

Hands-on FMEA

Jennifer L Johnson, MS, MBA

2014 AAPM Spring Clinical Meeting

Denver, CO

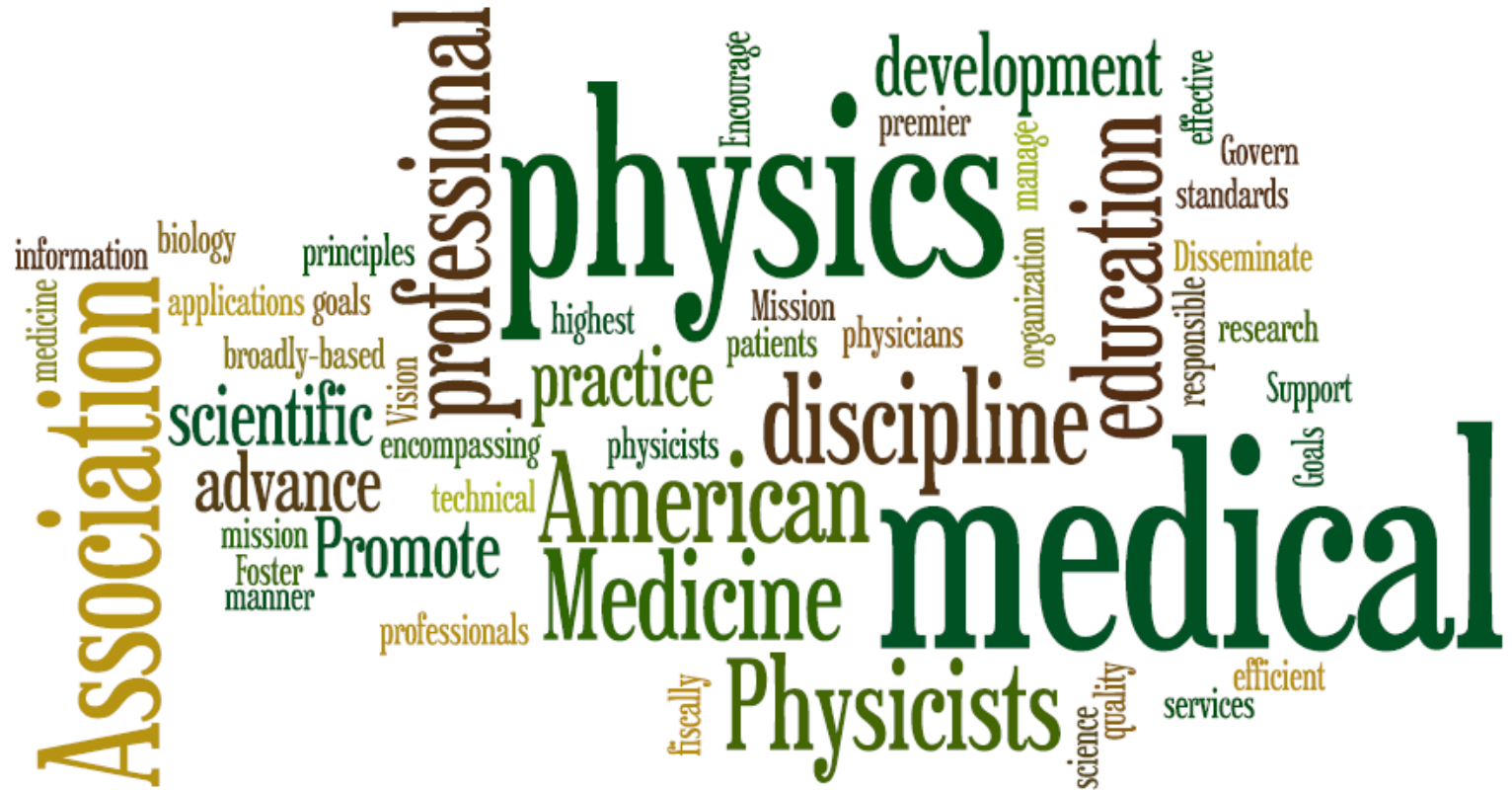
Outline

- Introduction – our responsibilities
- FMEA –
 - Specifics
 - Example
- Clinical examples
 - Emergency treatments
 - DIBH breast
- Breakout session
- Feedback
- Getting started at home
- Wrap up

Learning Objectives

- By the end of this session, the participant will be able to
 - 1) Describe process failure mode and effects analysis (FMEA) concepts.
 - 2) Apply FMEA on a single process step in a 2D case.

What Are Our Responsibilities?



What Are Our Responsibilities?



(Hendee and Herman, 2010) www.wordle.net

What Are Our Responsibilities?

- “The application of radiation to the human body entails risk. ...Medical physicists...ensure the safety and effectiveness of radiological procedures by verifying the appropriate type, dosage, and application of radiation to the body.”

