Iterative Approach to Improve Failure Modes and Effects Analysis through Feedback Systems

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Uniklinikum Erlangen

Disclosures and Acknowledgments

- Disclosures:
  - Both the Universitätsklinik Erlangen and IBA Dosimetry GmbH received **funds by the Bavarian Ministry of Economic Affairs, Regional Development and Energy**
  - Dominik Kornek, Christoph Bert, David Menichelli and Andreas Lämmerzahl have a **patent pending** about some functionality of the described software

- Acknowledgments:
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  - **Risk conferences**: Christoph Bert, Carolin Brandl, Gabi Heumann, Michael Lotter, Katja Ott, Oliver Ott
  - **Software**: David Menichelli, Jörg Leske, Michael Hoffmann, David Antkiewicz

Introduction
Purpose of the Failure Mode & Effects Analysis (FMEA)

- Risk assessment tool, identifies potential failures **before harm occurs**
- **Improves** processes & use of ressources, **increases** patient satisfaction
- May be a (legal) **requirement** (e.g., 2013/59/Euratom, ISO 9001)
- Optimal situations for performing FMEA before
  - **introducing** new processes
  - **modifying** existing processes

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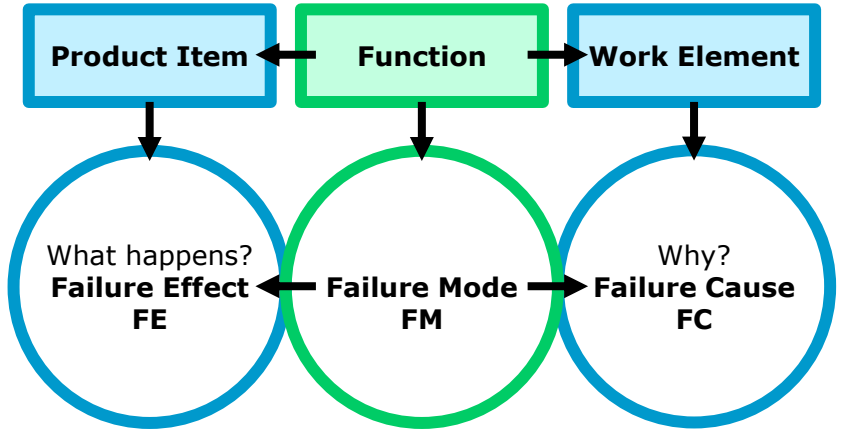

Theoretical failure chain model, modified [1]

[1] *AIAG & VDA FMEA-Handbook. Design FMEA, Process FMEA, Supplemental FMEA for Monitoring & System Response. First Edition Issued June 2019*. AIAG, VDA, 2019.

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Prerequisites & Challenges

- Team of 3–6 **experienced** members of different profession
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- **Time-consuming**, e.g., 2–6 months for SRS FMEA [2]
- **Complex**, e.g.,
  - 216 failure modes for IMRT [3],
  - 153 failure modes for MR-LINAC [4],
  - 361 failure modes for TSEI [5].

[2] Teixeira FC *et al. Med Phys,* vol. 43, no. 1, p. 171, Jan 2016, doi: 10.1118/1.4938065.
[3] Huq MS *et al. Med Phys,* vol. 43, no. 7, p. 4209, Jul 2016, doi: 10.1118/1.4947547.
[4] Nishioka S *et al. Phys Imaging Radiat Oncol,* vol. 23, pp. 1-7, Jul 2022, doi: 10.1016/j.phro.2022.06.002.
[5] Ibanez-Rosello B *et al. Clin Transl Oncol,* vol. 20, no. 3, pp. 330-65, Mar 2018, doi: 10.1007/s12094-017-1721-3.

Introduction
Motivation of the Work

- "*To be **effective**, FMECA must be **iterative** to correspond with the nature of the [...] process itself.*" [6]
- *"[...] preliminary analysis may be conducted during the early stages [...]; **more detailed analysis** may be conducted **when more information is available**.*" [7]

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[7] *IEC 60812:2018. Failure modes and effects analysis (FMEA and FMECA)*, 2018.

