PART III. CONCLUSIONS AND RECOMMENDATIONS

6. CONCLUSIONS AND RECOMMENDATIONS

6.1. GENERAL CONSIDERATIONS

This accident has confirmed a number of lessons that were well known from previous incidents and has also yielded specific lessons. The lessons of a more general character can be summarized as follows:

- The investigation of radiation accidents generally reveals faults that should have been corrected.
- Radiation accidents with severe and even fatal consequences do occur in medical facilities.
- Human error is the most common cause of radiation accidents.
- A properly operating machine does not guarantee good radiotherapy treatment. Adequate ancillary equipment, education and training, staffing and management are essential..
- Radiation accidents can have major short and long term psychosocial consequences.
- Accepted radiotherapy protocols have very little margin for error since both normal and malignant cells are killed. Significant overdoses (errors much larger than 10%) will result in an unacceptable incidence of severe consequences.
- Doses administered in fewer than the normal number of treatments with higher doses per treatment result in an excessive number of early and, particularly, late complications.
- When radiation therapy sources are replaced, the calibration should be done by appropriately trained persons and the calculations should be independently checked.
- Regulations should cover training and competence required to deal with potentially hazardous radiation sources.
- Specific training should be given after an individual working in a radiotherapy unit has received a thorough basic education and should not consist simply in attending occasional short courses.
- When there is a high incidence and severity of acute effects during radiotherapy treatment, the treatment should be stopped and the source calibration checked immediately.
- In radiotherapy accidents, the tumour dose may not be the parameter of primary interest. Often the biologically effective dose to sensitive structures such as the spinal cord, heart and intestine are more important.
- Early and reliable information and communication are crucial for good management of radiation accidents.
- Radiotherapy records should be uniform, clear, consistent and complete.

The following subsections contain the conclusions and recommendations that are specific to this accident. They have been classified following ICRP Publication No.73 [7].

6.2. FRAMEWORK FOR RADIATION PROTECTION

The application of radiation protection and safety in radiotherapy in Costa Rica is adequate in terms of justification but is deficient in several areas, particularly optimization of protection, accident prevention and institutional arrangements

6.3. JUSTIFICATION OF A PRACTICE

Conclusion

Radiation therapy is unquestionably necessary for the population in Costa Rica and it must be provided within the country. The patients seen had very good clinical evaluation and diagnostic/staging procedures. Every patient who was receiving radiotherapy clearly needed it.

No recommendation is necessary in this regard.

6.4. OPTIMIZATION OF PROTECTION

Conclusions

It is well known that radiotherapy administered in fewer than the normal number of treatments with higher doses per treatment result in an excessive number of early and, particularly, late complications.

There are deficiencies in the optimization of protection in radiotherapy in Costa Rica relating to both (1) the design and construction of the facility and (2) day to day working methods:

1. The shielding was inadequate, as a result of which the beam directed to the ceiling could not be used safely, and therefore the treatment geometry was severely restricted.
2. In day to day practice, no planning of doses or wedges, organ shielding, immobilization devices or other ancillary equipment that could be tailored to individual patients to reduce unnecessary

doses and thus reduce complications had been employed. This exacerbated the harmful consequences of the accident.

Recommendations

It is recommended that the Costa Rican authorities strengthen radiation therapy in these areas, especially by improving the installation of the Alcyon II so that its use can be unrestricted, and make more use of accessories and ancillary devices to individually tailor and optimize the treatments.

6.5. ACCIDENT PREVENTION

Conclusions

There was no sufficient defence in depth in the radiotherapy service in the San Juan de Dios Hospital. The fact that there was no redundant and independent calibration, such as for the determination of the absorbed dose, made it possible for a mistake to remain undiscovered until it resulted in an accident. With an appropriate degree of defence in depth, the accident might have been prevented.

Prior to the accident, the IAEA/WHO TLD postal dose check had detected discrepancies in the determinations of the absorbed dose rate. In addition, external auditing had detected the poor quality of record keeping, the lack of redundancy in procedures and the inadequate level of education and training. Had actions been taken on these findings, the accident might have been prevented.

Recommendations

Defence in depth for safety critical tasks should be introduced. For example, redundancy, independence and diversity should be applied to safety critical tasks, such as calibration at commissioning and after a source change. Redundancy and independence can be achieved by two persons making independent determinations of the absorbed dose rate. This is feasible by using

resources rationally and for selected tasks. Diversity can be achieved by cross-checking the results of the beam calibration against the certificate of the source manufacturer, corrected for decay.[3]

6.6. INSTITUTIONAL ARRANGEMENTS

Conclusions

Some deficiencies related to institutional arrangements (responsibilities, management, education and training and compliance with regulations) were indirect causes of the accident.

The fact that discrepancies were detected and not corrected reveals that responsibilities were not properly delegated or exercised and that there were managerial problems of supervision. Education of responsible persons was inadequate and there was no quality assurance programme. Record keeping was also a problem, although this did not contribute directly to the accident. The Expert Assessment in July 1997 and the previous expert review conducted in July 1996, prior to the accident, noted deficiencies in both these areas.

