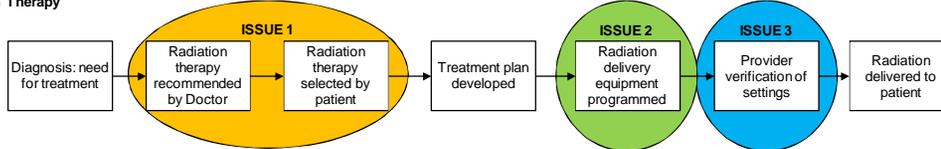


Applying the Proposed FDA Initiatives to Fatal Radiation Overdose from Cancer Treatment

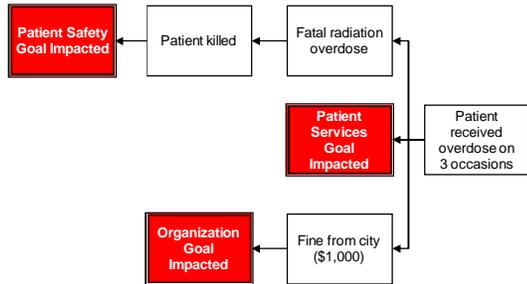
Process Map Radiation Therapy



ISSUE 1: Patient/Doctor choose radiation therapy over other options

The FDA initiative aims to ensure medical justification and informed decision-making by patients and their doctors. In order for the decisions to be informed, the FDA notes that patients must have comprehensive understanding of both the risks and benefits of the use of radiation. If patients were more aware of the risks of the use of radiation, it's possible that Jerome-Parks and others would have chosen alternative approaches or would have selected facilities based on their experience or safety rating. Currently, because reporting requirements for errors involving radiation are inconsistent (or there are none at all), it's nearly impossible for patients to make these sorts of comparisons.

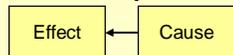
Cause Map Radiation Overdose



Issue 3: Lack of training and quality assurance practices

The FDA has also noted the lack of training and quality assurance practices for some radiation delivery practitioners. Several medical organizations are attempting to create standardized training and quality assurance methods to provide practitioners with the information they need to properly use radiation delivery equipment. The FDA is also planning to partner with the Center for Medicare and Medicaid Services (CMS) to incorporate appropriate quality assurance practices into accreditation and participation criteria for medical facilities, further supporting the safe use of radiation delivery equipment.

Why?



NOTE: Read the Cause Map from left to right with the phrase "Was Caused By" in place of each arrow.

ISSUE 2: Inadequate safeguards on equipment

Another issue raised by Jerome-Parks case is the lack of safeguards on the radiation equipment itself. Jerome-Parks received seven times the radiation dose on three occasions, and nobody noticed. The FDA proposes that equipment designed to deliver radiation be equipped with safeguards that optimize radiation doses and/or provide alerts when radiation exceeds a reference level or range. These safeguards would alert providers when radiation doses are higher than expected, giving them another chance to verify that the settings are correct. Hopefully this will prevent many occurrences of radiation overdose.