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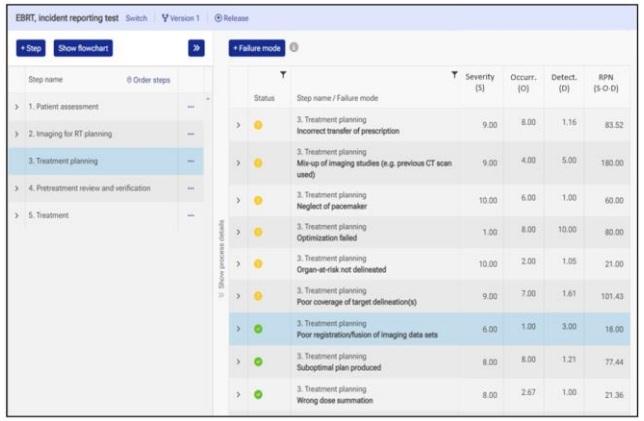
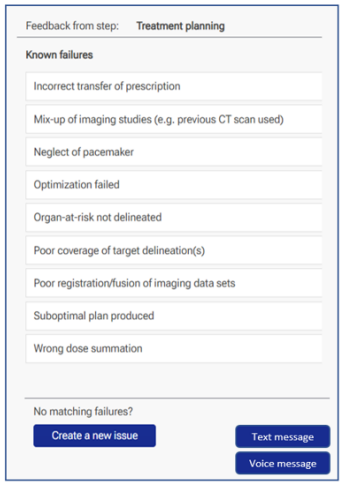
- Approach #1**: Integration** with **incident reporting** [8–10]
- Approach #2**: Periodic revisions** (e.g., annually, triennially)

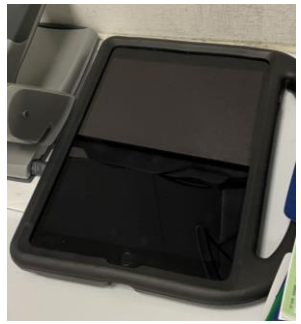
[6] *MIL-STD-1629A. Military Standard. Procedures for Performing a Failure Mode, Effects and Criticality Analysis*, Washington, DC, 1980.
[7] *IEC 60812:2018. Failure modes and effects analysis (FMEA and FMECA)*, 2018.
[8] Paradis KC *et al. Pract Radiat Oncol,* vol. 11, no. 1, pp. e106-e13, Jan-Feb 2021, doi: 10.1016/j.prro.2020.02.015.
[9] Yang F *et al. Med Phys,* vol. 42, no. 6, pp. 2777-85, Jun 2015, doi: 10.1118/1.4919440.
[10] Kessels-Habraken M *et al. Int J Qual Health Care,* vol. 21, no. 6, pp. 427-32, Dec 2009, doi: 10.1093/intqhc/mzp043.

Materials & Methods
Software

- Software application (prototype)
  - **Prospective**: FMEA & fault tree analysis [11]
  - **Retrospective**: Incident reporting interface (→ feedback)
    - proffer FMs and/or free text fields to staff for fast reporting
    - 4 incident types selectable: none, inconvenience, near event, event
    - clients: work stations & handheld computers







