

# Failure Modes and Effects Analysis in Image Guided High-Dose-Rate Brachytherapy: A Single Institutional Study

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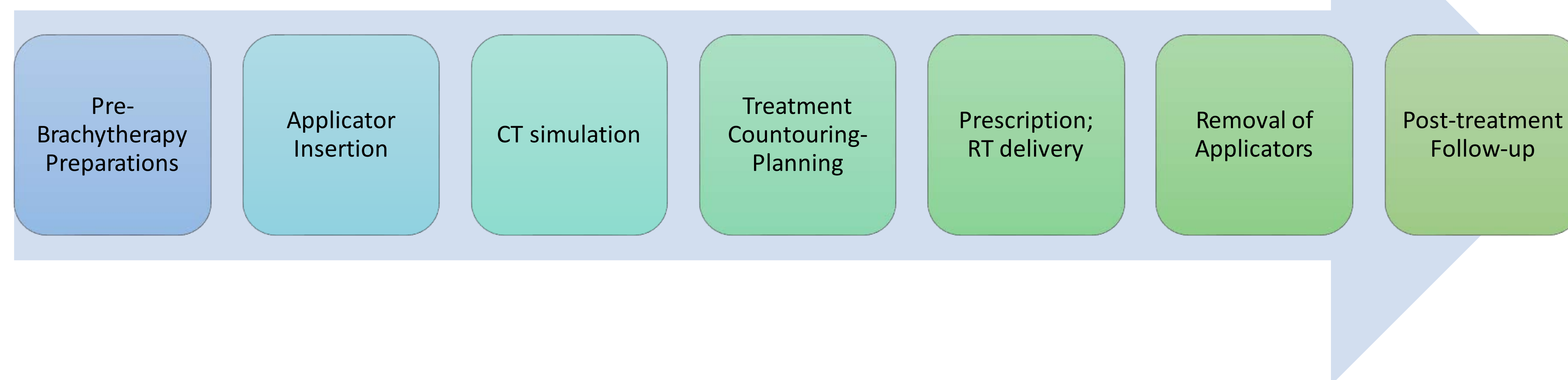
## Background and Objective

Image Guided Brachytherapy (IGBT) in the Philippines is relatively new approach for delivering brachytherapy. A risk assessment should be conducted to recognize potential hazards, ascertain their causes, and formulate mitigation schemes. The purpose of this paper is to improve current practice by analyzing the potential risk for each steps in Image Guided Brachytherapy using the application of Failure Modes and Effects Analysis and create necessary adaptation in workflow that will provide efficient and safe environment for patients and staffs.

## Methods

A multispecialty team which includes Radiation Oncology Residents, Medical Physicists, Radiation Therapy Technologists, and Oncology Nurses participated in this activity. Detailed problem list was created for each IGBT treatment process. The team was able to identify failure modes for each processes and score all failure modes using the ten point scale risk priority number (RPN) scoring method, based on the product of severity (S), occurrence (O), and detectability (D) scoring. Scores was rank and stratify for each of the sub-processes. As already applied in previous FMEA studies in RT, the value RPN = 125 was considered as a threshold below which the risk can be considered acceptable.

Figure 1. IGBT Treatment Process



## Results and Discussion

The study was able to generate with an average of 12 failure modes per sub-processes namely Patient Evaluation, Pre-Brachytherapy Preparations, CT Simulation, Treatment Contouring, Prescription and Treatment Delivery, Removal of Applicators, and Post-Treatment Follow-up. We stratify each failure modes and will report top 3 for each sub-process.

Figure 2. IGBT Problem List & Risk Priority Number

| Problem List                             | S  | O | D  | RPN | Rank |
|--|----|---|----|-----|------|
| <b>Patient Evaluation</b>                |    |   |    |     |      |
| Prolonged time-interval                  | 9  | 9 | 6  | 486 | 1    |
| Delay in scheduling                      | 8  | 8 | 2  | 128 | 2    |
| Incomplete requirements                  | 9  | 7 | 2  | 126 | 3    |
| <b>Pre-Brachy Preparations</b>           |    |   |    |     |      |
| Improper sterilization                   | 6  | 6 | 8  | 288 | 1    |
| Incomplete materials                     | 7  | 7 | 4  | 196 | 2    |
| Inadequate patient preparation           | 6  | 5 | 5  | 150 | 3    |
| <b>Applicator Insertion</b>              |    |   |    |     |      |
| Uterine Perforation                      | 10 | 4 | 5  | 200 | 1    |
| Blood contaminating open-ended catheter  | 8  | 5 | 4  | 160 | 2    |
| <b>CT Simulation</b>                     |    |   |    |     |      |
| Improper immobilization                  | 9  | 8 | 10 | 720 | 1    |
| Incorrect CT sim protocol                | 9  | 6 | 8  | 432 | 2    |
| Unavailable CT simulator                 | 10 | 7 | 2  | 140 | 3    |
| <b>Treatment Contouring and Planning</b> |    |   |    |     |      |
| Incorrect contour of volumes             | 9  | 8 | 9  | 648 | 1    |
| Mislabeling of needles/applicators       | 8  | 6 | 7  | 336 | 2    |
| Prolonged treatment planning             | 8  | 7 | 4  | 224 | 3    |
| <b>Treatment Delivery</b>                |    |   |    |     |      |
| Emergency preparedness                   | 7  | 9 | 7  | 441 | 1    |
| Transfer tube near patient skin          | 5  | 8 | 9  | 360 | 2    |
| Incomplete dose delivery                 | 9  | 5 | 6  | 270 | 3    |
| <b>Removal of Applicator</b>             |    |   |    |     |      |
| No radiation survey                      | 8  | 5 | 5  | 200 | 1    |
| Failure to secure tube caps              | 9  | 6 | 3  | 162 | 2    |
| Source stuck-up                          | 9  | 3 | 5  | 135 | 3    |
| <b>Post Treatment Follow-up</b>          |    |   |    |     |      |
| Insufficient patient instruction         | 9  | 8 | 7  | 504 | 1    |
| Lost to follow-up                        | 8  | 6 | 4  | 192 | 2    |
| Incomplete laboratories                  | 7  | 5 | 4  | 140 | 3    |

Legend: S-Severity, O-Occurrence, D-Detectability, RPN-Risk Priority Number

## Conclusions

- The application of FMEA from the Patient Evaluation to the Post-treatment Follow-up has led to deeper investigation of various failure modes.
- Utilizing the ten point scale in assessing the potential risk for each event permitted stratification of these failure modes in order of importance and the ability to define priorities for future risk mitigation, with the goal of optimizing quality management system.
- On the basis of the results obtained in this study and of the experience accrued by the Multispecialty Team, further investigation on safety barriers to promote risk mitigation using Fault Tree Analysis (FTA) are proposed in the near future.

## References

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