Mesh brachytherapy quality management and medical event definition

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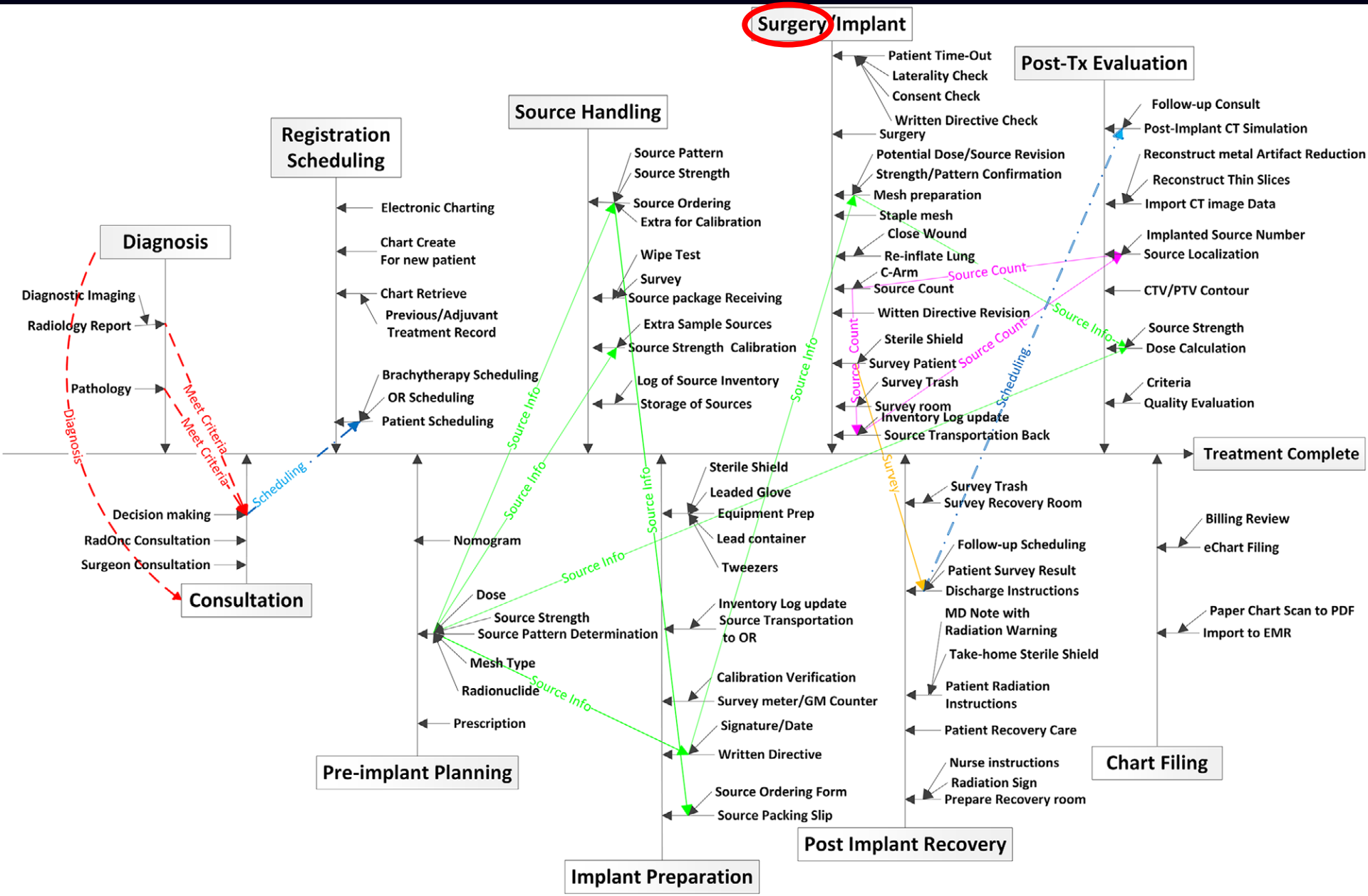
Learning Objectives:

- Review recommendations for quality management unique to mesh brachytherapy.
- Understand the definition of a medical event and specific nuances to mesh brachytherapy.

