

Module 2.6: Miscalibration of beam (Costa Rica)

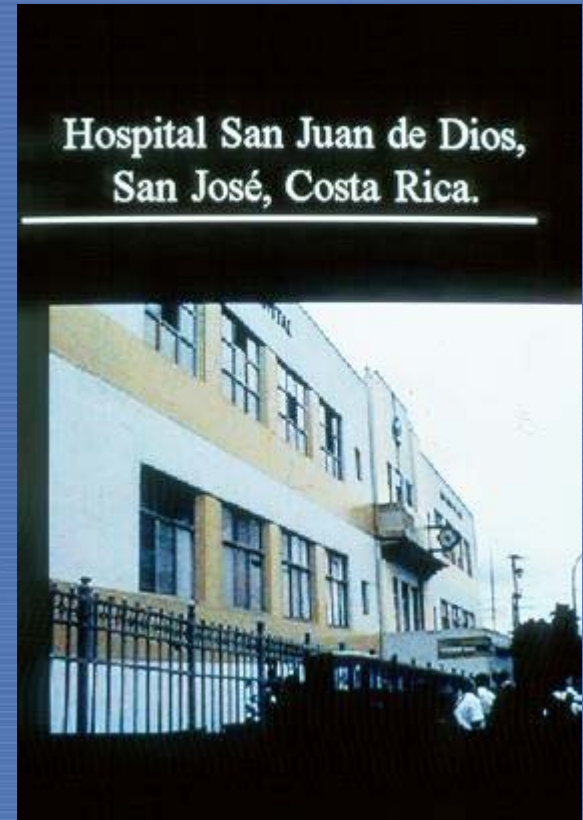


IAEA

International Atomic Energy Agency

Overview

- Error in calculation
- Overdosage
- 115 patients affected
- Person in charge of dosimetry not appropriately qualified
- Failure to act on advice



Prior to the event: problems

- The radiotherapy department had participated in the IAEA / WHO Postal Dose Quality Audit
- Since 1977 significant differences between the dose stated by the hospital and the dose determined by the IAEA's laboratory
- Since no satisfactory explanation was found, an **expert mission was sent in** July 1996, shortly before the event

Prior to the event: mission

The purpose of the mission was to:

- Find out the reasons for the discrepancy
- Evaluate the physical aspects of Quality Assurance
- Check the application of the IAEA code of practice for absorbed dose determination
- Check compliance with the Basic Safety Standards (BSS)

Prior to the event: findings

Problems

- The same “output” values were used for PDD as for TAR
- It revealed confusion between the concepts of kerma in air and absorbed dose to water

Action

- The expert brought it to the attention of the radiation oncologists and the person responsible for dosimetry

Prior to the event: responses

Responses

- The response was skeptical, arguing that no clinical abnormal reactions had been observed so far
- The expert insisted that the errors detected were underdosage errors, which, would not manifest in acute patient reactions, but would only manifest later in poor tumour control

Time scale prior to the event

July 1996

- Investigation by the IAEA Expert Group

August 1996

- The source of the Alcyon teletherapy unit was exchanged and put into operation



Alcyon CGR II unit

The event and its discovery

- A radiation oncologist from another hospital (hospital Calderón Guardia) whose patients were treated in San Juan de Dios Hospital (where the event occurred) **noticed some unusually severe reactions** in some of the patients treated on the Alcyon unit
- These reactions were related to the skin and low intestinal track, *e.g.*, diarrhoea and abdominal pain

The event and its discovery

Detection

- He compared the patient charts and realized that the indicated dose rate from the Alcyon was lower than from the Theratron, despite the fact that the activity of the new unit was higher

Action

- He reported it to the person responsible for the dosimetry in the San Juan de Dios Hospital

The discovery of the mistake

- On 27 September 1996, after one month working with the new source, the person responsible for dosimetry contacted the physicist at another hospital and asked him to measure the dose rate
- The value obtained was 2.02 Gy/min (at the point of maximum dose), while the value that had been used for treatments had been 1.22 Gy/min

According to the information provided ...

