OBSERVING BEST PRACTICE IN ACCIDENTAL EXPOSURES IN RADIOTHERAPY: A REVIEW ARTICLE

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INTRODUCTION

Radiotherapy is the use of ionizing radiation in the treatment of disease of disease, the commonest being cancer. Radiotherapy is concerned primarily with tumour cure or palliation. Modern radiotherapy has three major concerns, efficacy, quality of life and safety.[1] It is always necessary to be aware of the potential for an accident, the relative importance of human factors, and the wider consequences of an accident.[1,2]

A radiation accident is defined as an unintended event (operator error, equipment failure, or other mishaps) that has or may have adverse consequences. Depending on the type of persons exposed, accidents can be divided into three major groups: [3,4]

- Members of the general public, irradiated as a result of failure of implementation of radiation protection and safety rules;
- Clinical staff irradiated during preparation of radiation sources or patient treatment and maintenance staff irradiated during installation, repairs, source change or other equipment servicing;
- Patients, injured during treatment.

The use of the term 'radiation accident' for events involving the public and staff i.e. groups (1) and (2) has a relatively straightforward interpretation as neither workers nor public are intentionally irradiated, this makes it easier to distinguish a normal exposure from an accidental one. For patient undergoing treatment, i.e. group (3) the use of the term 'accident' deserves special consideration. The major focus is in preventing injury to patients. The majority of radiation therapy accidents have occurred in category (3).[3]

Accidental exposure to radiation is not uncommon. A lot of accidents have been documented in developed world. It is very pertinent to learn from the causes and implications of the documented accidental exposures in radiotherapy in the developed countries so as to mitigate such happenings in our environment. [4,5,6]

LITERATURE REVIEW OF CASE HISTORY

Below are the various causes and main contributing factors to accidental exposure in radiotherapy in the developed centers as documented in the literature[3,712]

i. Linear Accelerator software problem in USA and Canada 1985 1987
ii. Use of Incorrect Decay Data in USA 1974 1976
iii. Incorrect repair of fault in therapy Machine in Spain 1990
iv. Linear Accelerator Malfunction in Poland 2001
v. Error in Treatment Planning System in UK 1982 1991
vi. Computer File not being updated in USA 1987 1988
vii. Error in Treatment Planning System in Panama 2000
viii. Miscalibration of beam in Costa Rica

1996.

ix. Malfunctioning of High Dose Rate Brachytherapy equipment in USA 1992.
x. Error in the calibration of Co-60 therapy unit in UK 1988.
xi. Error in the identification of Cs-137 brachytherapy sources, UK 1988-89.
xii. Error in dose calculation, Germany 1986-87.

MAJOR REPORTED ACCIDENTAL MEDICAL EXPOSURES INVOLVING PATIENTS UNDERGOING EXTERNAL BEAM RADIOTHERAPY AND BRACHYTHERAPY TREATMENTS

COUNTRY	YEAR	NO OF PATIENTS AFFECTED	CAUSES AND MAIN CONTRIBUTING FACTORS
USA	1974-76	426	^{60}Co dose calculations based on erroneous decay curve (varying overdoses). No independent verification of dose calculations. More than two years without beam measurements.
Canada & USA	1985-87	3 deaths from radiation	Accelerator software for the control of treatment features was transferred from other equipment without sufficient consideration to safety.
Germany	1986-87	86	^{60}Co dose calculations based on erroneous dose tables varying overdoses). No independent determination of the dose rate.
UK	1988	207	Error in the calibration of a ^{60}Co therapy unit (25% overdose) No independent calibration of the beam.
UK	1988-89	22	Error in the identification of ^{137}Cs brachytherapy sources (dosimetry errors between 20% and +10%). No independent determination of source strength.
USA	1987-88	33	A computer file (of a treatment planning system) for the use of trimmers was not updated for a new ^{60}Co source because it was not intended for further use. The computer file was used (overdoses of 75%). There was no manual verification of the calculated treatment time. There was no independent verification of the treatment time.
Spain	1990	27 (15 deaths directly from radiation; two deaths with radiation as major contribution).	Error in the maintenance of a clinical linear accelerator. Procedures for transferring machine from/to maintenance (notification of physicists) not followed. Conflicting signals and displays not analyzed. Procedures for periodic beam verification not implemented or insufficient. Overdoses ranging from 200% to 600%
UK	1982-91	1,045 (492 patie+nts developed a local recurrence, as a result of the underdose)	Inappropriate commissioning of a computerized radiotherapy Treatment Panning System (5-30% underdose). Lack of quality control.