Outline:

1. Workflow
2. Quality Management
3. Medical Event
4. Recommendation

Workflow: Process Map



Workflow: Source Counting - prior to implant

- Source ordered number
  - from Nomogram + extra for calibration
- Source received number
  - verify consistent with ordered and in certificate
  - Inventory log update
- Source calibrated number
  - At least 10%

Workflow: Source Calibration - prior to implant

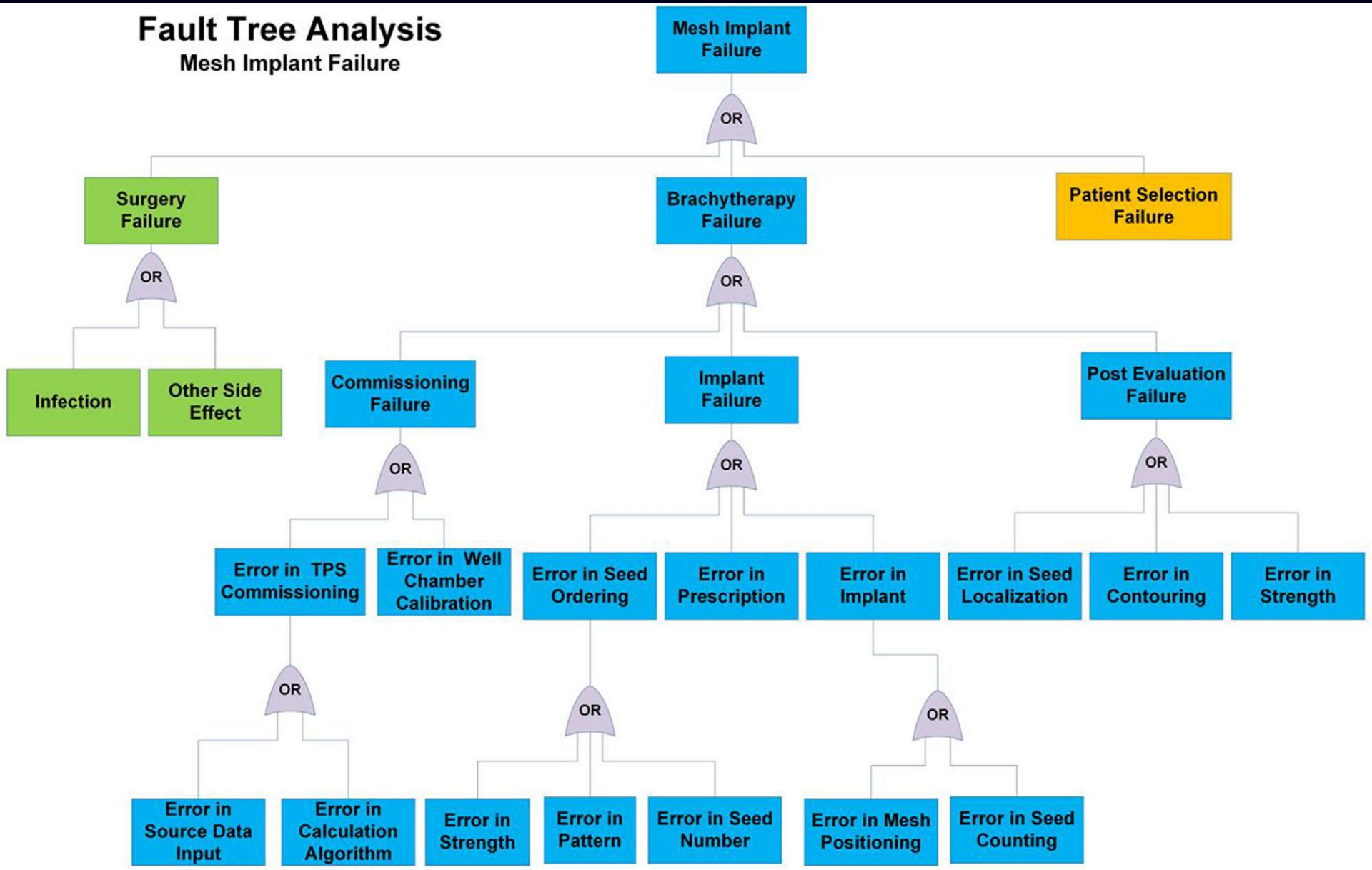
- measure at least 10% of the total number of strands using a strand calibration coefficient
- order extra nonsterile loose seeds and perform measurements on at least 10% of the total number of sources

