

Supplementary Table S1 - Search queries

Date	Database	Search query	Results
31/10/2023	PUBMED	("healthcare failure mode and effect analysis"[MeSH Terms] OR "Risk Assessment"[Mesh]) AND ("Failure mode and effects analysis" [Title/Abstract] OR FMEA[Title/Abstract]) Filters: English, Italian Sort by: Most Recent	262
31/10/2023	EMBASE	('healthcare failure mode and effect analysis'/exp OR 'risk assessment'/exp) AND ('failure mode and effects analysis'/exp OR 'failure modes and effects analysis:ab,ti' OR 'fault mode and effect analysis':ab,ti OR 'fmea':ab,ti OR 'failure mode and effects analysis':ab,ti) AND ([article]/lim OR [article in press]/lim OR [review]/lim) AND ([english]/lim OR [italian]/lim) AND [humans]/lim	351

Supplementary Table S2 - List of all the selected articles on the use of FMEA in healthcare setting. Studies related to infectious diseases, antimicrobials and infection control are highlighted in bold type (ADHD: attention-deficit/hyperactivity disorder; CBC: complete blood count; CIEDs: cardiac-implanted electronic devices; ED: emergency department; ICU: intensive care unit; IVF: in vitro fertilization; MDROs: multi-drug resistant microorganisms; MRI: magnetic resonance imaging; N/A: not applicable; OPAT: outpatient parenteral antimicrobial therapy; USA: United States of America).

Study reference	Year	Country	Type of Study	Category	Sub-category	Detailed application area	Number of failure modes	Suggested corrective actions
[1]	2019	China	Systematic review	Hospital management Healthcare process	Healthcare process	Healthcare process	N/A	N/A
[2]	2022	Tunisia	Prospective analytical study	Healthcare process	Medication use process	Medication use process	24	Yes
[3]	2013	United Kingdom	Prospective analytical study	Healthcare process	Surgery	Robotic surgery	51	Yes
[4]	2021	USA	Prospective analytical study	Healthcare process	Radiation therapy	Total body irradiation	87	Yes
[5]	2015	Egypt	Prospective analytical study	Healthcare process	Medication use process	Infusion therapy in ICU	11	Yes
[6]	2014	Saudi Arabia	Prospective analytical study	Hospital management	Communication and patient handoff	Treatment of septic patients from ED	48	Yes
[7]	2017	Iran	Cross-sectional study	Hospital management Healthcare process	Medication administration. Testing in clinical laboratory. Infectious diseases, antimicrobials and infection control.	Common clinical errors in neonatal ICU	57	Yes
[8]	2021	Brazil	Prospective analytical study	Healthcare process	Other treatment processes	Organ donation-transplantation process	30	No
[9]	2020	Egypt	Cross-sectional study	Healthcare process	Blood transfusion	Blood transfusion	38	Yes
[10]	2020	Sri Lanka	Systematic review	Hospital management Healthcare process	Medication administration. Medication use process	Medication safety	N/A	N/A
[11]	2017	Spain	Prospective analytical study	Healthcare process	Medication use process	Use of oral syringes	5	Yes
[12]	2017	Spain	Retrospective analytical study	Healthcare process	Other treatment processes	Dialysis	21	Yes
[13]	2014	Spain	Retrospective analytical study	Healthcare process	Other treatment processes	Neonatal parenteral nutrition	82	Yes
[14]	2012	Iran	Prospective analytical study	Healthcare process	ICU process	ICU process	48	Yes

