From Excel-based HFMEA towards myQA PROactive

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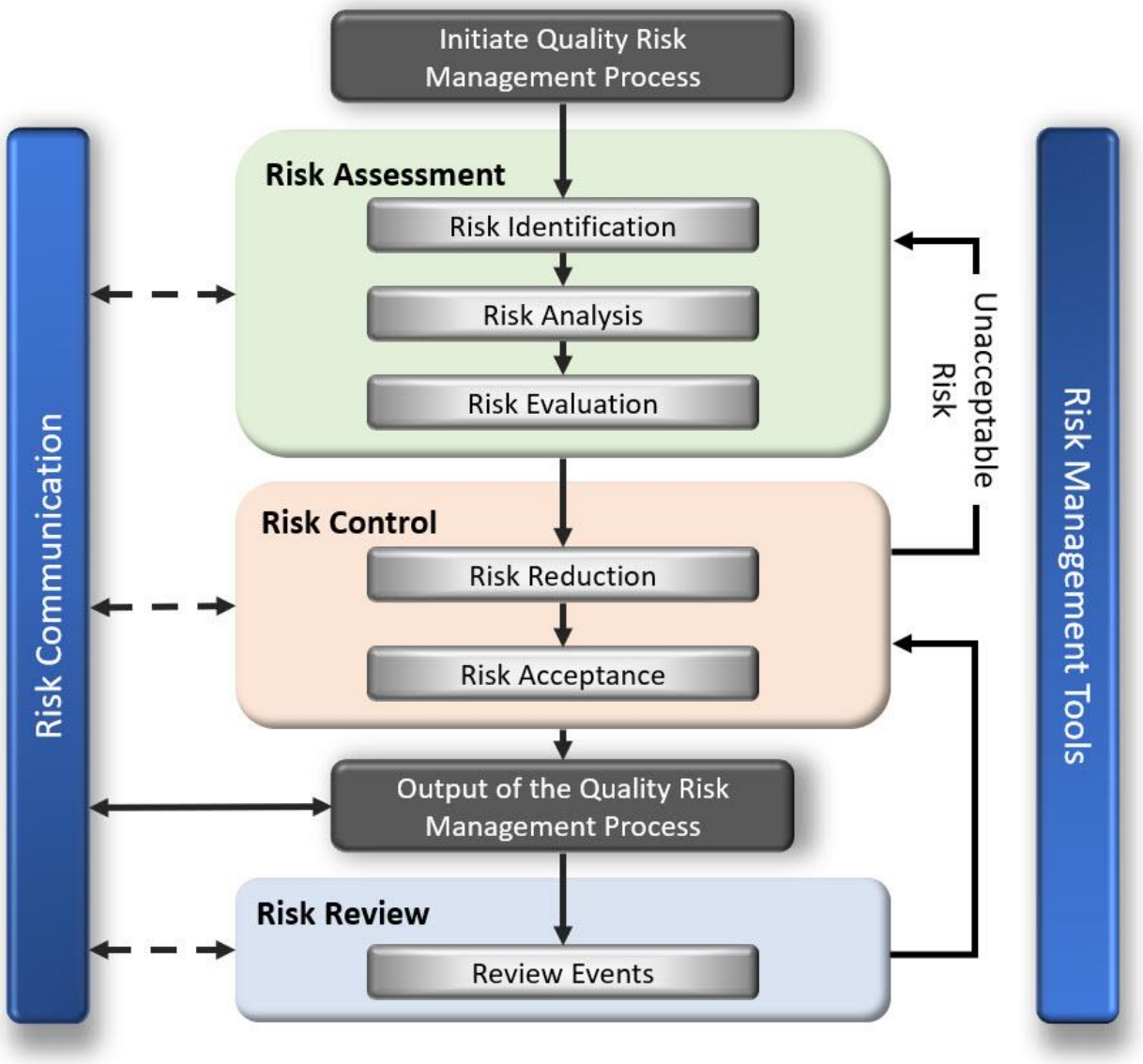
Excel-based HFMEA experience

