AI in Healthcare: The Risk of Insufficient Governance

FMEA

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Failure Mode Effect Analysis

To mitigate potential reliability and safety concerns, this white paper will provide a Failure Mode Effect Analysis (FMEA) to study the development and integration of AI-based healthcare delivery tools across five main steps:

1. Health IT Organizations (AI development partners) produce innovations in Health AI and submit preliminary findings to the proposed governance program's Institutional Review Board (IRB). See Figure A1(1) for a detailed overview of the process and Table A1 for further analysis.
2. Once approved, healthcare organizations can update software and hardware according to the developers' specifications. See Figure A1(2) for a detailed overview of the process and Table A2 for further analysis.
3. Once software and hardware functionalities have been validated, healthcare organizations can implement these new tools in patient care settings. See Figure A2(3) for a detailed overview of the process and Table A3 for further analysis.
4. Healthcare organizations and the governance program must begin monitoring the tool for quality and reliability. See Figure A2(4) for a detailed overview of the process and Table A4 for further analysis.
5. Healthcare organizations and providers must report errors and other patient safety concerns when they occur. The governance program's IRB must review these error reports and determine a course of action that upholds patient safety standards and reliable healthcare delivery. See Figure A3(5) for a detailed overview of the process and Table A5 for further analysis.

Appendix A

Figure A1

FMEA Process Flow (Steps 1 & 2)