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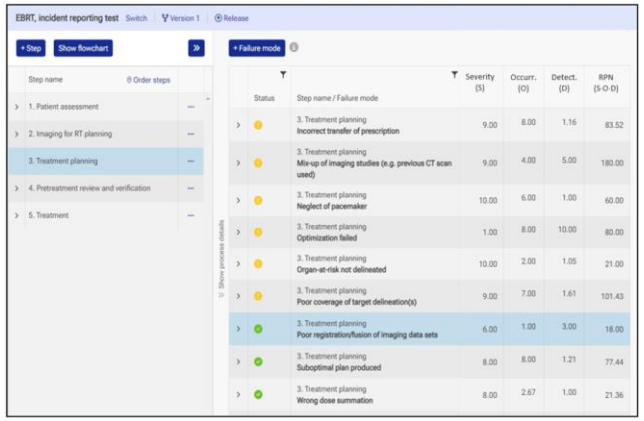
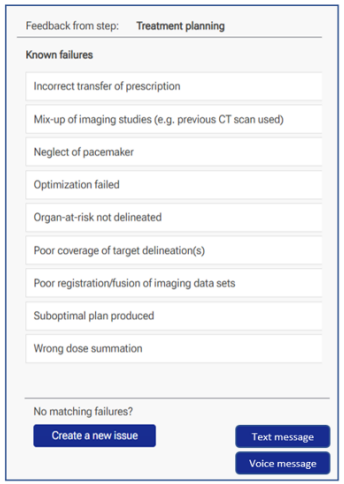
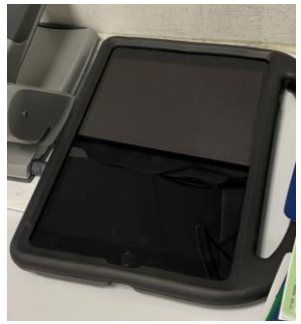
    - 4 incident types selectable: none, inconvenience, near event, event
    - clients: work stations & handheld computers
  - **Integration** of FMEA and incidents
  - Manual **triage**
    - Report **relevant** for risk assessment?
    - If so, **update** FM **ratings** AND/OR **deduce** new FMs