- Requirement for JCI accreditation

- Advised by quality team
  - Take source of risk into account
  - Work systematically
  - Multidisciplinary group
  - Analyze risks and define action points
  - Assign and review (!) action points

Risk management process



HFMEA for CT-simulator

- Pro-active:
  - room in renovation, CT to be installed
- 11 process steps, 363 risk sources
- Occurrence, severity and risk score:

Frequency
Weekly
Monthly (≥ 6x/y)
Yearly (< 6x/y)
Less than once a year

Risk Matrix	Catastrophic	Major	Moderate	Minor
Weekly	Very high	Very high	High	Low
Monthly	Very high	High	Low	Very low
Yearly	High	Low	Low	Very low
Less than once a year	Low	Very low	Very low	Very low

Severity	Definition	Effective dose
Catastrofic	death or permanent serious injury	>2000 mSv
Major	permanent injury, not serious	1000-2000 mSv
Moderate	temporary injury	200-1000 mSv
Minor	no injury	0-200 mSv

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Risk analysis

- Failure modes
  - High or Very high risk scores were analyzed
    - Eliminate, control or accept
  - low or very low risk but high in number and resolved easily
    - Eliminated
- Action points were defined
- Responsible persons were assigned

- No flow chart or fault tree analysis performed

Performed HFMEA in RT

- VersaHD (pro-active)
  - 11 process steps, 362 risk sources, 40 action points
- HDR afterloader
  - 11 process steps, 289 risk sources, 10 action points
- Review of CT-simulator after 5 year
  - Still 16 out of 45 open action points (!)
- TPS RayStation
  - 29 process steps, 527 risk sources, 142 action points
  - Time consuming !

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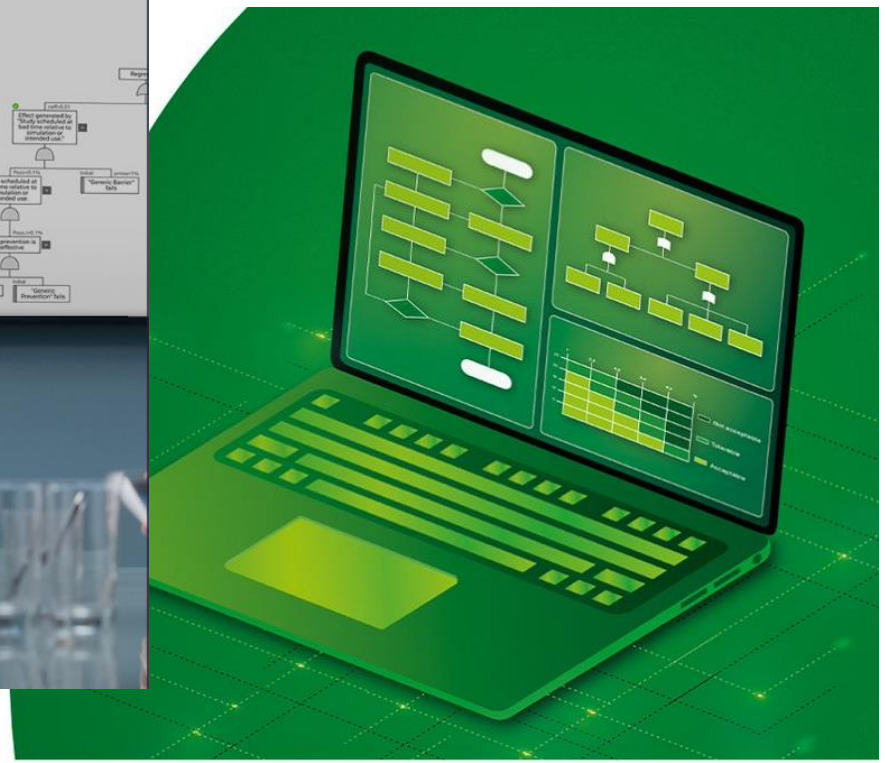
Performed HFMEA outside RT

- Nuclear medicine, RX and connected departments :
  - To define number of required RPO
- Radiation safety hospital wide
  - All types of radiation risks
    - Radioactive waste
    - Patients nuclear medicine
    - Mobile RX machine
    - …