[15]	2017	Iran	Systematic review	Hospital management Healthcare process	Medication administration. Medication use process	Medication administration. Medication use process	N/A	N/A
[16]	2011	United Kingdom	Prospective analytical study	Healthcare process	Chemotherapy	Chemotherapy administration	30	Yes
[17]	2020	Germany	Prospective analytical study	Healthcare process	Radiation therapy	Radiation oncology	29	No
[18]	2013	Italy	Prospective analytical study	Hospital management	Communication and patient handoff	Communication failures among health professionals working in the ED	22	Yes
[19]	2023	Morocco	Prospective analytical study	Healthcare process	Medication use process	Cytotoxics preparation	12	Yes
[20]	2014	Italy	Prospective analytical study	Healthcare process	Other treatment processes	Dialysis	92	Yes
[21]	2021	USA	Prospective analytical study	Healthcare process	Radiation therapy	Breast radiotherapy	57	Yes
[22]	2023	Italy	Prospective analytical study	Healthcare process	Chemotherapy	Chemotherapy administration	22	Yes
[23]	2019	Italy	Prospective analytical study	Healthcare process	Other treatment processes	Testicular sperm extraction	19	Yes
[24]	2013	Italy	Prospective analytical study	Healthcare process	Radiation therapy	Scanned proton beam radiotherapy	44	Yes
[25]	2023	Italy	Prospective analytical study	Healthcare process	Healthcare support activities	Colorectal cancer screening	23	Yes
[26]	2009	Italy	Systematic review	Healthcare process	Testing in clinical laboratory	Blood cross-matching, clinical chemistry analytes, and point-of-care testing	N/A	N/A
[27]	2023	Spain	Cross-sectional study	Healthcare process	Surgery	Surgery	26	No
[28]	2015	USA	Prospective analytical study	Healthcare process	Infectious diseases, antimicrobials and infection control	Antimicrobial drugs interaction with anticoagulants	134	Yes
[29]	2020	USA	Prospective analytical study	Hospital management	Healthcare support management	Simulation-based clinical systems testing in pandemic response	109	Yes
[30]	2007	USA	Prospective analytical study	Hospital management	Healthcare support management	Patient registration process	8	Yes
[31]	2006	USA	Prospective analytical study	Healthcare process	Other treatment processes	Dialysis	6	Yes
[32]	2015	Iran	Cross-sectional study	Healthcare process	Blood transfusion	Blood transfusion in pediatric emergency	77	Yes

[33]	2012	USA	Prospective analytical study	Healthcare process	Radiation therapy	Radiation oncology	108	Yes
[34]	2023	Bahrain	Prospective analytical study	Hospital informatization	None	Medication delivery	9	Yes
[35]	2017	USA	Prospective analytical study	Healthcare process	Radiation therapy	Intensity modulated radiation therapy	11	No
[36]	2021	USA	Prospective analytical study	Healthcare process	Chemotherapy	Chemotherapy preparation	16	Yes
[37]	2016	Croatia	Prospective analytical study	Healthcare process	Testing in clinical laboratory	Preanalytical process	5	Yes
[38]	2009	USA	Prospective analytical study	Healthcare process	Radiation therapy	Radiation oncology	127	Yes
[39]	2018	Australia	Prospective analytical study	Healthcare process	Radiation therapy	Radiation oncology	83	Yes
[40]	2010	USA	Prospective analytical study	Healthcare process	Surgery	Laparoscopic surgery	35+	No
[41]	2016	Italy	Systematic review	Healthcare process	Radiation therapy	Radiation oncology	N/A	N/A
[42]	2021	United Kingdom	Prospective analytical study	Healthcare process	Radiation therapy	Lung radiotherapy	36	Yes
[43]	2023	USA	Prospective analytical study	Healthcare process	Radiation therapy	Total body irradiation	128	Yes
[44]	2016	The Netherlands	Prospective analytical study	Healthcare process	Healthcare support activities	Delivery of surgical instruments	74	Yes
[45]	2016	The Netherlands	Prospective analytical study	Healthcare process	Healthcare support activities	Delivery of surgical instruments	172+158	Yes
[46]	2020	Spain	Prospective analytical study	Healthcare process	Testing in clinical laboratory	Analytical performance	10+6	Yes
[47]	2019	USA	Prospective analytical study	Healthcare process	Healthcare support activities	Doffing enhanced personal protective equipment	103	Yes
[48]	2021	USA	Prospective analytical study	Medical equipment/production	None	Infusion pump	17	Yes
[49]	2013	South Korea	Cross-sectional study	Healthcare process	Blood transfusion	Blood transfusion	4 to 22	Yes
[50]	2021	Jordan	Prospective analytical study	Healthcare process	Testing in clinical laboratory	Blood sampling	29	Yes
[51]	2023	China	Retrospective analytical study	Healthcare process	Other treatment processes	Emergency endoscopy esophagogastric variceal bleeding	18	Yes
[52]	2011	Taiwan	Prospective analytical study	Hospital management	Healthcare support management	Medical waste management	19	Yes
[53]	2022	Taiwan	Prospective analytical study	Healthcare process	Radiation therapy	External beam radiotherapy	201	No