COUNTRY	YEAR	NO OF PATIENTS AFFECTED	CAUSES AND MAIN CONTRIBUTING FACTORS
USA	1992	1 (Death from radiation)	High dose rate brachytherapy source left inside the patient. Source dislodged from equipment. Conflicting monitor signals (display at the machine and area monitor) ignored. A survey with an available portable instrument was not conducted.
Costa Rica	1996	114 (17 deaths from radiation)	Error in the calibration of a ^{60}Co therapy unit. Lack of independent beam calibration and quality control. Recommendations of external audit ignored. Overdoses of about 60%
Panama	2000	28 (Several deaths due to radiation)	Modified procedure for data entry into the treatment-planning computer without verification prior to treatment.
Poland	2001	5 patients with severe injuries.	Failure of more than one layer of safety in an electron accelerator (failure of the power supply to the monitor chambers and of the relevant interlock).

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The fact that the listed countries with experience of accidental exposure in radiotherapy are mainly developed countries does not exonerate the developing world. *It is most likely that they are not being reported. The causes of accidental exposure to radiotherapy are so numerous and it will suffice to discuss the causes and contributing factors from collections of accidental exposure from those accidents listed above.*

The usual procedure in the radiotherapy (Teletherapy) unit in most centers is that once a patient has been designated for radiotherapy by the attending oncologist, the patient's treatment is planned by the radiotherapist in terms of site, field size, number of fields, use of accessory (like Wedges, Bolus, Compensators, shielding block etc.), Energy of machine for treatment, Anatomical landmarks, Total dose, dose per fraction, duration of treatment, immobilization devices etc this planning is achieved. with the use of simulator machine and knowledge of anatomy and natural history of the disease. Once these parameters have been determined, the medical physicist uses this information on the treatment planning system (computers) and/or manual calculation to determine the treatment time or monitor units to deliver the prescribed dose. Once the treatment time/ monitor units are calculated, the treatment card containing all relevant information for treating the patient is sent to the therapy radiographer who is to administer the treatment. Usually the attending oncologist is present during the first treatment set-up to confirm that treatment is as planned.

Subsequently a patient goes for his daily treatment on the therapy machine, only to be seen during the *check clinic* where compliance to treatment, side effects, response, patients' complaints etc. are assessed and treated. During this check clinic, counseling, prognosis and other medical and non-medical problems are attended to by the attending oncologist, usually 1-2 times a week except if patient desired to see his doctor.

Errors which could lead to accidents could occur at any level, during dose calculation, patient set-up and use of accessories, patients' identification, choice of energy/ beam characteristics, dose delivery and e.t.c. Similarly errors could result from the geometrical/ electrical systems of the treatment machine before or after maintenance repairs are carried out. In those using cobalt-60 machine there may be failure of source to retract. The safety mechanism in the treatment room may be faulty at any time.

The problems identified, including the above major cases, can be summarized as follows:

Common to External beam and Brachytherapy:

1. Equipment not meeting IEC (International Electro technical Commission) or equivalent National standards;
2. Maintenance errors;
3. Errors in the identification of patient and treatment site;
4. Conflicting signals and displays misinterpreted or not followed up;
5. Communication errors, transmission of information and misunderstanding of prescription and protocols, or use of obsolete protocols;
6. Use of obsolete files and forms, which remained accessible.

External beam therapy:

1. Errors in acceptance tests and commissioning or lack of tests of both radiation equipment and sources and treatment planning systems;
2. Errors in the calibration of radiotherapy beams;
3. Errors in the preparation of tables and curves from which the treatment time is calculated;
4. Errors in the use of treatment planning systems for individual patients.

Brachytherapy:

1. Using an incorrect source or incorrect units of source strength;
2. Dislodging of HDR brachytherapy sources;
3. Mistakes in source handling by nurses during brachytherapy treatment;
4. Leakage of sealed sources;
5. Sources left in patient and loss of radiation sources;

The following contributing factors allowed

these errors to remain undetected until becoming accidental medical exposures:

i. Insufficient education of radiation oncologist, medical physicist, radiotherapy radiographers/technologist, maintenance engineers and brachytherapy nurses;

i. Overloaded staff when new equipment was purchased or workload increased;
ii. Insufficient quality assurance and lack of independent checks for safety critical activities, such as beam calibration;
iii. Lack of a programme for acceptance testing and commissioning;
iv. Lack of a maintenance programme;
v. Poor, misunderstood or violated procedures;
vi. Lack of operating documents in a language that is understandable to the users;
vii. Inattention (environment prone to distraction); and
viii. Inconsistent use of different quantities and units.