Complexity and Risk Explosion

3D-CRT

MLC

EDW

IMRT

SRS

SBRT

IGRT

CBCT

Tomotherapy

VMAT

HDR

Cyberknife

GATING

DIBH

FFF

- Need a formal, structured way to approach risk

Failure Mode and Effects Analysis (FMEA)

- Systematic, proactive approach for identifying possible failures in a design, process or service
 - Failures = any errors, either potential or actual
 - Failure modes = ways in which something might fail
 - Effects analysis = studying the consequences of those failures
- Reduce the risk of harm by proactively correcting the processes to prevent the failures

Failure Mode and Effects Analysis (FMEA)

- Focus on the highest risk failure modes
- Failure modes prioritized based on how
 - Frequently they occur (O),
 - Easily they can be undetected (D), and
 - Severe (S) are the consequences
 - Scale each
 - 1 (low) – 10 (high);
 - Alternatively 1 – 3 or 1 – 5

Failure Mode and Effects Analysis (FMEA)

Table 4–3. Descriptions of the O, S, and D values used in the TG–100 FMEA

Rank	Occurrence (O)		Severity (S)		Detectability (D)
	Qualitative	Frequency	Qualitative	Categorization	Estimated probability of failure going undetected
1	Failure unlikely	0.01%	No effect		0.01%
2		0.02%	Inconvenience	Inconvenience	0.2%
3		0.05%			0.5%
4		0.1%	Minor dosimetric error	Suboptimal plan or treatment	1.0%
5		<0.2%	Limited toxicity or tumor underdose	Wrong dose, dose distribution, location or volume	2.0%
6	Occasional failures	<0.5%			5.0%
7		<1%	Potentially serious toxicity or tumor underdose		10%
8		Repeated failures	<2%		
9	<5%		Possible very serious toxicity or tumor underdose	20%	
10	Failures inevitable	>5%	Catastrophic		>20%

(Thomadsen *et. al.*, 2013)

Failure Mode and Effects Analysis (FMEA)

Table 1. Example scoring system of severity, frequency of occurrence, and detectability for input into failure mode and effects analysis

Score	Severity	Occurrence	Detectability
1	No effect	Less than every 5 years	
2	Dose Δ 5%	Every 2–5 years	Very easy to detect
3		Once a year	
4	Minimal delay in care	Several times a year	Easy to detect
5		Once a month	
6	Allergic reaction; moderate delay in care	Several times a month	Mildly difficult to detect
7		Once a week	
8	Dose Δ 20%, reportable	Several times a week	
9		Once a day	
10	Patient dies	Several times a day	Impossible to detect

(Ford *et. al.*, 2009)

Failure Mode and Effects Analysis (FMEA)

- Calculate risk priority number (RPN) = $O * D * S$
 - Higher RPN means failure mode is more likely to occur, be undetected, have greater severity
 - Range 1 to 1000
 - Alternatively 1 to 27 or 1 to 125
- Rank RPN
- Plan improvements