[54]	2017	Spain	Prospective analytical study	Healthcare process	Other treatment processes	Propofol sedation in digestive endoscopy	47	Yes
[55]	2008	USA	Prospective analytical study	Healthcare process	Radiation therapy	Radiation oncology	4	No
[56]	2023	USA	Prospective analytical study	Healthcare process	Infectious diseases, antimicrobials and infection control	Infectious diseases outbreak in Radiotherapy	90	No
[57]	2021	Iran	Prospective analytical study	Healthcare process	Medication use process	Medication use process	10	No
[58]	2015	USA	Prospective analytical study	Healthcare process	Radiation therapy	Tomotherapy-based radiation therapy	72	Yes
[59]	2019	USA	Prospective analytical study	Healthcare process	Radiation therapy	Radiation planning assistant	68	Yes
[60]	2021	Germany	Prospective analytical study	Healthcare process	Radiation therapy	Magnetic resonance-guided radiotherapy	89	Yes
[61]	2020	Israel	Prospective analytical study	Healthcare process	Radiation therapy	Patient identification in Radiology department	15	No
[62]	2022	Japan	Prospective analytical study	Healthcare process	Radiation therapy	Anaphylaxis reduction due to contrast media in Radiology	177	Yes
[63]	2023	Germany	Prospective analytical study	Healthcare process	Radiation therapy	Radiation oncology	36	No
[64]	2005	New Zealand	Prospective analytical study	Healthcare process	Medication use process	Neonatal ICU medication use process	72	Yes
[65]	2022	Italy	Prospective analytical study	Healthcare process	Other treatment processes	Dialysis	31	No
[66]	2012	Italy	Prospective analytical study	Healthcare process	Other treatment processes	Drugs prescription and administration in paediatric wards	37	Yes
[67]	2021	Morocco	Prospective analytical study	Healthcare process	Infectious diseases, antimicrobials and infection control	Drugs prescription and administration during SARS-CoV-2 pandemic	12	Yes
[68]	2017	South Korea	Prospective analytical study	Healthcare process	Healthcare support activities	Clinical trials	114	Yes
[69]	2017	USA	Prospective analytical study	Healthcare process	Radiation therapy	Ocular brachytherapy	188	Yes
[70]	2021	The Netherlands	Prospective analytical study	Healthcare process	Other treatment processes	Drug adherence for patients with pheochromocytoma	69	Yes
[71]	2017	China	Prospective analytical study	Healthcare process	Infectious diseases, antimicrobials and infection control	Prevention of catheter-related infection in ICU	25	Yes