In a number of the accidents there was a combination of several of the above contributing factors. When several contributing factors coincide together, this may be an indication of a more general problem involving:

i) Lack of commitment of the licensee (hospital administrators and managers of departments);
ii) Staff insufficiently educated or trained; and
iii) Insufficient quality assurance and *defense in depth* (the application of more than a single protective measure for a given safety such that the objective is achieved even if one of the protective measures fails, for example, multiple independent checks).

CONSEQUENCES OF ACCIDENTAL EXPOSURE

From the above it implies that high level of alertness and competence is required to prevent accidental exposure in radiotherapy. It is also very obvious that it is a multi-disciplinary team approach within the department involving the radiation oncologist, medical physicist, therapy radiographer, mould room technologist, oncology nurses etc. that are involved in the care of the patients undergoing radiotherapy. Errors in any of the various stages in administering radiotherapy to patients can lead to either over-dosage (over exposure) or under-dosage with the attendant sequelae.

A situation where the patient is treated with doses below the recommended dose due to application of e.g. wrong decay factor, use of wrong accessory etc. may occur. Obviously, there is going to be poor tumour control, residual tumour, relapse, etc, and as a result, there is poor quality of life for the patient, and eventually metastases from uncontrolled local disease and death ultimately. The cost cannot be quantified. Similarly, if there is over dosage, the tumour may be controlled or eradicated, but late complications if patients survive are usually unbearable. Over dosage can lead to permanent disability and death if vital structures are within irradiated area. For example:[3,7]

i. Nervous system: Brain: atrophy, necrosis, decreased cognitive function, headaches, mood alteration, seizures, decreased intellectual function. Spinal: paralysis, quadriplegia and paraplegia.
ii. Skin: fibrosis, atrophy, contraction, indurations, oedema, pigmentation, pruritus, hypersensitivity, pain.
iii. Lower gastrointestinal tract: chronic or bloody diarrhoea, bowel stenosis, stricture, fibrosis, obstruction, fistula, and perforation.
iv. Bladder: dysuria, haematuria, contracture, incontinence.
v. Vascular and lymphatic: stenosis, premature arteriosclerosis.

It is obvious that doses received during radiotherapy are on the upper edge of tolerable doses to normal tissues. As a result, accidental overdosages have often had devastating and sometimes fatal consequences. Accidental exposures involving a 10% or more overdosages should be detectable by a well-trained clinician, based upon an unusually high incidence of acute adverse patient reactions. Underdosage accidents are difficult to detect clinically and may only be manifest as poor tumour control during follow up.[3]

Radiotherapy is increasing worldwide and accidents may be expected to increase in frequency, if measures for prevention are not taken. While a number of serious and fatal radiotherapy accidents are reported, it is likely that many more have occurred but were either not recognized or reported to regulatory authorities or published in the literature. The complex equipment and techniques used in radiotherapy mandate that for accident prevention, there must be sound and risk-informed regulations, managerial commitment at the hospital level, an adequate number of trained staff, adequate resources, a functional implemented quality assurance programme, good communication, and continuing education. There is a danger in not fully appreciating that modern equipment and new technologies require more quality assurance and highly qualified maintenance. It is advisable that persons in charge of radiotherapy facilities should ensure that there is proper commissioning of new equipment and proper decommissioning of old equipment and sources.

CHECKLIST FOR THE PREVENTION OF ACCIDENTAL EXPOSURES

Organization, functions and Responsibilities

i. Have all necessary functions and responsibility been allocated?
ii. Are all functions and responsibilities understood?
iii. Is the number of staff commensurate to workload?
iv. Is this number re-assessed when workload increases, or when new equipment is purchased?

Education and Training

i. Is every member of the staff educated and trained according to their responsibilities?
ii. Is this education and training documented?
iii. Is there a programme for continuing and personnel development?
Iv. Are lessons from accidents and their prevention included in continued training?
v. Are there provisions for additional training (new equipment, new procedures)?
vi. Are emergency plans exercised as part of the training?