- From discussions upon this cross-check, it emerged that during the beam calibration upon source exchange ...
- ...the reading of the irradiation timer had been confused
- The value of 0.3 minutes (18 seconds) was taken as 30 seconds, thus resulting in an overestimation of the treatment time by about 66%
 - $\frac{30}{18} = 1.66$

The outcome

- As a result the dose rate was underestimated by the same factor and therefore the dose to patients would have been higher than intended
- Subsequent treatment times calculated with the lower dose rate were about 60% longer than required
- 115 patients were affected and two years after the event, at least 17 patients had died from the overexposure

Immediate action

- The person in charge of dosimetry at San Juan de Dios contacted the Section for Control of Ionizing Radiation of the Ministry of Health of Costa Rica
- Ministry immediately **ordered unit to cease operation and initiated an investigation**

Use of linear quadratic model

- Since fraction dose was higher than normal, the higher fraction size might have an influence on late effects
- This effect was estimated for some selected patients
- Linear Quadratic (LQ) model was used to calculate the biologically effective dose (BED) and the dose that would produce the same effect, if it were given in 2 Gy fractions

Some example results for BED and equivalent to 2 Gy/fraction

Patient No	Tissue	Total absorbed dose (Gy)	Equivalent treatment with 2 Gy/fraction (Gy)
54	Thoracic spinal cord	52	71
54	Brain	59	67
47	Brain	68	75
109	Brain	58	72

Error recalled

- The value of 0.3 minutes (18 seconds) was taken as 30 seconds, thus resulting in an overestimation of the treatment time by about 66%
- Subsequent treatment times calculated with the lower dose rate were about 60% longer than required
- **Total dose and dose per fraction were increased** - increased late effects

Potential effects

- **Cranial and spinal over exposure**
 - Significant neurological consequences including quadriplegia
- **Pelvic over exposure**
 - Severe bloody diarrhoea
- **Limited lifespan**
 - Tumour related or further complications
- **Quality of remaining life and life expectancy may have been significantly reduced**

Assessment of the impact

Assessment was carried out at 10 and 25 months

	July 1977	August 1998
Total patients evaluated	73 (70 examined)	53 (51 examined)
Severe/catastrophic effects	4	2
Marked effects / at high risk	16	12
Not severe / low risk	26	22
RT discontinued (underexposure) / at risk of recurrence	3	2
Deceased / radiation related	7	13
Deceased / possibly related	0	4
Deceased / not related	22	35
Deceased / insufficient data	13	9

Difficulties in retrospective dose assessment

- No running record of tumour dose or the time for delivery of each fraction
- No indication of who treated the patient on a given day
- It was not always possible to know which fractions had been used on which machine
- No indication of whether charts reviews were performed during the course of therapy
- The charts for the other hospital (Hospital Calderón Guardia) were better documented

Causes of the error

- **Arithmetical mistake**
 - The value of 0.3 minutes (18 seconds) was taken as 30 seconds, thus resulting in an overestimation of the treatment time by about 66%
 - Subsequent treatment times calculated with the lower dose rate were about 60% longer than required
- **Contributory factors and root causes**
 - Inadequacy of hospital's radiation protection programme
 - Inadequacy of staffing levels and expertise
 - Lack of
 - QA programme
 - accident prevention measures
 - an education and training programme

Other small errors that were combined with the main error ...