National external audits

- Request to perform proactive risk analysis
- Not many departments have knowledge of RA
  - Do not know how to start or what to include
    - Radioprotection, uncontrolled access, fire safety,…
- Clear need for easier tool for (proactive) risk analysis

Request to test myQA® PROactive



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- Copy CT-sim HFMEA into the import file
  - Convert values for severity and occurrence into S-O-D table using TG100

	Severity		Occurrence
Catastrophic	9	Weekly	8
Major	7	Monthly	7
Moderate	5	Less than 6x/year	6
Minor	2	Less than 1x/year	3

- No preventions nor barriers added

Step name	Substep name	Cause of failure	Failure Mode	Initial Preventions	Initial Barriers	Severity	Occurrence, initial	Detectability, initial	RPN, initial	Added Preventions	Added Barriers	Severity	Occurrence, mitigated	Detectability, mitigated	RPN, mitigated
Wachtzaal CT-sim		door Simverpleegkundigen	patiënt wordt vergeten			2	3	1							
Wachtzaal CT-sim		doordat patient in verkeerde wachtzaal zit	patiënt wordt vergeten			2	3	1							
Wachtzaal CT-sim		patiënt sticht brand	brand thv wachtzaal			7	3	1							
Wachtzaal CT-sim		TV ontbrandt	brand thv wachtzaal			7	3	1							
kleedkamer (omkleden)		Medische redenen	vallen			5	3	1							
kleedkamer (omkleden)		Doorgankelijkheid	vallen			5	6	1							
kleedkamer (omkleden)		Te weinig comfort (houvast)	vallen			5	6	1							

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Processtap	Potentiële faalwijze	Potentiële oorzaken	Ernst	Kans	Risico score	Kritiek moment / controleer-baarheid / detecteerbaarheid	Door-gaan?
	6) Patiënt wordt vergeten						
		door Vervoer (extern/intern)	Kl	Ja	ZL		
		door Simverpleegkundigen	Kl	<Ja	ZL		
		doordat patient in verkeerde wachtzaal zit	Kl	<Ja	ZL		
	7) Brand thv wachtzaal						
		patiënt sticht brand	Gr	<Ja	ZL	rookdetectoren werken niet	
		TV ontbrandt	Gr	<Ja	ZL	brandtoestel defect of ontbrekend	
						MW kent proceduren niet	
Kleedkamer (omkleden)	1) Vallen						
		Medische redenen	Ma	<Ja	ZL		
		Doorgankelijkheid	Ma	Ja	L		
		Te weinig comfort (houvast)	Ma	Ja	L		

Step name	Substep name	Cause of failure	Failure Mode	Initial Preventions	Initial Barriers	Severity	Occurrence, initial	Detectability, initial	RPN, initial	Added Preventions
Wachtzaal CT-sim		door Simverpleegkundigen	patiënt wordt vergeten			2	3	1		
Wachtzaal CT-sim		doordat patient in verkeerde wachtzaal zit	patiënt wordt vergeten			2	3	1		
Wachtzaal CT-sim		patiënt sticht brand	brand thv wachtzaal			7	3	1		
Wachtzaal CT-sim		TV ontbrandt	brand thv wachtzaal			7	3	1		
kleedkamer (omkleden)		Medische redenen	vallen			5	3	1		
kleedkamer (omkleden)		Doorgankelijkheid	vallen			5	6	1		
kleedkamer (omkleden)		Te weinig comfort (houvast)	vallen			5	6	1		