Regulations were promulgated in March 1995 in Costa Rica through Executive Decree 'Reglamento de protección contra las radiaciones ionizantes' (Regulations for protection against ionizing radiation). These regulations establish that the Section for Radiation Control of the Ministry of Health is the Regulatory Authority. The regulations require authorization for radiation sources and installations as well as for the persons handling the radiation sources. They include radiation protection requirements for medical practice, such as the existence of a quality assurance programme. At the time of the accident the regulations had just begun to be implemented, but it should be noted that more than one year after their promulgation fewer than half of the requirements had apparently been met.

Recommendations

Responsibilities should be well defined, procedures should be developed and compliance with procedures should be supervised.

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[3] Despite differences stemming from the collimation used at the source manufacturer's laboratory and that of the therapy machine (which influence the absorbed dose rate), a cross-check should point out any major inconsistency.

Additional educational programmes should be implemented for staff engaged in radiotherapy.

The existing regulations should be implemented, monitored and enforced as soon as possible.

A safety culture should be established and fostered and education and training should be provided.

A quality assurance and record keeping programme should be implemented. Particular attention should be directed to ensuring that quality assurance programmes are operational. These programmes should include:

- verification of the physical arrangements (sources, beam and geometry) and clinical aids (patients' charts) used in the treatment of patients;
- verification of the appropriate calibration and conditions of operation of dosimetry equipment and confirmation that the absorbed dose determination be traceable to a Standards Dosimetry Laboratory;
- regular and independent quality audit reviews of the programme;
- participation in intercomparison exercises such as the IAEA/WHO postal dose check service combined with positive procedures to take actions if a prescribed deviation is found.

Radiotherapy records should be uniform, clear, consistent and complete.

6.7. MEDICAL EFFECTS OF OVEREXPOSURE

A wide range of effects of overexposure to radiation were noted in the 115 patients. These ranged from minimal detected or expected adverse effects to clearly developed catastrophic effects and several deaths as a result of overexposure. At least two-thirds of the patients were or are at significant risk. The circumstances of the accident can be expected to result in a high incidence of serious late effects. Psychological, social and other harmful effects for many patients have been, are or will be major.

Many of the surviving patients may be expected to develop further effects over the next five years. The medical and psychological needs of these patients will be very great. Owing to the location of

the tumours for some patients and to the sensitivity of certain tissues, the incidence of effects relating to the central nervous system and gastrointestinal, cardiovascular and skin effects has been and will continue to be higher.

Table IV summarizes the findings from the direct examination of patients while Table V summarizes the findings from the review of records of the deceased patients (see Appendix II).

TABLE IV. SUMMARY OF FINDINGS FROM DIRECT EXAMINATION OF PATIENTS

Number of patients	Findings of adverse effects for surviving patients
4	Severe or catastrophic effects
16	Marked effects with high risk of future effects
26	Radiation effects not severe at the time of examination; some risk of future effects
22	No definite effects of significance at the time of examination, low risk of future effects
2	Underexposed patients as therapy was discontinued (when the error was discovered)
3	Could not be seen; one possibly at risk of future effects
73	*Total*

TABLE V. SUMMARY OF FINDINGS FROM REVIEW OF RECORDS OF DECEASED PATIENTS

Number of fatalities	Findings for deceased patients
3	Exposure as the major factor in the cause of death
4	Exposure as a substantial contributory factor
22	Death related to tumour or cause other than exposure
5	Not enough data to judge
8	Data on patients not reviewed by Expert Team
42	*Total*

6.8. FOLLOW-UP OF PATIENTS

Recommendations

Since these radiation problems are unique and are rare, it is strongly recommended that the patients with specific radiation related problems all be referred to certain specialists rather than being referred to many different specialists.

The follow-up for the patients should be structured to allow for both optimal individual care and scientific evaluations.

Baseline data should be collected according to internationally recognized systems (e.g. according to RTOG/ESTRO for normal tissue effects and according to the International Commission on Radiological Units and Measures (ICRU) for doses/fractionation).

Data should be stored in a special database to permit continuous upgrading. Data that are already available should also be put into the database (data on the patients at the Calderón Guardia Hospital have largely already been obtained and stored). Additional factors such as the results of biopsies may prove to be important. Structured information obtained by post mortem examinations about the cancers and the normal tissue is also extremely important for determining the cause of death and for use in the evaluation of future accidents.

It is recommended that one physician (or, better, two physicians) be responsible for running this registry, and be assigned the resources and the authority to do so.

6.9. FUTURE WORK

It is important that a report be issued on this accident in order to help prevent accidents in the future. Further investigation after several more years is necessary to determine the full extent of the consequences of this accident.

6.10. USE OF THIS REPORT

This report presents the situation of the patients as of July 1997. Any analysis of patients for compensation for medical care should take into account early effects, the current medical evaluation and the risk of specific future effects in addition to those that are described in this report.

6.11. SUMMARY RECOMMENDATIONS

Recommendations to the Government of Costa Rica:

- Radiation therapy is necessary and should be continued in Costa Rica.
- Existing regulations should be implemented and enforced as soon as possible.
- Quality assurance programmes should be developed and implemented.
- Education and training for radiation therapy staff should be improved.
- Record keeping in radiotherapy charts should be improved.

- Radiotherapy in general should be improved to avoid unnecessary and unacceptable harmful outcomes.
- If external auditing discovers significant, persistent and continuing problems, another channel of communication to the authorities should be sought.
- Major medical and psychosocial support should be provided now to many patients and will probably be needed for at least the next five years.
- A registry of data on patients should be set up.

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