- If the source strength on the vendor certificate is verified within 5% of the mean of the measured seeds, then the sources to be implanted are inferred to be the same as the measured seeds
- If a difference more than 5% is observed after reperforming the measurements, the physicist should contact the vendor and notify the radiation oncologist toward deciding how to proceed

Workflow: Source Counting – implant day

- Source transferred to OR
  - Inventory log update
  - Differentiate sterile and non-sterile
- Source implanted
  - Visual counting
  - Imaging verification in OR with C-Arm, CT, etc
- Source unused
  - Visual counting
  - Transfer back to hotlab
  - Inventory log update
- If source count not matching,
  - Additional imaging by varying beam angle and FOV
  - Survey staff before leave room
  - Carefully survey room, patient, staff and trash

Quality Management: Fault Tree Analysis



Quality Management: prior to implant

- Commissioning of TPS and Well Chamber Calibration
  - End to End test with gel phantom
  - Order calibration source from same vendor
  - Make sure ADCL calibration stay current
- Pre-implant planning and written directive
  - Prescription dose based on lookup table from ABS
- Seed Ordering/Calibration
  - from Nomogram + extra for calibration
  - Order as early as possible, in case some emergency like storm, Covid, etc

Quality Management: implant day

- Implant including mesh handling and seed counting
  - Ring badge, sterilation issue
  - Leaded glove, typically not used
  - Securely sutured to mesh, no loose source
- Post-implant source courting
  - Written directive update based on implanted source strength
  - Update before leaving OR

Quality Management: post implant

- Post implant evaluation
  - CT based
    - Thin slice
    - Metal artifact reduction
  - dosimetric metrics
    - Target D90, D100, V95, and V100 as well as dose and volume constraints to healthy tissues
    - Not directly used for Medical Event evaluate

Medical Events: Evolving History

- NRC 35.3045 historical definition
  - "the total dose delivered differs from the prescribed dose by 20 percent or more."

- Special considerations for lung mesh brachytherapy: Dramatically different geometries of the deflated lung when implanted compared to the inflated lung after implantation.

- NRC 35.3045 current definition after 08/17/2017
  - The total source strength administered differing by 20% or more from the total source strength documented in the post-implantation portion of the written directive
  - The total source strength administered outside of the treatment site exceeding 20% of the total source strength

Medical Events: NRC 35.3045 current definition

- The total source strength administered differing by 20% or more from the total source strength documented in the post-implantation portion of the written directive
- The total source strength administered outside of the treatment site exceeding 20% of the total source strength
- An administration that includes any of the following:
  - The wrong radionuclide;
  - The wrong individual or human research subject;
  - Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or
  - A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.
- any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

Recommendation Summary: prior to implant

- Examine the radioactive materials license, potential license amendment
- Commission and implement preimplant and postimplant treatment planning methods to guide correct source ordering
- Prepare a quality management program that includes all direct stakeholders in its refinement.
- Provide proper training for source handling and radiation safety to all involved staff
- Utilize a prescription based on table lookup of intended dose, depth, and treatment area
- Assay and evaluate sources from the same manufacturer lot (use sources from same lot for a single patient) preceding implantation

Recommendation Summary: implant day

- Utilize a written directive based on the implanted source strength, not target-volume dose coverage
- Follow the whole team-approved workflow during the implantation process to ensure implant accuracy according to the written directive and to follow good radiation safety practice and compliance
- Survey patient, staff and room, follow patient release criteria

Recommendation Summary: post implant

- Calculate postimplant dosimetry with the AAPM TG-43 formalism with point source approximation
- Perform dose estimates using an MBDCA (if available) for scientific evaluation of a given anatomic site and brachytherapy treatment modality
- Evaluate treatment quality using target dosimetric metrics such as D90, D100, V95, and V100 as well as dose and volume constraints to healthy tissues
- Evaluate if meet Medical Event criteria

Acknowledgement

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  - 9/16/2011 - 12/31/2022

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