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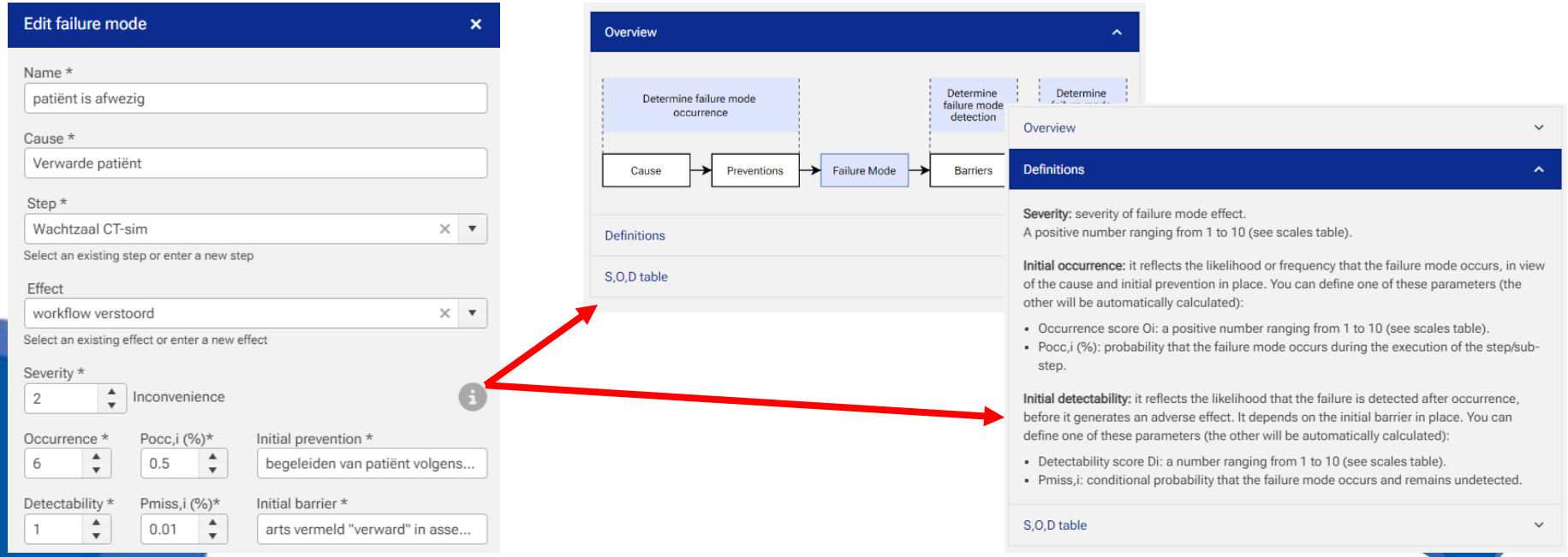
- severity, occurrence and detectability
  - Something to get used to work with
  - But helpful explanation available in software



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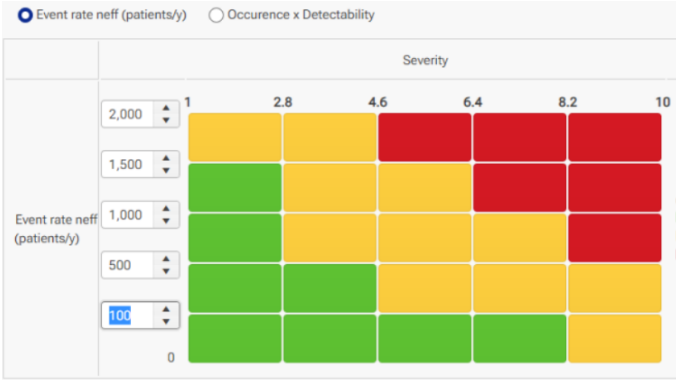
- Introduced effects and multiple barriers
  - Evaluate influence on risk level

Initial patiënt identificatie	Pocc,i 100%	**patiënt met nefropathie krijgt contrast** Show branch	Pocc 0.01 % ~~100%~~	Initial GFR controle door arts	Pmiss,i 100%		neff < 0.01 ~~200.00~~	nierblokkage	Neff < 0.01 ~~200.00~~
Potential gezichtsherkenning	pmiss 0.01%			Potential ER controleert GFR	pmiss 1%				
				Potential software	pmiss 0.01%				
				Active secretariaat controleert GFR	pmiss 10%				



