National School of Healthcare Science

NHS England

IACC 2023 Case-based discussion (CBD) scenario

Specialty:	Clinical Bioinformatics Genomics

CBD Scenario

CBD Scenario Title	Documentation Errors									
CBD Scenario Aim	For the trainee to demonstrate their understanding of the importance of correct documentation, the implications of poor documentation, and the process for handling errors in documentation if they are identified.									
CBD Focus (please provide the codes of the module(s) this scenario addresses)	SBI129 competence 6 SBI126 competence 6 SBI120 competence 1		SCC110 competence 21							
GSP Domains covered (enter X to indicate all that apply)	**GSP 1**	X	**GSP 2**	X	**GSP 3**	X	**GSP 4**		**GSP 5**	
CBD Scenario description	You discover that some patient results were incorrectly interpreted because the standard operating procedure, describing the variant filtering process had not been updated following a version release of the decision support software used in the laboratory. What immediate actions should be taken to address the error, and what recommendations would you make to avoid this happening in the future?									
CBD Scenario model answer/ assessor guidance Detailed guidance that will be available for the assessors. Include guidance on what kinds of behaviours, actions, comments should secure a pass. What should the assessor expect to see? Assessors will be asked	**Pass indicators** Some or all of the following points discussed: Immediate actions: • Identify how many patient cases might have been impacted by the error and ensure that arrangements are made for them to be checked to ensure patients get the correct results to support their care									

to plan questions in advance including links to trainee's IACC submission.	• Communicate with the relevant staff/teams within the laboratory to make sure no more patient data is processed until the standard operating procedure is updated
	• Update the standard operating procedure to the correct process
	• Record the error in the quality management system (e.g. by raising a CAPA in Q-Pulse or logging a non-conformance) and carry out a root cause analysis
	
	Recommendations:
	• These will depend on the outcome of the root cause analysis
	• Consider reviewing the process for software updates to ensure updating relevant documentation is included
	• Make sure that documents such as standard operating procedures are stored in the quality management systems and are being reviewed as appropriate
	
	General points:
	• Trainee notes that they would work alongside other colleagues for most of the above, who may include:
	  ○ their supervisor,
	  ○ other members of the bioinformatics team,
	  ○ the quality manager or members of the quality team,
	  ○ Clinical Scientists in Genomics who might be analysing the data
	• Importance of good communication between all those involved.
	
	Fail indicators
	• No mention of potential impact on patient care
	• No mention of logging the error

Trainee instructions Please include any specific information to be provided to the trainee as part of the CBD scenario	

Criteria being assessed by this CBD scenario

Aspect	Please indicate if this criterion is being assessed
1. Understands the clinical context of the scenario, including priority setting and testing strategies	X
2. Understands scientific principles of scenario	

3. Can discuss the relevant procedures involved in the scenario and associated health and safety issues	X
4. Understands and applies the appropriate test validation, IQC, EQA, relevant professional/clinical guidelines	
5. Understands and applies associated IT/bioinformatics and other appropriate resources	
6. Is able to interpret and report patient results and provide appropriate clinical advice	
7. Can discuss the significance of patient results within the clinical context of the referral	
8. Understands the ethical, legal and social implications of the scenario	X
9. Is aware of the importance of audit and can use this tool effectively	
10. Output meets accepted laboratory/professional standards	
11. Demonstrates awareness of the limits of responsibility and when to seek advice	X
12. Consideration of patient/professionalism	X
13. Overall ability to perform	