Acceptance testing and commissioning

i. Is there a programme for formal acceptance of equipment in place?
ii. Is it carried out according to international or national standards?
iii. Is there a programme of commissioning in place?
iv. Does it include treatment equipment as well as treatment planning systems and simulators and other ancillary equipments?

Quality Assurance Programme

i. Is a programme of QA established?
ii. Is the programme based on accepted protocols? Which ones?
iii. Are all tasks of the QA clearly assigned to the right persons?
iv. Are the necessary tools and instruments available?
v. Are audits part of the programme?

Communication

i. Is a communication policy in place and understood by the staff?
ii. Is reporting of unusual equipment behaviour required?
iii. Is reporting of unusual patient reactions required?
iv. Are procedures for equipment transfer for maintenance and return in place?

Patient and Site Identification

i. Are there procedures to ensure correct identification of patient and site?
ii. Is there a protocol for patient's chart check?

External Beam

Calibration

i. Are there provisions for initial beam calibration?
ii. Is independent verification in place, foreseen and planned?
iii. Is there an accepted protocol? Which one?
iv. Is a programme for follow-up calibration in

place?

v. Is participation in an audit programme part of the programme?

Treatment Planning (Clinical Dosimetry)

i. Are treatment-planning systems included in the programme of acceptance and testing?
ii. Is treatment planning documented according to accepted protocol?
iii. Are cross-checks and redundant and independent verification included?

In-vivo dosimetry

i. Has a system for in-vivo dosimetry been considered?

Brachytherapy

Source activity and identification

i. Are there provisions for source activity verification and identification of the source before use?

Dose calculation and treatment planning

i. Are there provisions for dose calculation and cross-checks?

Source positioning and source removal

i. Are there provisions to verify source position and to ensure that positions remain?
ii. Are there provisions to ensure that sources do not remain in the patient, including monitoring of patients and clothes?

EMERGENCY PROCEDURES

An emergency plan should include:

i. List of predictable incidents and accidents and measures to deal with them;
ii. Persons responsible to take actions, with complete relevant information, including phone Numbers;
iii. Responsibilities of individual personnel in emergency procedures (radiation oncologist, medical physicists, radiation technologist, etc);
iv. Set of concise instructions posted in a visible area;
v. Availability or quick access to persons responsible for carrying out emergency response action;
vi. Equipment and tools necessary to carry out the procedures;
vii. Training and periodic rehearsal; and
viii. Recording and reporting system.

Emergency Procedures should also include:

i. Immediate measures to avoid unnecessary radiation doses to patients, staff and public (such as removal of patients from a Teletherapy unit, removal of implants, return of sources to the shielded position in remote control brachytherapy and teletherapy);
ii. Measures to prevent access of persons to the affected area during the time that the sources are exposed and normal conditions are restored; and
iii. In the case of leaking sources, measures to prevent dispersion of contamination and access of persons to the contaminated area.

RECOMMENDATIONS

It thus implies that all hands must be on deck to prevent the accidental medical exposure in radiotherapy facilities. In view of the above, the following recommendations are being made and emphasized:

i. Double independent checks in the various procedures of radiotherapy and manual calculations should be used to check computer calculations where possible.
ii. Pro-active equipment maintenance (preventive maintenance) should be done routinely and all repairs on the treatment machine must be accompanied with quality control and follow up of the equipment faults with the manufacturers.
iii. Training and re-training of all cadres of staff involved in the care of patients.
iv. A system of Collective Departmental Responsibilities if there is near accident or accidents. i.e. No allocation or apportioning of blames to individuals so as to encourage reporting of accidents.
v. A written instructions and drills to simulate emergency procedures for beam control failure (e.g. when source failed to retract).
vi. Patients having unusual side effects or complaints in irradiated area seen by the

therapy radiographer must be sent to the attending oncologist for verification and assessment and Check clinic should be established in centers where it is absent.

vii. Facilities for proper documentation of faults on the radiotherapy machine, like logbook, Communication Network, treatment records etc should be available.

viii All procedures/instructions either from the radiation oncologist, medical physicist etc should be written down. Verbal instructions should be discouraged.

ix. There should be proper identification of patients so that wrong patient or wrong sites are not treated due to similar names e.g. Use of special treatment number and photographs.

x. Regulations for radiation safety should be in place and enforced and compliance should be monitored.

Finally, accidental medical exposure can occur in the most sophisticated centers. No center is immune against accidental exposure. The only way out is the *ABCD* of safety in Radiotherapy.