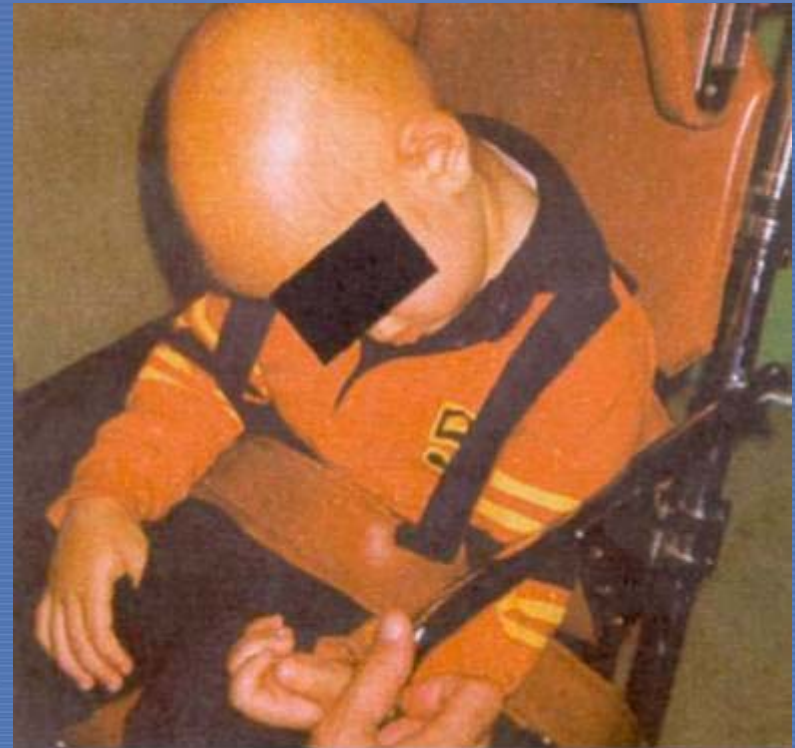
- The main error was **combined with a number of smaller errors** that were present, even before the event. These were:
 - Errors in the computer home-made programme to determine the treatment time (about 5%)
 - Error of 2 cm with the optical distance indicator - treating at 78 cm rather than 80 cm (1.053)
 - Confusion between kerma in air and absorbed dose to water at dose maximum

Radiotherapy protocols

- Expert team noted differences in the radiation therapy practices and protocols for the same disease
- Some protocols involved very large fields with the treatment of each field every other day
- More than half of the prescribed radiation treatments had fewer than normally accepted number of fractions

Clinical consequences

- Child affected by overdose to brain and spinal cord
- Loss of ability to speak and walk



Clinical consequences

- Young woman who became quadriplegic as a result of accidental overexposure to the spinal cord



Public impact

- **Loss of confidence in the health care system**
 - Inaction relative to complaints and problems
 - Loss of confidence in some physicians as a result of being ignored or taken too lightly when they complained of severe side effects during treatment
- **The Minister of Health notified the public very promptly of the accident and was commended for this**

Review of the findings

- No records were kept on calibration of radiation beams
- No information available on
 - equipment used
 - the working conditions prevailing
 - The dose determination protocols followed
 - Results obtained
 - Calculation of output/absorbed dose in a computer programme written for calculation of the treatment time

Status of charts

- No documentation on how calculations of the time had been made following source change
- No indication that any review had been made of the treatment time calculation
- No running record of
 - Tumour dose
 - Time for each fraction
 - Who treated the patient on any given day
 - Portal films acquired - when and by whom
 - Chart review during treatment

Failure to ...

- ... perform independent calibration
- ... notice that treatment times were too long for a new source with higher activity

Facts

- Radiation accidents with severe and even fatal consequences do occur in medical facilities
 - Human error is the most common cause of radiation accidents
- Prior to the accident (**external audit had already detected**)
 - Poor quality record keeping
 - Lack of redundancy in procedures
 - Inadequate education and training

Lessons to learn

- Carry out an investigation if the results of audit indicate a discrepancy
- If there is a high incidence and severity of acute effects it must be investigated

Lessons to learn

- Ensure a high level of training and competence in order to deal with potentially hazardous sources
- Specific training should be additional to basic education and not simply attending occasional short courses

Lessons to learn

- Radiotherapy records should be
 - Uniform
 - Clear
 - Consistent
 - Complete
- Early and reliable information and communication is crucial for good management

Recommendations – Expert Group to the Government

- Radiation protection regulations should be implemented, enforced as soon as possible and kept up to date
- QA programmes should be developed and implemented
- Education and Training for radiotherapy staff should be improved

Recommendations – Expert Group to the Government

- Record keeping in radiotherapy charts should be improved
- External audit - **where persisting problems are revealed** - another channel of communication to the authorities should be sought
- Registry of data on patients should be set up

Clinical Recommendations

- Follow up visits should be structured to allow for
 - Optimal individual care
 - Scientific evaluation
- Baseline data should be compiled according to internationally recognized systems
 - RTOG/ESTRO normal tissue effects
 - ICRU doses/fractionation

Reference

- IAEA: Accidental Overexposure of Radiotherapy Patients in San José, Costa Rica (1998)

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