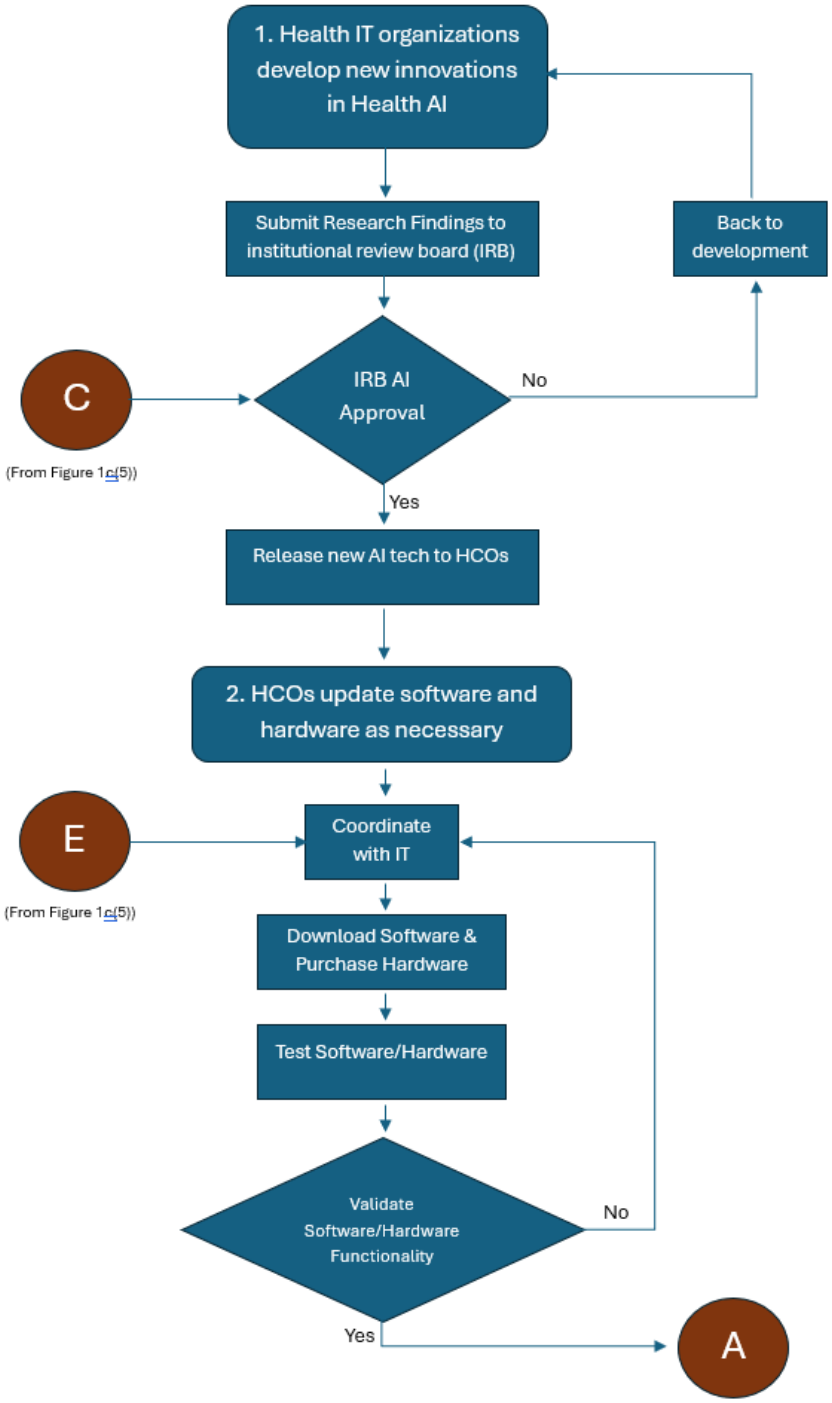

Figure A2

FMEA Process Flow (Steps 3 & 4)

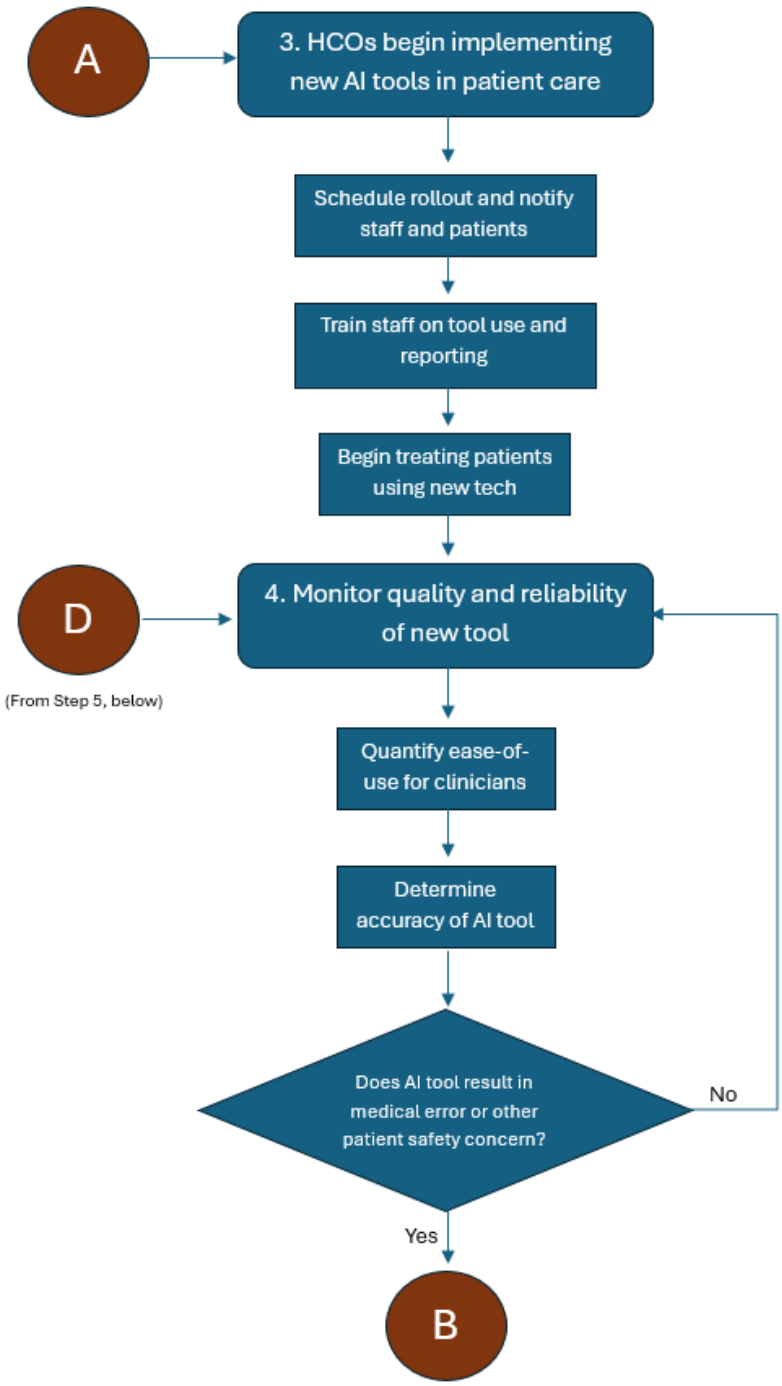

Figure A3

FMEA Process Flow (Step 5)