A. Awareness of the fact that there is possibility of accidents
B. Be careful of the various procedures in the radiotherapy department
C. Competent individuals are needed.
D. Designation of responsibilities

A written, comprehensive and functional quality assurance programme should be adopted and implemented by every radiotherapy institution. This should include a clear chain of responsibilities and procedures for purchasing, acceptance test and commissioning, calibration, treatment planning and delivery maintenance, two-way communication and incident reporting.

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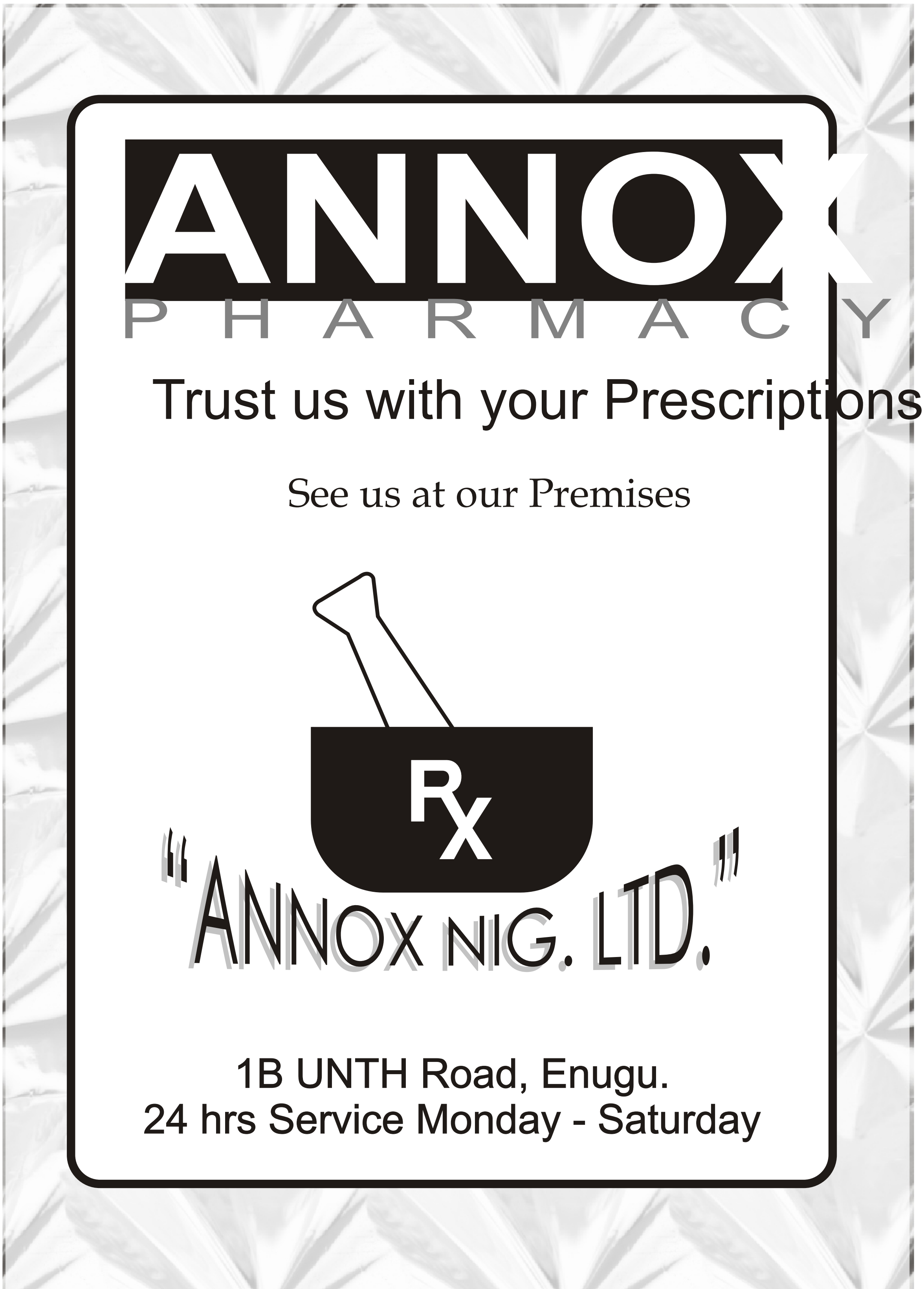
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