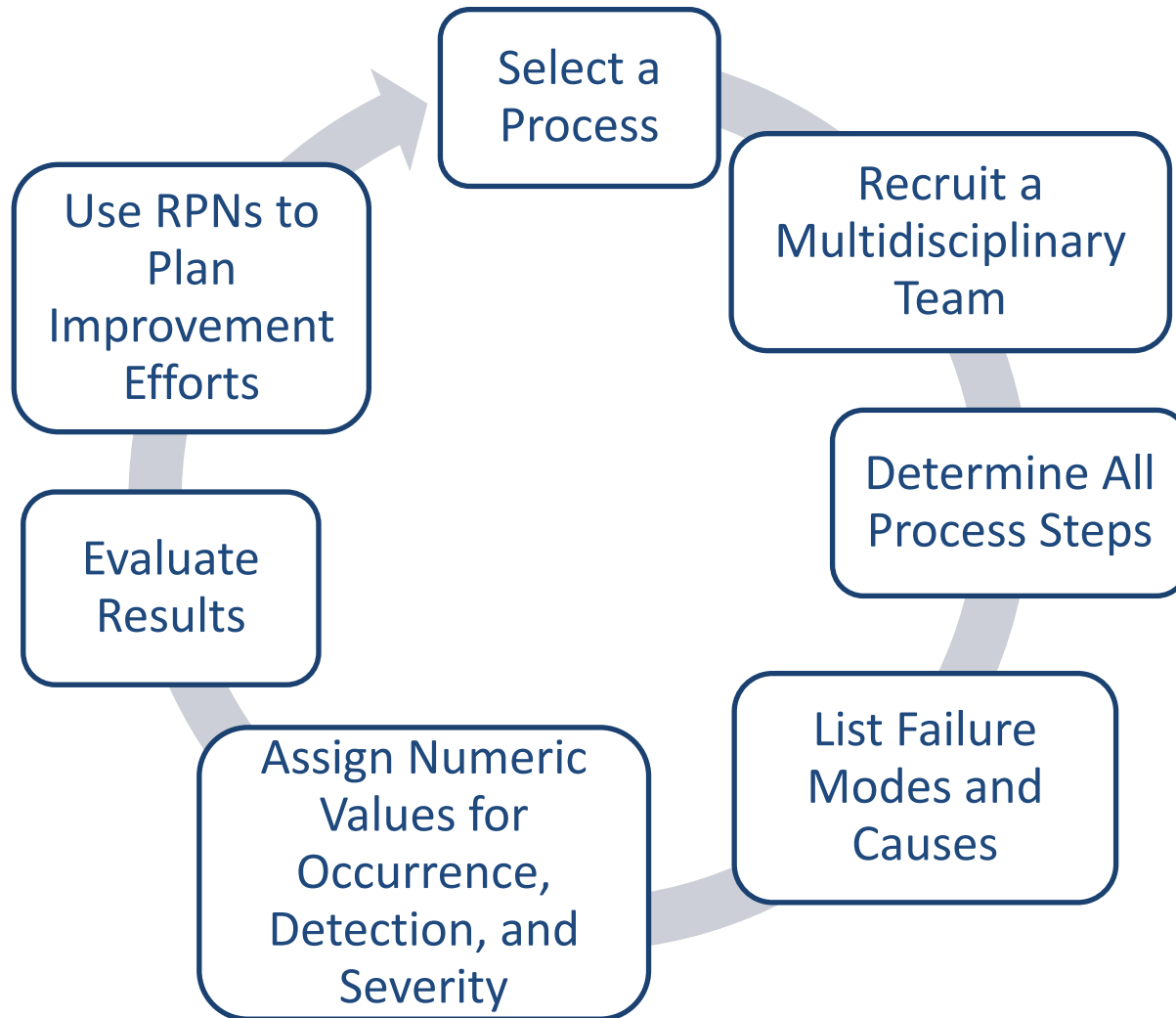
Using FMEA

- Plan actions to reduce harm from failure modes
 - Likely to Occur
 - Eliminate any or all causes
 - Add a forcing function making it impossible
 - Add verification step (e.g., double check, bar codes, alert screens)?
 - Modify other contributing processes
 - Likely to be unDetected
 - Identify prior events that can serve as “flag” of the failure mode
 - Add a step to intervene
 - Technological alerts when values approach unsafe limits

Using FMEA

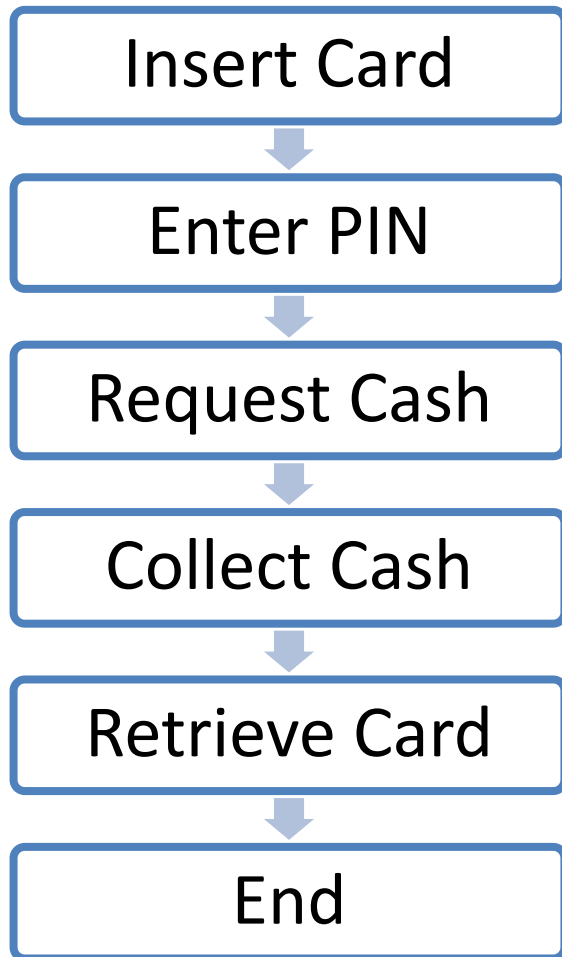
- Likely to cause Severe harm
 - Identify early warning signs and train staff to recognize them
 - Provide information and resources at points of care for events
- Evaluate potential impact of considered changes
- Monitor and track improvement over time

Steps to Completing FMEA



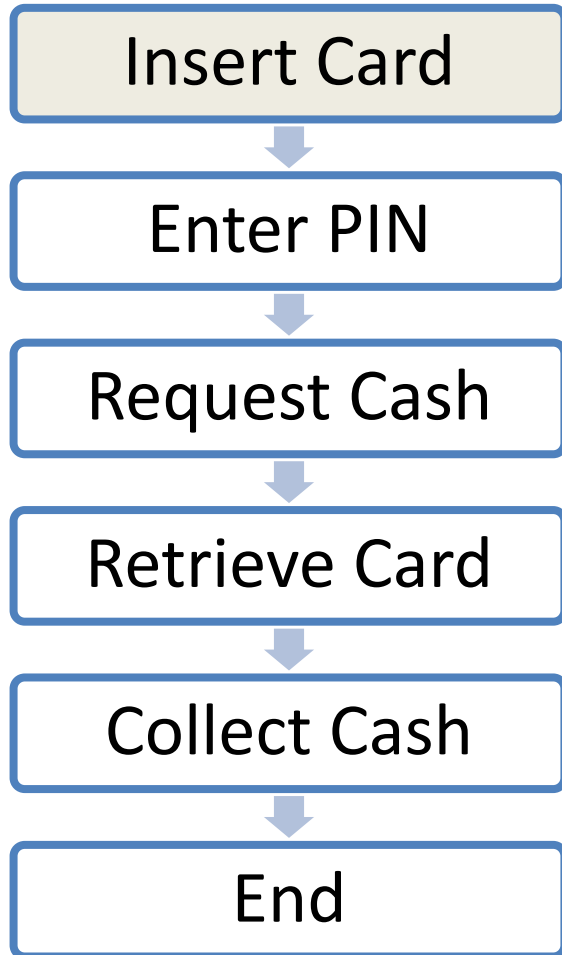
(Institute for Healthcare Improvement, 2004)