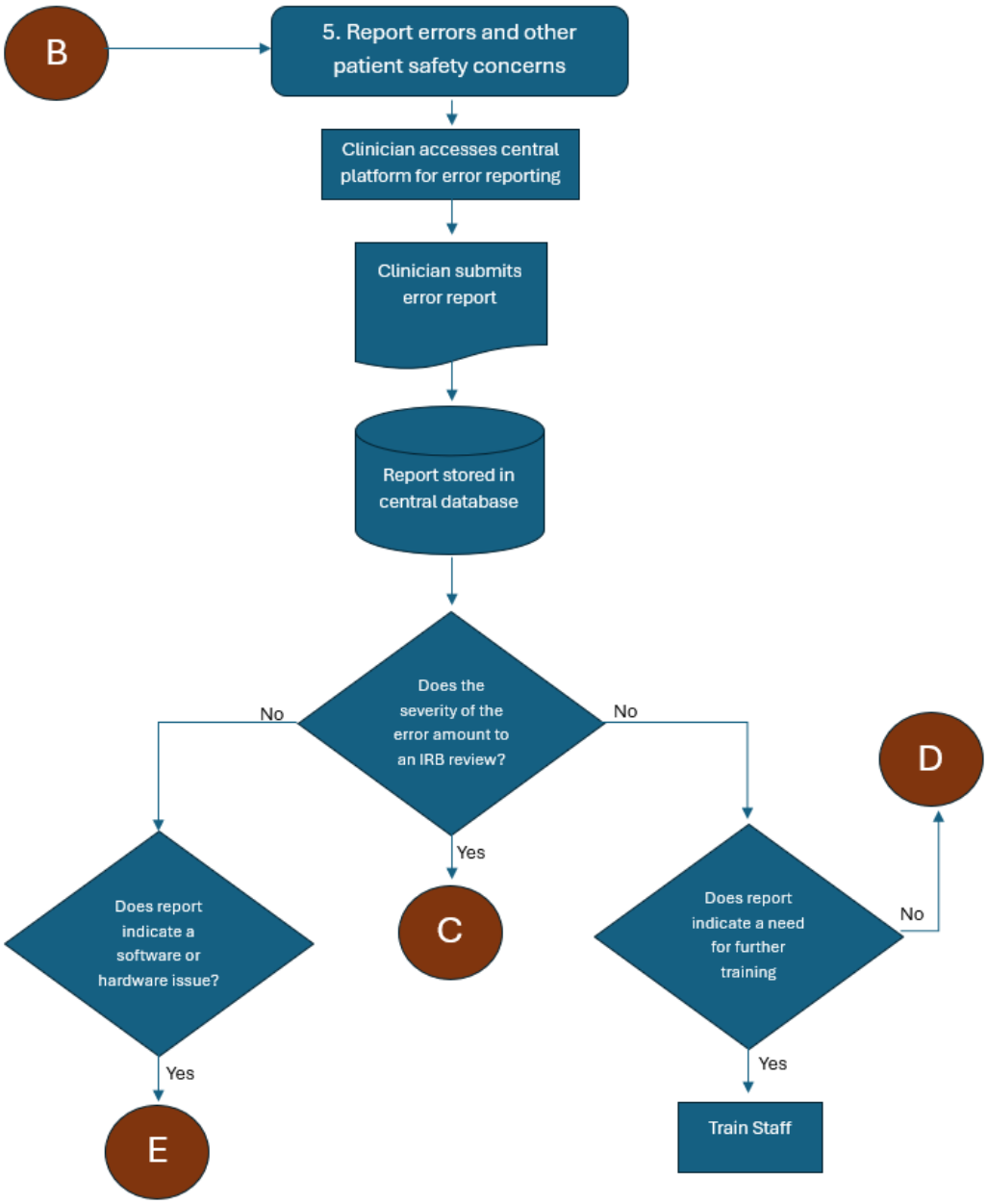

Table A1

FMEA Process Step 1 – Health IT Develops New AI Tool

Process Step #1	1	Process Step	Health IT Develops new AI tool		
	2	Potential Failure Mode	The AI model is overtrained/inaccurate	AI model uses the wrong statistical model	AI model integrated into faulty software
	3	Potential Cause	A small amount and low variety of training data	Wrong statistical assumptions made during development	Improper programming techniques
	4	Severity	Major	Major	Moderate
	5	Probability	Frequent	Uncommon	Uncommon
	6	Hazard Score	12	6	4
	7	Action	Eliminate	Eliminate	Control
	8	Description of Action	1. Ensure the model has access to variable data 2. Use actual data to develop a model 3. Check for overfitting using standard ML/AI methods	1. Validate the statistical method using test data 2. Remove the model from patient care to prevent severe error 3. Report findings to IRB and developer	1. Report software bugs as soon as they are found 2. Enroll the IT department to communicate faults with the developer 3. Coordinate with developers to maintain software patches