[72]	2021	China	Quality improvement study	Healthcare process	Infectious diseases, antimicrobials and infection control	Prevention of MDROs infection in ICU	5	Yes
[73]	2022	China	Prospective analytical study	Healthcare process	Chemotherapy	Chemotherapy in lung cancer	60	Yes
[74]	2020	Canada	Prospective analytical study	Healthcare process	Radiation therapy	Near misses in radiation therapy	107	No
[75]	2022	USA	Prospective analytical study	Healthcare process	Healthcare support activities	Mechanical thrombectomy for stroke	7	Yes
[76]	2023	USA	Quality improvement study	Healthcare process	Blood transfusion	Manual vs automated blood grouping processes	5	Yes
[77]	2013	China	Quality improvement study	Healthcare process	Blood transfusion	Blood transfusion	19	Yes
[78]	2023	China	Quality improvement study	Healthcare process	Testing in clinical laboratory	Laboratory testing (CBC)	6	Yes
[79]	2011	USA	Prospective analytical study	Healthcare process	Medication use process	Drug shortages	8	Yes
[80]	2020	Italy	Quality improvement study	Healthcare process	Healthcare support activities	IVF process	10	Yes
[81]	2020	Italy	Quality improvement study	Healthcare process	Radiation therapy	Radiation oncology	67+27	Yes
[82]	2022	USA	Narrative review	Healthcare process	Other treatment processes	Skin biopsy	1	No
[83]	2017	USA	Quality improvement study	Healthcare process	Other treatment processes	Paediatric anaesthesia	8	Yes
[84]	2023	Sweden	Prospective analytical study	Healthcare process	Healthcare support activities	Drugs supply chain	11	Yes
[85]	2014	Italy	Prospective analytical study	Healthcare process	Radiation therapy	Intracranial stereotactic radiation surgery	116	Yes
[86]	2015	USA	Prospective analytical study	Healthcare process	Radiation therapy	Gynecologic brachytherapy	170	Yes
[87]	2015	USA	Prospective analytical study	Hospital management	Communication and patient handoff	Operating room to ICU handoff	79	No
[88]	2022	Italy	Prospective analytical study	Healthcare process	Other treatment processes	Perioperative management model of oral anticoagulant therapy	17	Yes
[89]	2016	Spain	Quality improvement study	Healthcare process	Healthcare support activities	Patient safety in paediatric emergency care	49	Yes

[90]	2019	Spain	Quality improvement study	Healthcare process	Blood transfusion	Blood transfusion	34	Yes
[91]	2022	Spain	Quality improvement study	Healthcare process	Healthcare support activities	Patient safety in paediatric emergency care	106+110	Yes
[92]	2017	Brazil	Quality improvement study	Healthcare process	Healthcare support activities	Orthotics, prosthetics, and special materials	16	Yes
[93]	2017	Iran	Quality improvement study	Healthcare process	Blood transfusion	Blood transfusion	31	Yes
[94]	2014	Denmark	Prospective analytical study	Healthcare process	Other treatment processes	Obstructed breech delivery	40	No
[95]	2022	Japan	Prospective analytical study	Healthcare process	Radiation therapy	Magnetic resonance-guided radiotherapy	153	No
[96]	2018	Israel	Quality improvement study	Healthcare process	Healthcare support activities	Consultations	44	No
[97]	2014	USA	Prospective analytical study	Hospital management	Treatment process management	Clinical implementation of adaptive radiotherapy	216	Yes
[98]	2021	USA	Prospective analytical study	Healthcare process	Radiation therapy	Prostate brachytherapy	29	No
[99]	2016	Israel	Quality improvement study	Medical equipment/production	None	Ready-to-use diluted potassium chloride solution	13	Yes
[100]	2019	USA	Prospective analytical study	Hospital management	Communication and patient handoff	Documentation discrepancies at transfer out of the pediatric ICU	N/A	No
[101]	2022	Italy	Quality improvement study	Hospital informatization	None	Remote patient telemonitoring	N/A	Yes
[102]	2016	Italy	Prospective analytical study	Healthcare process	Chemotherapy	Subcutaneous vs intravenous chemotherapy	35	No
[103]	2020	USA	Quality improvement study	Healthcare process	Other treatment processes	Analgesia, sedation, and paralysis order set	3	Yes
[104]	2020	Spain	Quality improvement study	Healthcare process	Chemotherapy	Chemotherapy preparation	9	Yes
[105]	2019	USA	Prospective analytical study	Healthcare process	Radiation therapy	Breast radiotherapy	97	No
[106]	2019	United Kingdom	Quality improvement study	Medical equipment/production	None	Pre-prepared standardized concentrations of morphine for paediatric analgesia	5	Yes