ATM Example



- Process map for ATM Cash Machine
- *Bank's view:* High risk of collecting cash then leaving card in machine – (Cost \$\$\$ to replace)
- What to do to minimize the risk?

ATM Example



- Process map for ATM Cash Machine
- *Your turn:* Risk of failure of inserting card
- What could be the failure modes?

ATM Example – Failure Modes

Insert Card

- Not insert card
- Insert card wrong direction
- Insert wrong card (debit vs. credit)

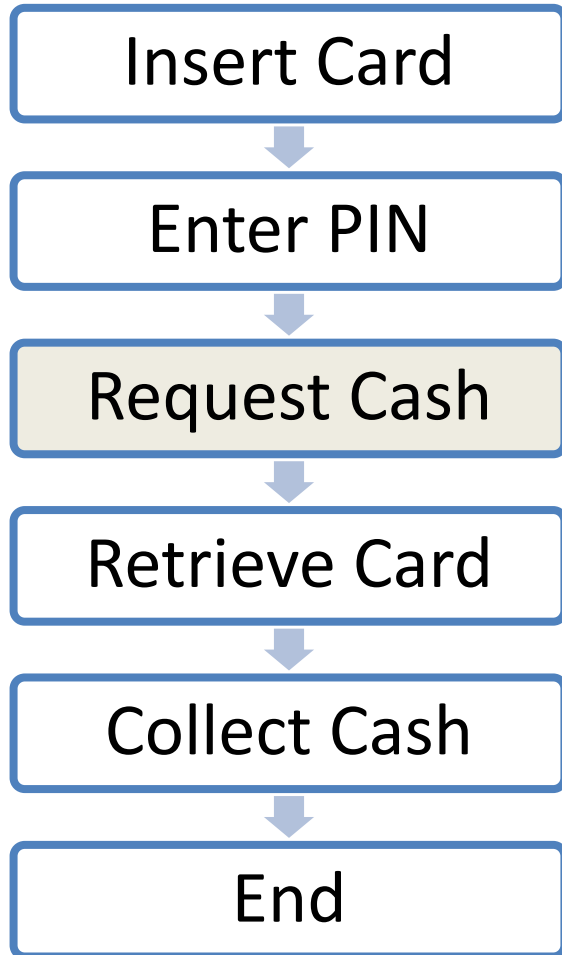
- For each, what could be the
 - Causes?
 - Effects?
 - Likelihood of
 - Occurrence?
 - Detectability?
 - Severity?
- What to do to minimize the risk?

ATM Example – Failure Modes

Failure Mode and Effects Analysis							
Steps in the Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1-10)	Likelihood of Detection (1-10)	Severity (1-10)	Risk Profile Number (RPN)
Insert card	Not insert card	Slip or lapse	Not get money	1	1	1	1
	Insert card wrong direction	Training;	Spits card back out	2	1	1	2
	Insert wrong card (debit vs. credit)	Look alike; Keep in same location	Proceed to withdraw from wrong account	3	3	4	36

- What to do to minimize the risk?

ATM Example



- *Your turn:* High risk of requested cash amount is incorrect
- What could be the failure modes?

ATM Example – Failure Modes

Request Cash

- Not enough
- Too much
- Typo

- For each, what could be the
 - Causes?
 - Effects?
 - Likelihood of
 - Occurrence?
 - Detectability?
 - Severity?
- What to do to minimize the risk?

ATM Example – Failure Modes

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Insert card	Not insert card	Slip or lapse	Not get money	1	1	1	1
	Insert card wrong direction	Training;	Spits card back out	2	1	1	2
	Insert wrong card (debit vs. credit)	Look alike; Keep in same location	Proceed to withdraw from wrong account	3	3	4	36
Request Cash	Not enough	Underestimate how much need; typo	Can't pay with cash	6	5	4	120
	Too much	Overestimate how much need; typo	Overdraw account; ATM doesn't give money	3	4	7	84

Radiation Therapy Process Examples

- TG-100 – IMRT and HDR brachytherapy (Huq *et. al.*, 2008)
- QA for dynamic MLC tracking systems (Sawant *et. al.*, 2010)
- Delivery of Lung SBRT (Perks *et. al.*, 2012)
- Intraoperative RT using mobile electron linear accelerators (Ciocca *et. al.*, 2012)
- Pretreatment phases in Tomotherapy (Broggi *et. al.*, 2013)
- HDR brachytherapy treatment planning (Wilkinson and Kolar, 2013)
- Scanned proton beam radiotherapy treatment planning (Cantone *et. al.*, 2013)