Table A2

FMEA Process Step 2 – HCO Software and Hardware Updates

Process Step #2	1	Process Step	HCO Software and Hardware Updates		
	2	Potential Failure Mode	Software update does not complete properly	Technical Infrastructure cannot support software	Updates cause unforeseen security issues
	3	Potential Cause	Insufficient technical infrastructure	Insufficient computing power	Faulty software design
	4	Severity	Minor	Moderate	Moderate
	5	Probability	Occasional	Occasional	Occasional
	6	Hazard Score	3	6	6
	7	Action	Eliminate	Eliminate	Eliminate
	8	Description of Action	1. Plan software updates during downtime 2. Dedicate IT resources to ensure software updates properly 3. Enlist the help of developers to ensure the software update completes	1. Check hardware requirements before initiating the upgrade 2. Upgrade infrastructure to ensure minimum hardware requirements 3. Ensure IT staff are available during hardware upgrades and software updates	1. Ensure cybersecurity systems are in place to monitor vulnerabilities 2. Deploy software updates in a siloed testing environment before deploying to production 3. Employ penetration testing to ensure that software updates do not introduce unforeseen vulnerabilities

Table A3

FMEA Process Step 3 – HCO Implements New AI Tool

Process Step #3	1	Process Step	HCO Implements New AI Tool		
	2	Potential Failure Mode	Staff reject AI tool	Patients reject AI tool	Delays in software rollout
	3	Potential Cause	Unfriendly user interface	Concerns over safety and privacy	Training, software, or hardware issues
	4	Severity	Minor	Minor	Minor
	5	Probability	Occasional	Frequent	Frequent
	6	Hazard Score	3	4	3
	7	Action	Control	Accept	Control
	8	Description of Action	1. Educate staff on tool benefits and provide significant opportunities for discourse 2. Develop and implement a significant training regimen 3. Use incentives to motivate staff to use tools	1. Educate the patient on the tool's functionality and answer questions 2. Respect patient's wishes not to receive AI-powered healthcare 3. Note the patient's wishes in their chart to prevent future difficulties	1. Coordinate with IT and staff to develop a software implementation plan 2. Design timelines with room for error 3. Ensure open channels of communication between various departments for setbacks or other errors

Table A4

FMEA Process Step 4 – Monitor Quality and Reliability

Process Step #4	1	Process Step	Monitor Quality and Reliability		
	2	Potential Failure Mode	Staff do not provide accurate feedback	Staff do not use AI tools per training	Staff reject AI tools
	3	Potential Cause	Fear and/or dislike of AI-based technology	Confusing user-interfaces	Inaccurate or unclear model outputs
	4	Severity	Moderate	Major	Minor
	5	Probability	Frequent	Frequent	Frequent
	6	Hazard Score	8	12	4
	7	Action	Control	Control	Control
	8	Description of Action	1. Incentivize honest feedback 2. Use quantitative metrics to gauge tool performance 3. Provide statistical and software education to staff to improve technical literacy	1. Provide regular training 2. Work with developers to improve software usability 3. Garner feedback from staff	1. Provide regular training 2. Communicate staff feedback with developers 3. Work with developers to improve model transparency and facilitate model augmentation

Table A5

FMEA Process Step 5 – Report Errors

Process Step #5	1	Process Step	Report Errors		
	2	Potential Failure Mode	Staff cannot access reporting tools on QMS platform	Reports are not databased properly	Reports are not flagged for review properly
	3	Potential Cause	QMS platform servers are under maintenance	Errors in report submission, Invalid responses	Inadequate description of the issue
	4	Severity	Minor	Minor	Major
	5	Probability	Occasional	Frequent	Occasional
	6	Hazard Score	3	4	9
	7	Action	Control/Eliminate	Eliminate	Eliminate
	8	Description of Action	1. Control: Schedule maintenance during non-peak hours. 2. Ensure users are alerted to planned maintenance well in advance. 3. Eliminate: Ensure significant redundancy in QMS-hosting servers	1. Ensure software can handle variations in data entry. 2. Communicate errors in data entry to the user before sign-off. 3. Save data as it is entered. 4. Choose no-SQL databases (if possible).	1. Provide training on reporting best practices. 2. Champion a culture of quality. 3. Ensure that reports are flagged appropriately by reviewers