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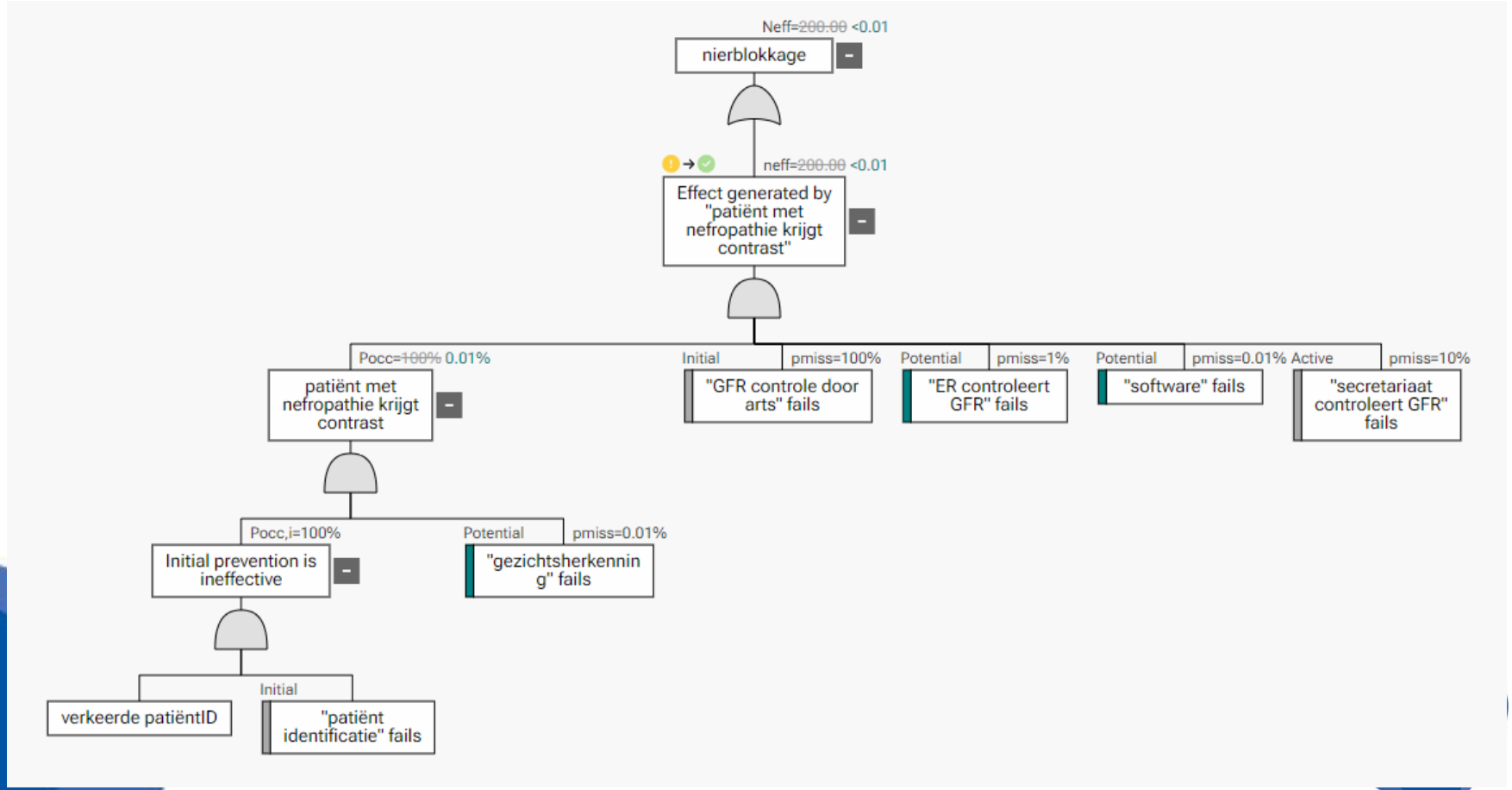
- Fault tree



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- Introduced some costs to evaluate the influence of added measures