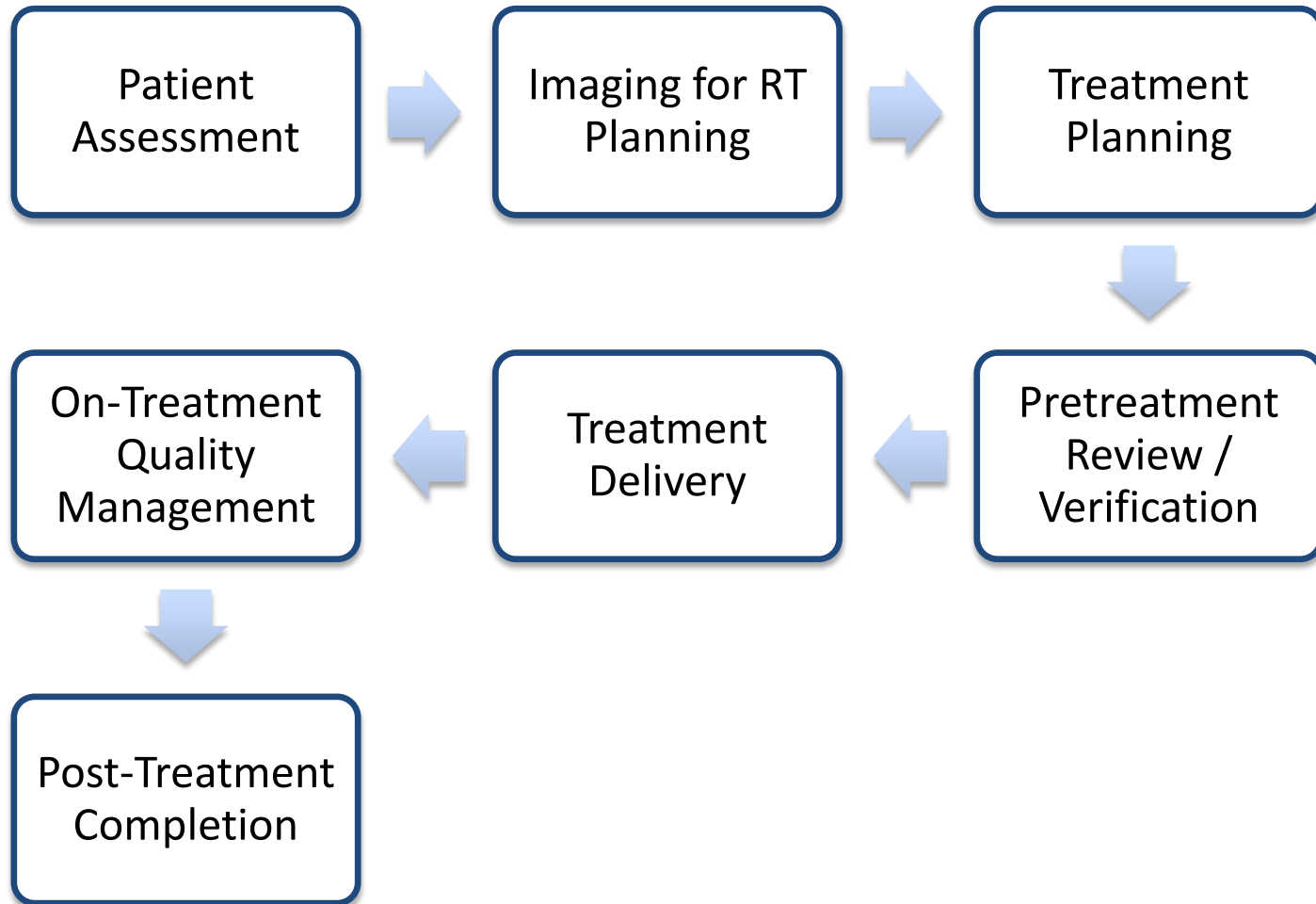
Breakout – T-Spine Example

- Problem: palliative spine treatment
- Prescription:
 - Site: T6, so field covers T5 – T7
 - Technique: AP/PA
 - Energy: 18 MV
 - Dose: 4 Gy / fraction
 - Field size: 8 x 10 (width x length)
 - SAD setup, AP/PA separation 20 cm