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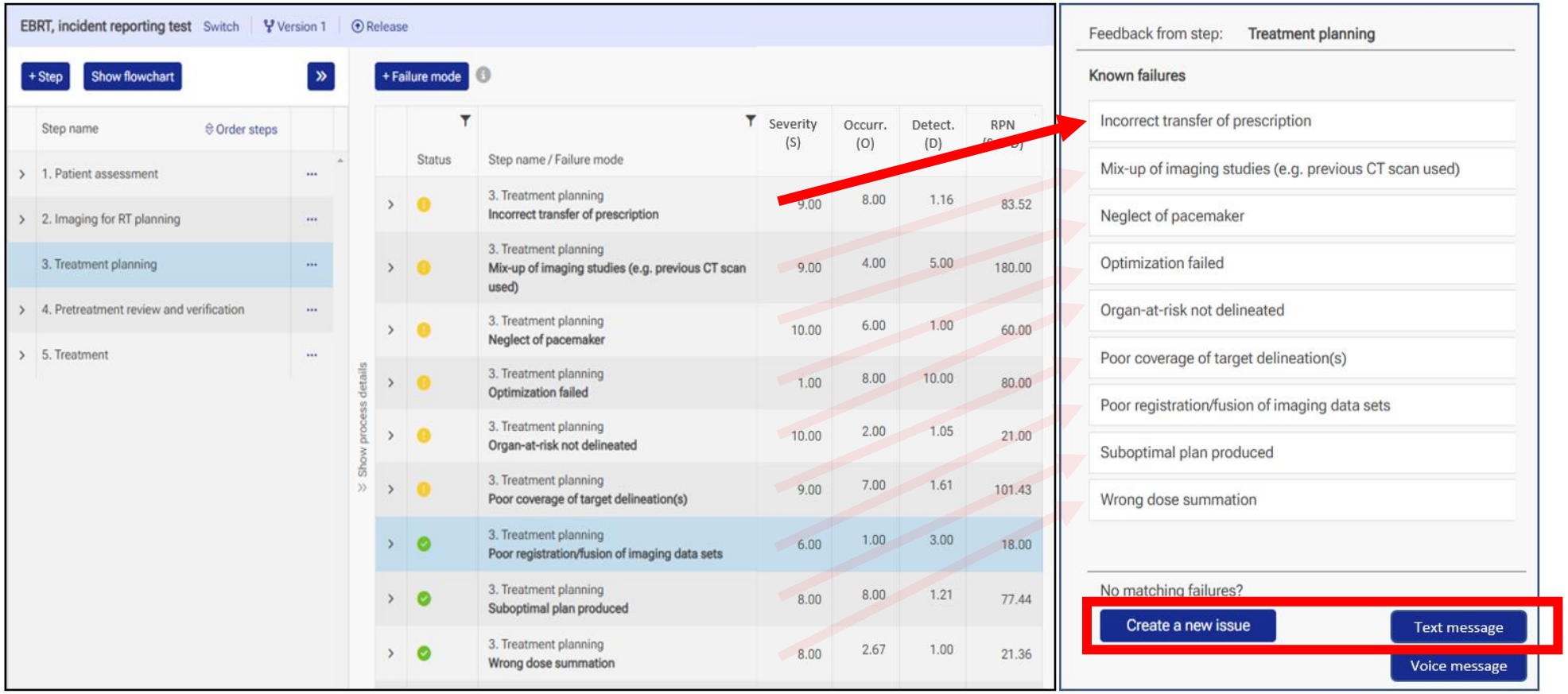
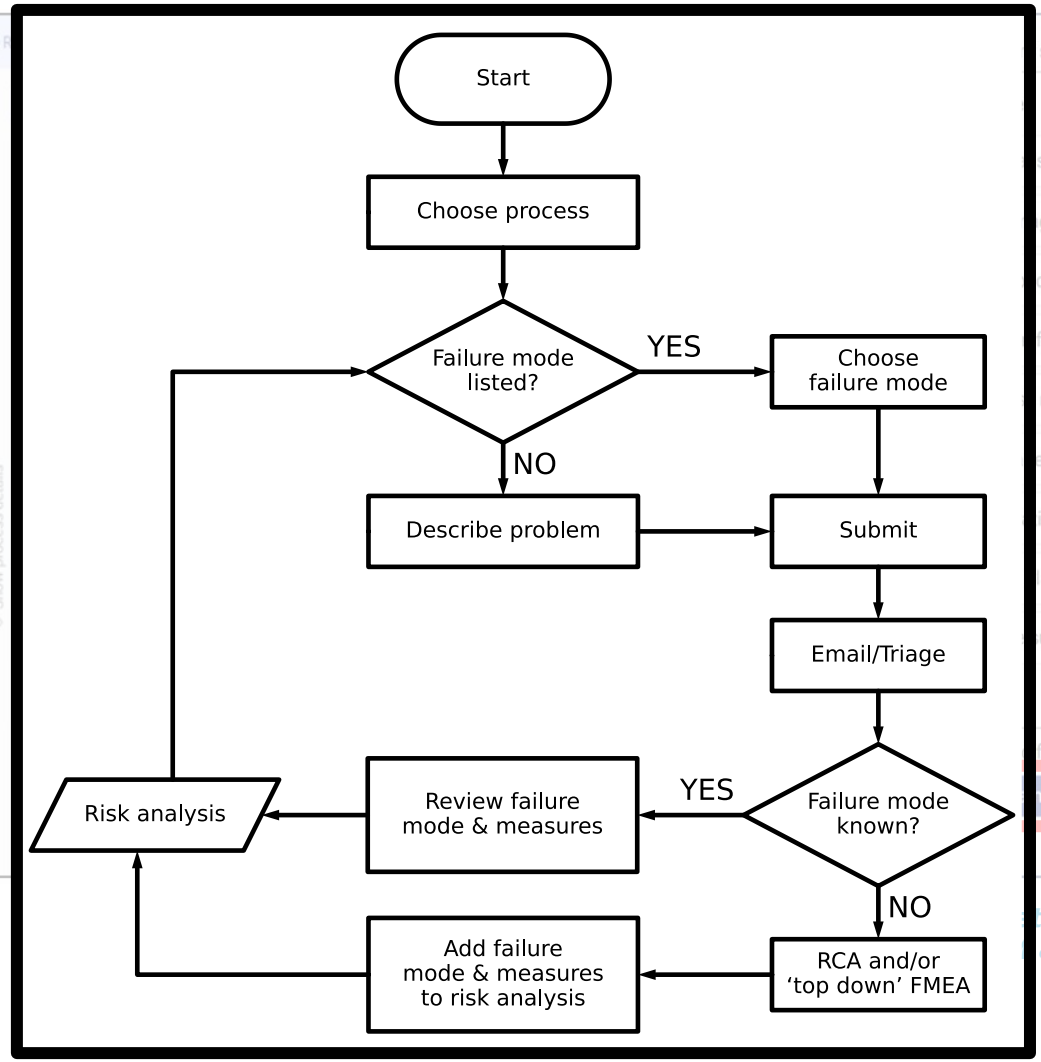