[107]	2020	USA	Prospective analytical study	Hospital management	Treatment process management	Initial plan check checklist in radiation treatment	50	No
[108]	2009	United Kingdom	Prospective analytical study	Hospital management	Communication and patient handoff	Communication in the ED	16	No
[109]	2018	Iran	Prospective analytical study	Hospital management	Healthcare support management	Patient journey process in surgery ward	13	No
[110]	2008	USA	Prospective analytical study	Healthcare process	Medication use process	Medication administration	3+6	No
[111]	2017	Italy	Quality improvement study	Hospital informatization	None	Implementation of an electronic witnessing system	293	Yes
[112]	2015	Italy	Quality improvement study	Hospital informatization	None	Implementation of an electronic witnessing system	32	Yes
[113]	2021	USA	Quality improvement study	Healthcare process	Radiation therapy	Brachytherapy	51+105	Yes
[114]	2017	Spain	Prospective analytical study	Healthcare process	Testing in clinical laboratory	Preanalytical process	24+16	Yes
[115]	2022	Spain	Quality improvement study	Healthcare process	Radiation therapy	Radiopharmacy	96	Yes
[116]	2014	USA	Prospective analytical study	Medical equipment/production	None	Universal anaesthesia machine	16	Yes
[117]	2020	USA	Prospective analytical study	Healthcare process	Radiation therapy	Liver radiotherapy	102	Yes
[118]	2020	Ireland	Quality improvement study	Hospital management	Treatment process management	MRI safety in patients with CIEDs	20	Yes
[119]	2021	USA	Prospective analytical study	Healthcare process	Infectious diseases, antimicrobials and infection control	OPAT	13+10	Yes
[120]	2016	Spain	Quality improvement study	Healthcare process	ICU process	Continuous renal replacement therapy	24	Yes
[121]	2020	Iran	Prospective analytical study	Hospital management	Others	Safety management in hospitals	84	No
[122]	2022	Greece	Narrative review	Healthcare process	Radiation therapy	Stereotactic radiation surgery	N/A	Yes
[123]	2016	USA	Prospective analytical study	Healthcare process	Medication use process	Medication administration	35	Yes
[124]	2015	USA	Prospective analytical study	Healthcare process	Radiation therapy	Skin brachytherapy	27	No