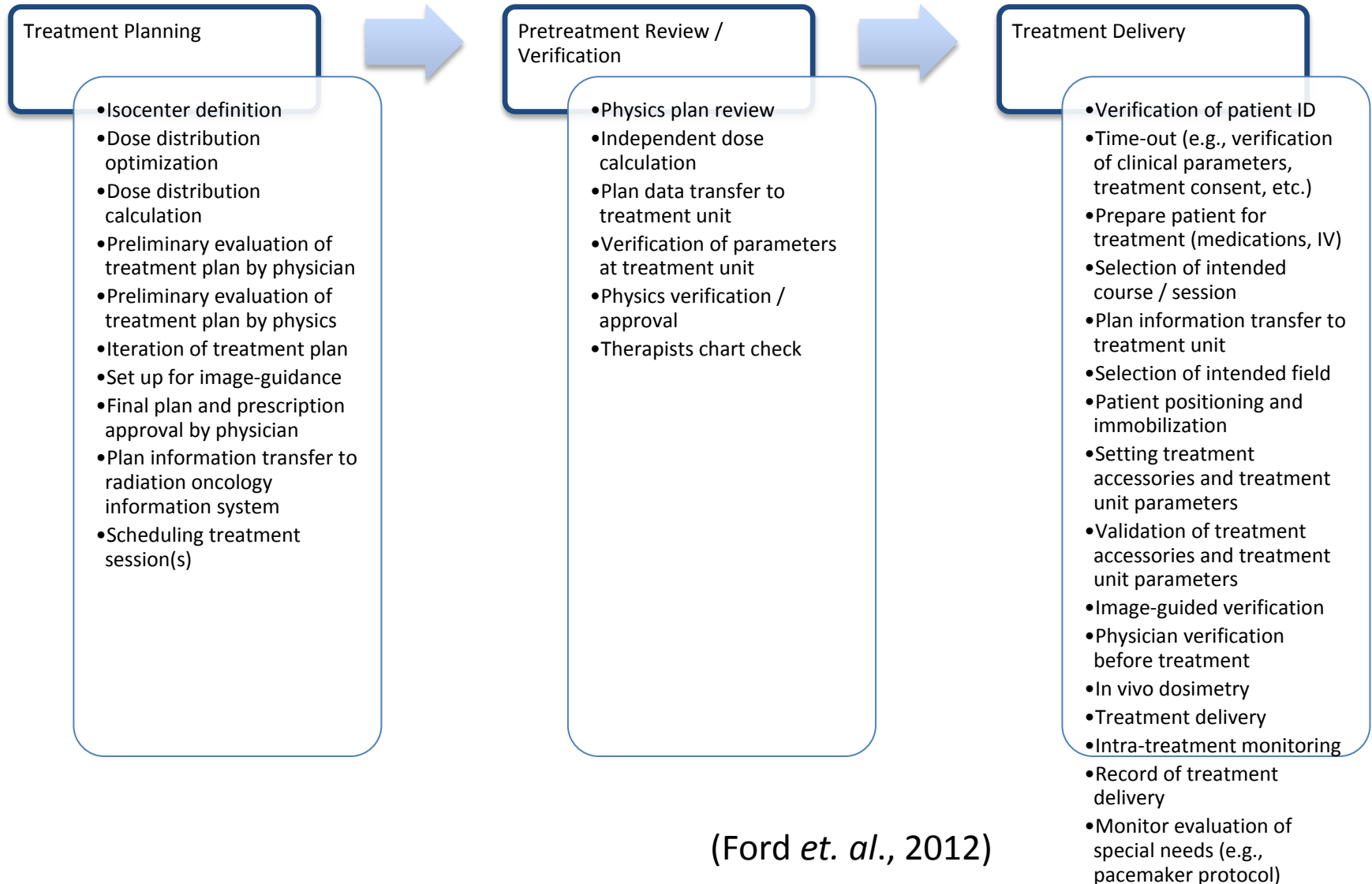
Breakout – T-Spine Example

- Using a part of the Process Map, pick a few subprocesses and calculate the RPN score