Prospective interface (FMEA)

Retrospective interface (FM & Incident reporting)

Materials & Methods
Software

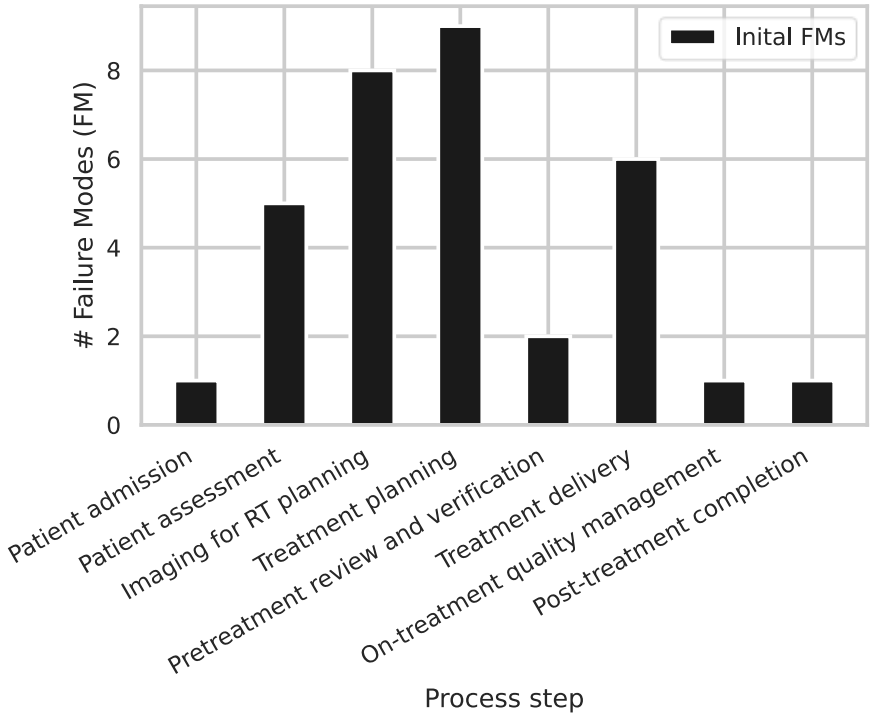
RCA: Root cause analysis
FMEA: Failure mode and effects analysis



Materials & Methods
Data

- Department of Radiation Oncology, Erlangen (maximum care)
  - 9 attending MDs, 17 residents, 37 RTTs, 12 MPEs
  - 1 imaging unit, 5 EBRT treatment units (~ 1600 pat./a), 4 BT treatment units (~ 500 pat./a)

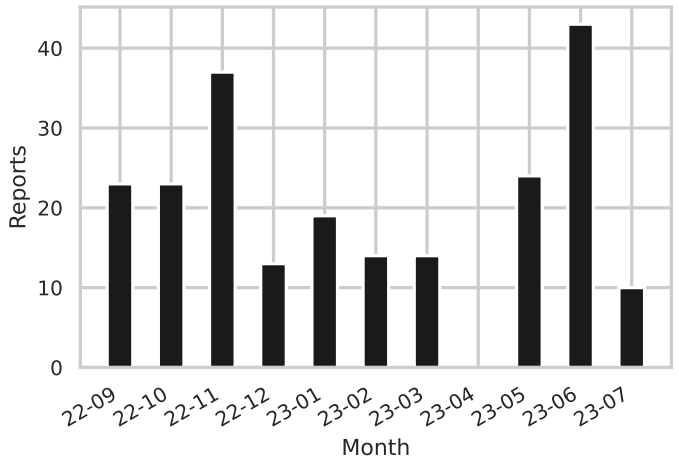
- FMEA (*previously conducted* [12])
  - External beam radiation therapy
  - 33 FMs, identified in 41@1h meetings