[125]	2021	Switzerland	Quality improvement study	Hospital management	Others	Hospital pharmacy relocation	86	Yes
[126]	2022	USA	Quality improvement study	Hospital management	Others	Patient no-show rates reduction	10	Yes
[127]	2022	China	Randomized clinical trial	Healthcare process	Other treatment processes	Craniocerebral injury treatment	N/A	Yes
[128]	2009	United Kingdom	Prospective analytical study	Healthcare process	Medication use process	Intrathecal drug delivery for pain management	50	Yes
[129]	2019	China	Quality improvement study	Healthcare process	Radiation therapy	Helical tomotherapy	122	Yes
[130]	2017	USA	Prospective analytical study	Healthcare process	Surgery	Bilateral same-day cataract surgery process	15	Yes
[131]	2020	The Netherlands	Prospective analytical study	Healthcare process	Radiation therapy	Radiation oncology	142	Yes
[132]	2023	USA	Quality improvement study	Healthcare process	Radiation therapy	Intensity modulated radiation therapy	100	Yes
[133]	2019	United Kingdom	Prospective analytical study	Healthcare process	Healthcare support activities	ADHD management	22	Yes
[134]	2003	USA	Narrative review	Healthcare process	Healthcare process	All	N/A	N/A
[135]	2021	Serbia	Systematic review	Healthcare process	Medication use process	Medication use process	N/A	N/A
[136]	2012	USA	Quality improvement study	Medical equipment/production	None	Smart infusion pump	39+69	Yes
[137]	2016	Iran	Prospective analytical study	Healthcare process	Surgery	Emergency surgical processes	217	Yes
[138]	2015	Brazil	Prospective analytical study	Healthcare process	Radiation therapy	Stereotactic radiation surgery	153+104+131	No
[139]	2021	Ethiopia	Cross-sectional study	Hospital management	Healthcare support management	Prevention of SARS-CoV-2 transmission in ED	22	Yes
[140]	2022	Italy	Quality improvement study	Healthcare process	Other treatment processes	Bone marrow donation	28	Yes
[141]	2011	USA	Prospective analytical study	Healthcare process	Radiation therapy	Radiation oncology	17	Yes
[142]	2013	The Netherlands	Prospective analytical study	Healthcare process	Other treatment processes	Supplemental oxygen therapy in preterm infants	134	Yes
[143]	2022	Belgium	Quality improvement study	Healthcare process	Testing in clinical laboratory	Preanalytical process	17	Yes

[144]	2018	Spain	Prospective analytical study	Healthcare process	ICU process	ICU process	101	Yes
[145]	2016	Spain	Prospective analytical study	Healthcare process	ICU process	Suctioning by orotracheal tube	32	Yes
[146]	2015	Italy	Prospective analytical study	Healthcare process	Radiation therapy	Stereotactic radiation surgery	19	Yes
[147]	2020	USA	Quality improvement study	Healthcare process	Radiation therapy	Radiation oncology	33	Yes
[148]	2011	Belgium	Prospective analytical study	Healthcare process	Radiation therapy	Radiation oncology	86	Yes
[149]	2016	Saudi Arabia	Prospective analytical study	Healthcare process	Radiation therapy	Brachytherapy	40	Yes
[150]	2013	USA	Prospective analytical study	Healthcare process	Chemotherapy	Pediatric oral cancer chemotherapy	69	Yes
[151]	2022	Germany	Prospective analytical study	Healthcare process	Chemotherapy	Intravenous cancer chemotherapy	52	Yes
[152]	2004	USA	Prospective analytical study	Healthcare process	Other treatment processes	Extracorporeal circuits for cardiopulmonary bypass	77	No
[153]	2011	USA	Prospective analytical study	Healthcare process	Chemotherapy	Oral chemotherapy	325	Yes
[154]	2006	USA	Prospective analytical study	Medical equipment/production	None	Smart infusion pump	200	Yes
[155]	2017	USA	Prospective analytical study	Healthcare process	Radiation therapy	Gamma Knife radiosurgery	86	Yes
[156]	2021	China	Prospective analytical study	Hospital management	Healthcare support management	Prevention of MDROs infections	7	Yes
[157]	2019	USA	Prospective analytical study	Healthcare process	Radiation therapy	Radiotherapy treatment delay	25	No
[158]	2015	USA	Prospective analytical study	Healthcare process	Radiation therapy	Stereotactic radiation surgery	63	No
[159]	2016	USA	Prospective analytical study	Healthcare process	Radiation therapy	Brachytherapy	174	Yes
[160]	2014	USA	Prospective analytical study	Healthcare process	Radiation therapy	Stereotactic radiation surgery	99	No
[161]	2018	Taiwan	Prospective analytical study	Hospital management	Healthcare support management	Infant abduction prevention	16	No
[162]	2019	China	Quality improvement study	Hospital management	Treatment process management	Prevention of posture syndrome of thyroid surgery	7	Yes
[163]	2021	China	Prospective analytical study	Hospital management	Communication and patient handoff	Intrahospital transport	64	Yes

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