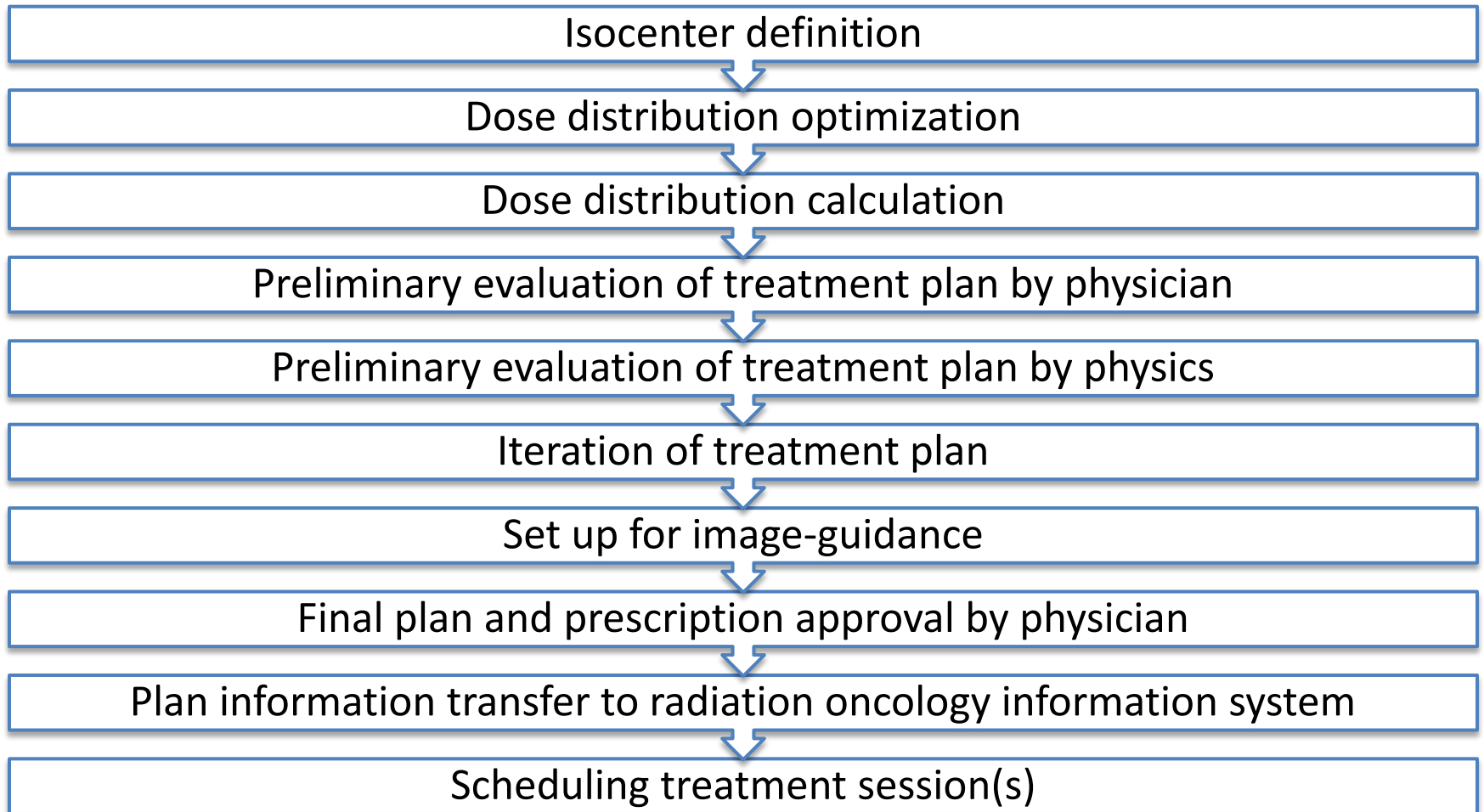
Radiation Treatment Process Map



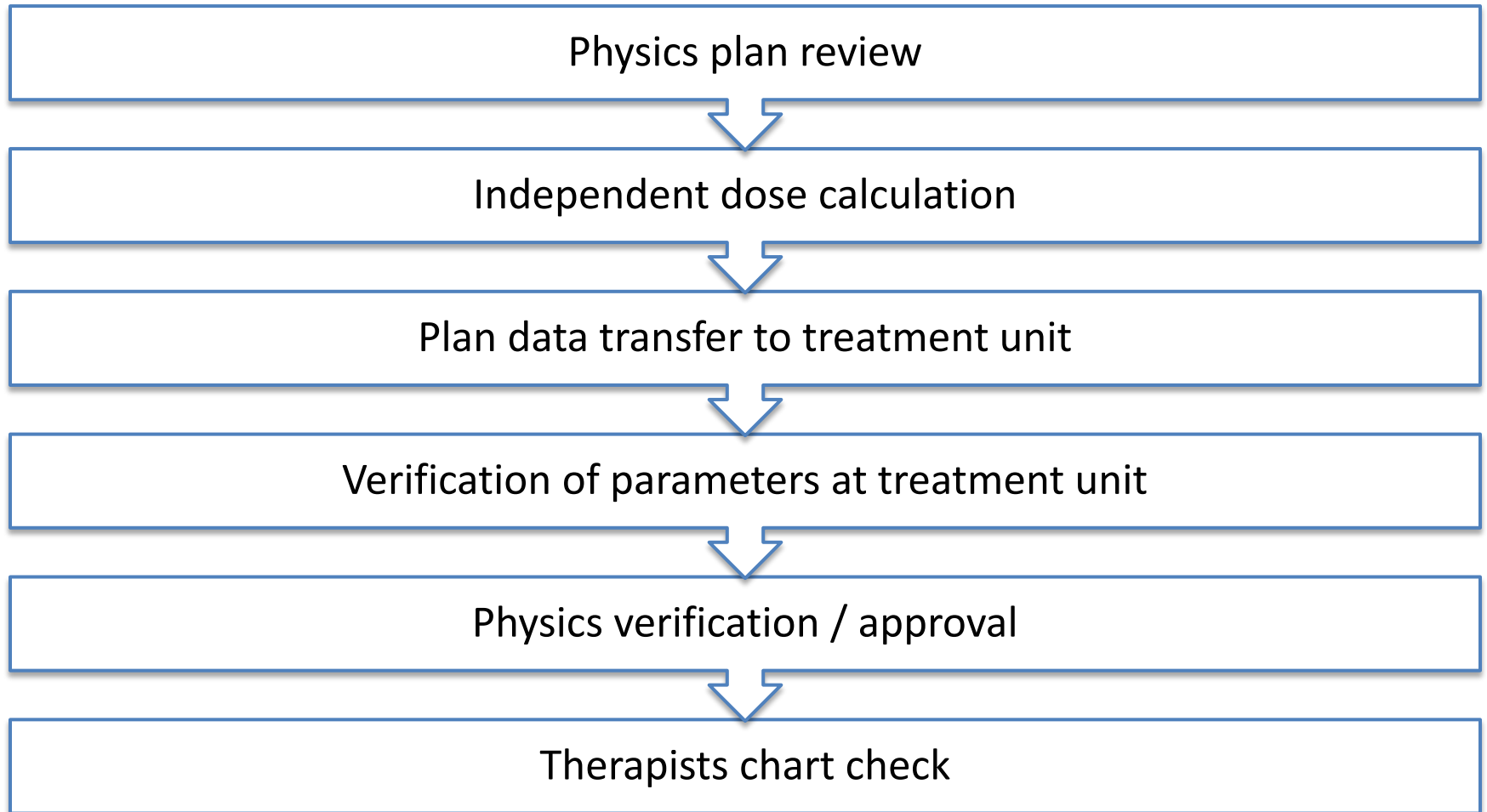
Radiation Treatment Process Map



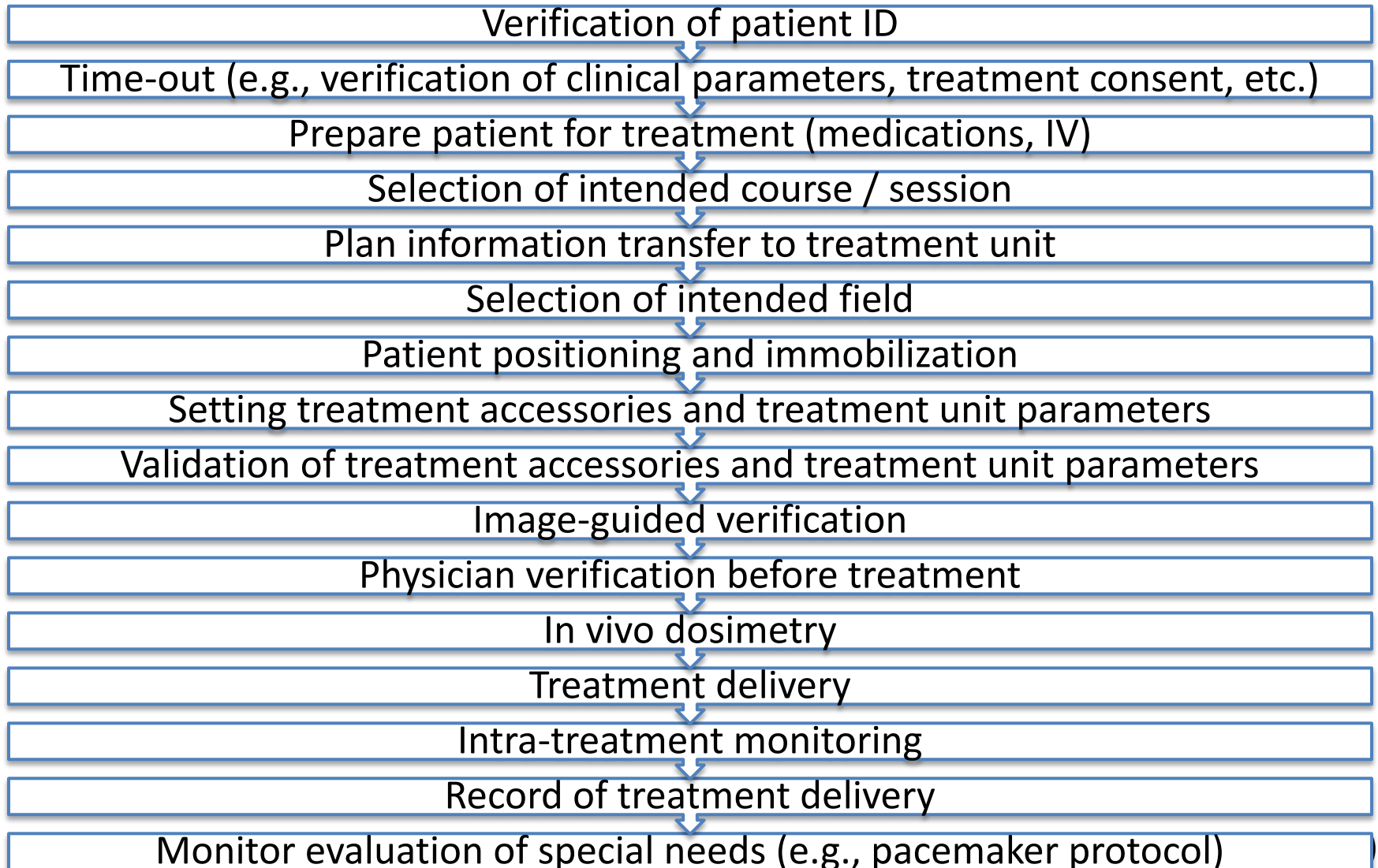
Treatment Planning Process Map



Pretreatment Review Process Map



Treatment Delivery Process Map



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