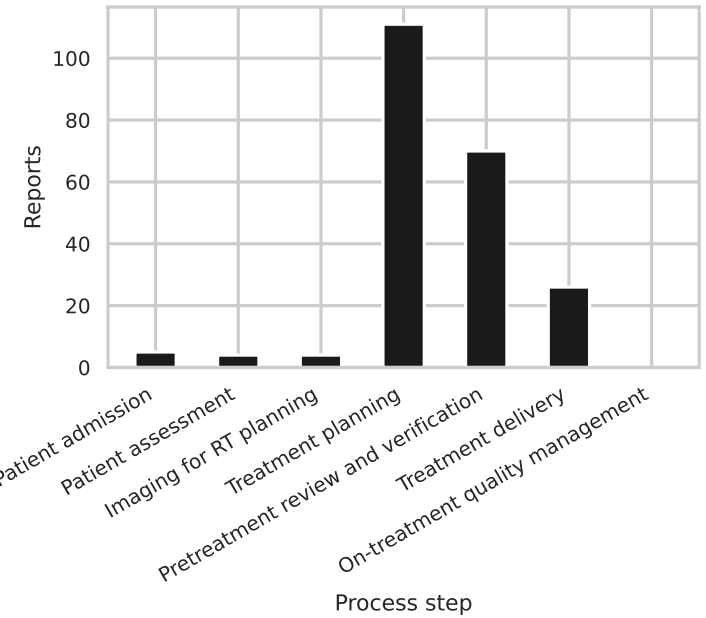


[12] Lohmann D *et al. Z Med Phys,* Jan 7 2022, doi: 10.1016/j.zemedi.2021.11.002.

Results
Overview

- Launch of feedback system: September 2022
- 220 reports
  - 77 reports containing known failure modes
  - 143 reports describing new issues (before triage)





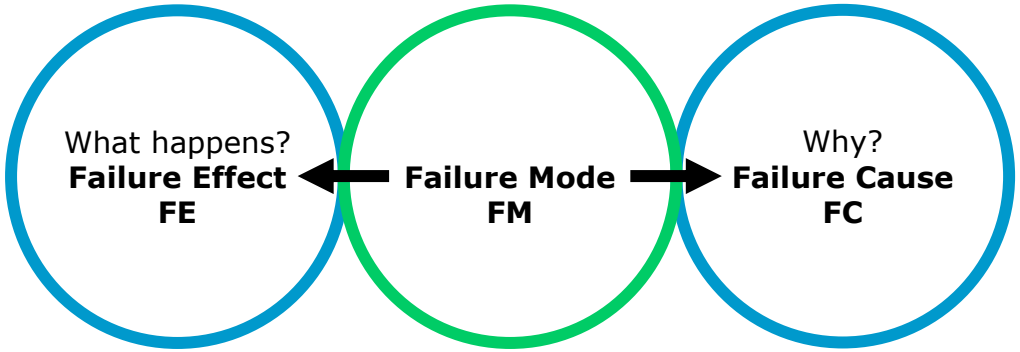
Results
Triage & Re-Classifcation

- Triage is **necessary**: 38.6% of reports were removed ($x \rightarrow$ none)

Incident type	# Before triage	# After triage
None	19	85
Inconvenience	185	105
Near event	7	30
Event	9	0
SUM	**220**	**220**

- # FMs incorrectly assigned by reporter: 3.6%
- # Reports without already existing FM: 5.4%

