outcomes, independent of relatedness or expectedness. ² Once Form 9b: Medical Device Adverse Incident Reports submitted to the MC CTU, it is the responsibility of the MC CTU to report the event to the Medicines and Healthcare products Regulatory Agency Adverse Incident Centre (MHRA AIC) via the online reporting system.

Expected AEs Associated with PICC Insertion that DO need to be recorded on Form 8: Related Adverse Events

Adverse Event Description
Cardiac tamponade
Catheter damage
Difficulty in successfully flushing catheter or other evidence of catheter blockage
Difficulty in removing catheter
Extravasation
Hypersensitive reaction to PICC (rifampicin or miconazole)
Perforation in line
Skin damage associated with line dressing
Swelling at line site / haematoma at line site

Flowchart for reporting of Adverse Events – Quick Reference Sheet



Key

- Start of Flowchart
- Relatedness
- Expectedness
- Seriousness
- Time window for completing the next action
- CRFs to complete and submit to MC CTU
- MC CTU action

*Local clinical management should also be followed for all adverse events

#CRF details AEs that are captured on other CRFs and therefore do not need reporting on this form.

In case of S/AE requiring reporting please contact Chloe Middleton
 Email: prevail@liverpool.ac.uk
 Phone: 0151 282 4716
 Fax: 0151 282 4721