	Measures				Cost/benefit					
Effect	Description	Type	Status	pmiss	Δneff (patients/y)	Overall ΔNeff (patients/y)	Event-related savings @5y (€)	Non-recurring cost (€)	Recurring cost (€)	Total cost @5y (€)
nierblokkage	secretariaat controleert GFR	Barrier	Active	10.00 %	<0.01	1,800.00	0	0	0	0
nierblokkage		Barrier		10.00 %	1,800.00					
nierblokkage	ER controleert GFR	Barrier	Potential	1.00 %	198.00	198.00	0	0	0	0
	ER controleert GFR		Active			<0.01	0	0	0	0
nierblokkage	gezichtsherkenning	Prevention	Potential	0.01 %	199.98	199.98	0	150,000	15,000	225,000
nierblokkage	software	Barrier	Potential	0.01 %	199.98	199.98	0	10,000	1,000	15,000

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- Introduced initial preventions and barriers and some additional barriers

Cause of failure	Failure Mode	Initial Preventions	Initial Barriers	Severity	Occurrence, initial	Detectability, initial	RPN, initial	Added Preventions	Added Barriers
Door eigen beslissing (geen geduld)	patiënt is afwezig	poster wachttijd max 30min	geen	2	6	1	12		
Te weinig ruimte (architectonisch)	agressie	voldoende zitplaatsen voorzien	geen	5	3	1	15		
Te lange wachttijden	patient wordt onwel	water en voldoende verluchting voorzien	geen	2	7	1	14		camera in wachtzaal
TV ontbrandt	brand thv wachtzaal	ABC poster	periodieke technische controle TV	7	3	1	21		
doordat patient in verkeerde wachtzaal zit	patiënt wordt vergeten	geen	RTT contacteert secretariaat	2	3	1	6	scansysteem	camera in wachtzaal
Mobiliteit	patiënt is afwezig	begeleiden van patiënt volgens protocol	arts vemeld mobiliteitsprobleem in assessment	2	7	1	14		
Delay ander OZ/behandeling	patiënt is afwezig	communicatie tussen diensten	haalbare planning	2	7	1	14		
Communicatie (taal, overtuiging)	agressie	tolkenlijst, informatiebrochures in andere talen	communicatietaal in KWS vermelden	5	3	1	15		
Te ziek	patiënt is afwezig	geen	geen	2	7	1	14		
patiënt sticht brand	brand thv wachtzaal	ABC en brandblusapparaten thv wachtzaal	geen	7	3	1	21		weinig brandbaar materiaal in
door Vervoer (extern/intern)	patiënt wordt vergeten	Logistiek medewerker regelt vervoer	geen	2	6	1	12		camera in wachtzaal
Geen/te weinig doorgankelijkheid	vallen	ruimte op orde houden	dagelijks onderhoud	5	6	1	30		