Results
Classification of Text Descriptions



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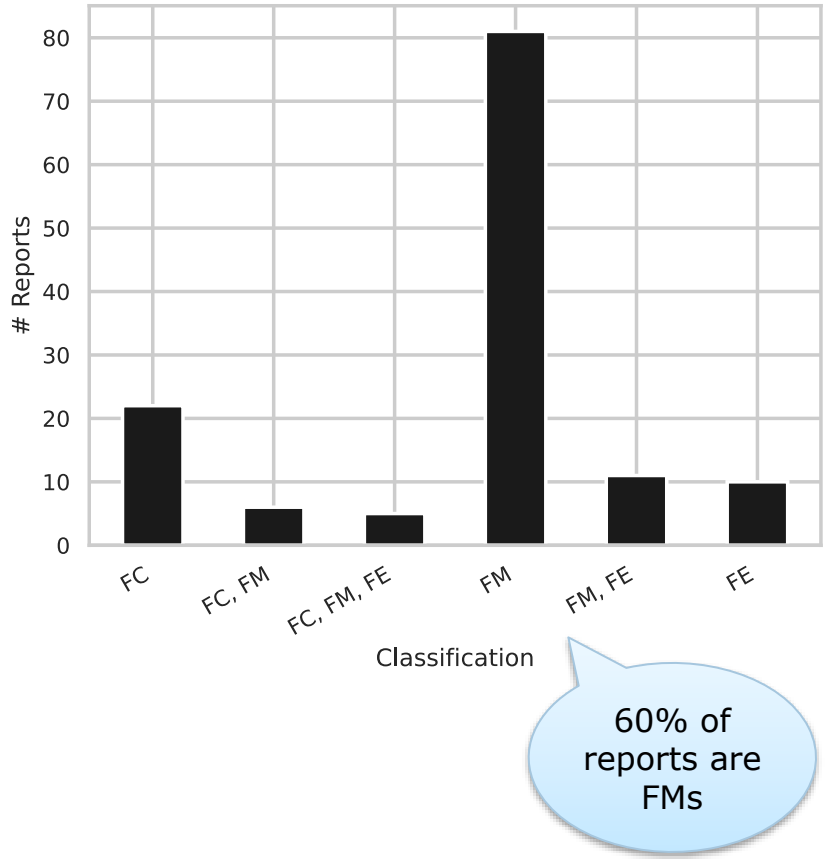

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Results
Reviewing and Deducing Failure Modes

- **15 of 33** inital FMs have been reported and updated (18 FM remain undetected)
- Occurrence O was underestimated by at least ~**1.5** (arithmetic mean)

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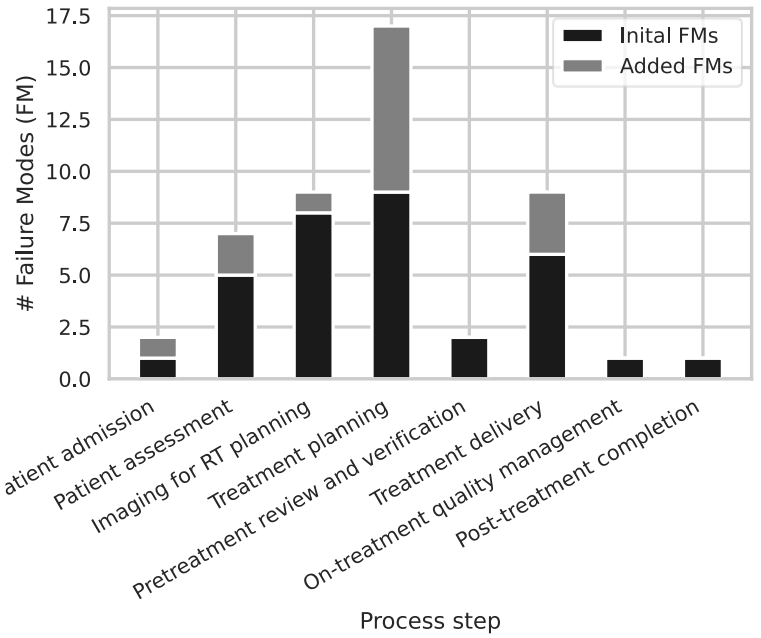
- Occurrence O was underestimated by at least ~**1.5** (arithmetic mean)
- **15 new** FMs have been added (+45%)

Failure Mode	# Reports
PTV(s) delineated/contoured too late	31
PTV contours incorrect (discrepant with prescription)	11
Patient irradiated too late	7



Conclusion

- Benefits**:**
  - **FMEA „on-the-fly“**
  - **Integrated** incident reporting **increased effectiveness of FMEA:** completeness, active risk monitoring, statistics & risk ratings
  - **All** staff **involved** with risk assessment
  - Insufficient measures **identified in a timely manner**

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- Limitations**:**
  - 84.5% of reports (nones + inconv.) **not especially relevant** for risk assessment; however, **very useful** for workflow optimization
  - **High dark figure** due to **underreporting** and **competing communication channels** (e.g., in-person, phone, mail, CIRS, etc.)