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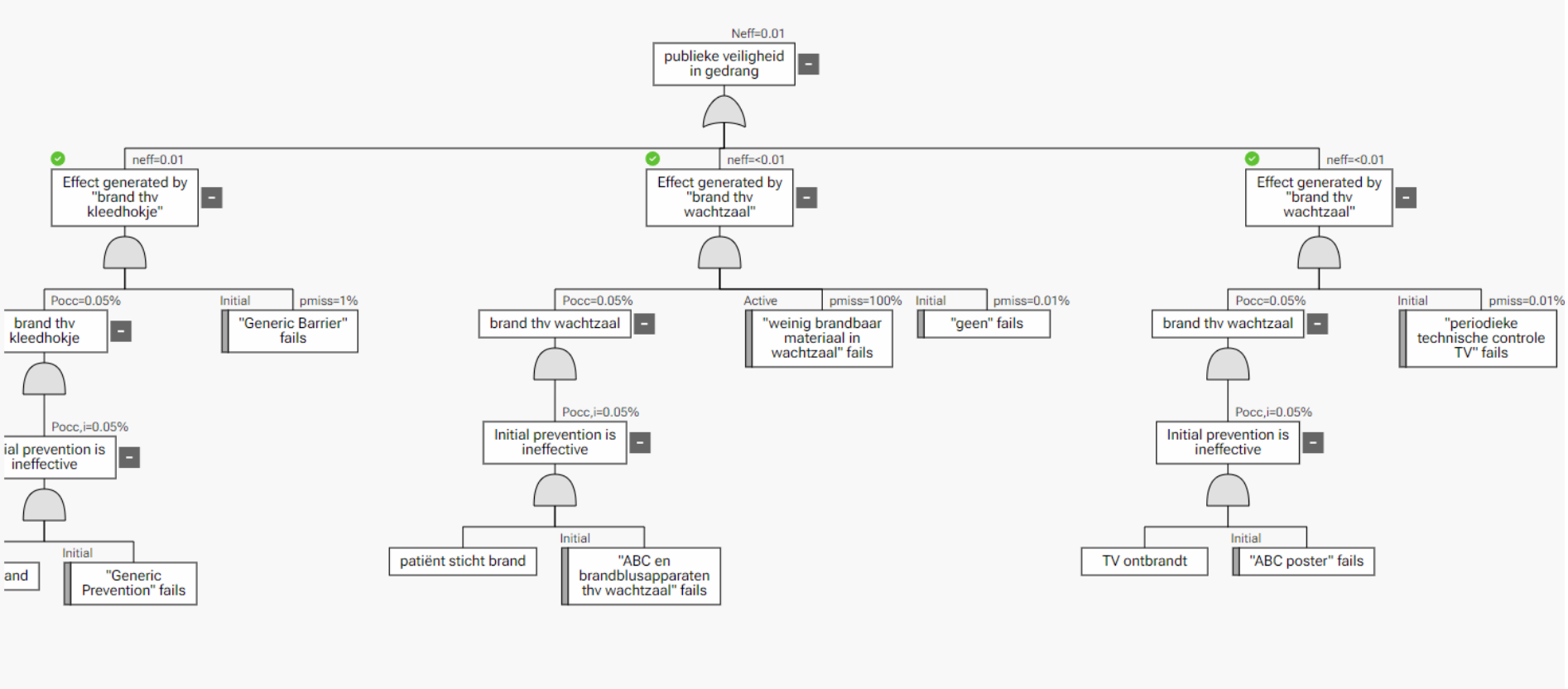
- Evaluated in fault trees



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Workshop conclusions

- Realized that we need to work on smaller processes
  - Less time consuming per process
  - Easier to keep team motivated

- Top 3 in change requests
  - Task manager
    - Assign tasks to users; send notifications; …
    - Important for review
  - More flexibility in tree structure
    - share causes between failure modes; link multiple causes in one failure mode; …
  - Scales optimization
    - Customize S,O,D scales (set range differently from 1-10; customize $P_{occ}(O)$ and $P_{miss}(D)$ relationships...)

Next step

- Create RA from scratch in myQA
  - Excel used for absolute dose calibration of linac
  - Required for MDR

p (hPa)	T (°C)	kTp	M1 (nC)	M2 (nC)	M3 (nC)	Mgemiddeld (nC)	D (cGy)	afwijking %
1014,5	21,8	1,0049005	-32,33	-32,31	-32,32	-32,32	201,66	0,8
1026	22,4	0,9956583	-32,72	-32,75	-32,75	-32,74	202,40	1,2
1026	22,4	0,9956583	-32,45	-32,41	-32,4	-32,42	200,43	0,2
1013	22,5	1,00877695	-32,05	-32,07	-32,08	-32,07	200,85	0,4
1020,5	22,9	1,00271791	-32,25	-32,26	-32,27	-32,26	200,85	0,4
1020,5	22,9	1,00271791	-32,25	-32,26	-32,27	-32,26	200,92	0,5
1016	23	1,00749928	-32,14	-32,15	-32,15	-32,15	201,17	0,6

- Start with creation of flow chart
- Define steps/sub-steps/failure modes/causes/effect
- Define per cause of failure
  - initial preventions & barriers / S-O-D / added preventions & barriers

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Benefits myQA over HFMEA

- More and visual information in RA
  - Flowchart
    - Helps to keep the overview during the analysis
  - Fault tree
  - Preventions & barriers
- Useful to prove necessity of investment (or not ☺)
- Report creation
  - No pdf export from excel needed
  - Clear overview for quality department

THANK
YOU