

How the NHS could better protect the safety of radiotherapy patients

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A patient-led investigation into prevention of adverse incidents in radiotherapy has uncovered major obstacles to an open, learning culture.

We uncovered a culture of secrecy and a failure to learn from radiotherapy incidents in the NHS when we lobbied the Department of Health (DH) over the issue of permitting linear accelerator (Linac) patients routine access to two-way intercoms.

We became interested in this issue as a result of personal experience and that of other radiotherapy service users. We read media reports¹ that a patient had received a serious radiotherapy overdose at Cookridge Hospital in Leeds in 2003. When we cited this as a reason for making two-way intercoms mandatory, the National Radiotherapy Advisory Group (NRAG) (part of the Cancer Services Collaborative Improvement Partnership) told us that an intercom would not have helped this patient. We were asked "not to reference" the incident again.

After this, whistleblowers wrote to one of us, anonymously, "anxious to protect our source of information who might suffer repercussions". The letter said:

"Despite the involvement of the DH ... the incident was successfully hushed up ... Openness and honesty is the best policy as it presents the best opportunity for full and thorough investigation (hopefully independent) and prevention of further incidents."

We were now becoming concerned with the wider issue of radiotherapy patients' safety and whether the NHS was learning from incidents and near-misses. We therefore obtained under the Freedom of Information Act (FOI) a "redacted" copy of Prof Brian Toft's report of the investigation into this incident². "Redaction" means masking of details identifying individuals in the report.

Prof Toft concluded that the incident was caused by inadvertent human error, due to a systems failure. The patient concerned was prescribed treatment which included a device known as a "wedge" to attenuate the radiation beam. Due to a technical scaling problem,

the representation of the wedge was omitted from a diagram used to enter data into the Linac computer database. Then, despite meticulous verbal double-checking, 11 conscientious radiographers, working in assorted pairs during 14 separate treatment episodes, failed to notice that the wedge on the treatment card had not been recorded in the computer's database and was therefore missing from the radiation beam. A similar accident could have happened in any busy NHS radiotherapy department.

Toft's report depicts a "manic and chaotic" working environment. It emphasises the NHS-wide risks of "high workload, a significant level of sickness absence, continual overtime, a lack of continuity and a complex case mix". We were shocked to discover that the report, with its 36 recommendations, had not been circulated to other centres, despite a hospital spokesman's promise that "these lessons will be shared throughout the NHS in general, and the radiotherapy community in particular"¹. In the Toft report's own words:

"Very little information seems to be collected or publicly shared on radiotherapy adverse events either nationally or internationally. Indeed, keeping such information confidential seems to take a higher priority than finding a way to use it to prevent similar accidents from taking place."

The concept of "involuntary automaticity", put forward by Toft in his report, did however reach the Royal College of Radiologists and appeared in a paper in *Healthcare Services Management Research*⁴.

FOI requests to SHAs

To determine whether the incident was a one-off we sent FOI requests to all English strategic health authorities (SHAs) and to the Greater Glasgow NHS Board, asking for brief anonymised details of their serious untoward incidents (SUIs) in radiotherapy over the last 20 years. The replies varied greatly, with a variety of acronyms in use as well as SUI, such as SAE (serious adverse event), SAI (serious adverse incident), PSI (patient safety incident) and RCI (red class incident).

Despite the existence of the DH's Strategic Executive Information System (STEIS), some SHAs held no data on radiotherapy SUIs and told us to contact individual hospital trusts. Others reported between zero and five radiotherapy SUIs since their records began in 2002.

We contacted a few individual trusts. Christie NHS Trust was exemplary in its openness and thorough reporting, with 15 radiotherapy SUIs since 1986. Lancashire Teaching NHS Trust was also very helpful, stating:

"... A clear definition of 'serious untoward' is not given in the request, so the view has been taken to include the definition used in the Ionising Radiations Regulations (1999) and the Ionising Radiation (Medical Exposure) Regulations (2000).

All incidents involving an overdose of radiation due to equipment failure should be reported to the Health and Safety Executive (HSE) under the IRR99 Regulations. We have not had any incidents reportable under these Regulations.

LEARNING AND EFFECTING CHANGE

At level A (an immature safety culture) "no attempts are made to learn from incidents unless imposed by external bodies such as public enquiries. The aim after an incident is to "paper over the cracks" and protect itself – the organisation considers that it has been successful when the media do not become aware of incidents. No changes are instigated after an incident apart from those directed at the individuals concerned."

At level E (a mature safety culture), "the organisation learns from internal and external information and experience and is committed to sharing this learning both within and outside the organisation. Patient safety incidents (including those that led to no harm or were prevented) are discussed in open forums ... Patients play a key role in learning and contribute to subsequent change processes."

Source: Manchester Patient Safety Framework (MaPSaF)³.

All incidents involving an overdose of radiation due to any other cause should be reported to the Secretary of State under the IR(ME)R 2000 Regulations. We have reported 11 incidents since the Regulations came into force in May 2000. Prior to that date incidents were not categorised.

Brief details of the 11 serious untoward incidents are given below. It is worth noting that although these were classed as serious, the "serious" aspect could be the failure of the procedure rather than harm or potential harm to a patient ... "

The national scale of incidents

To clarify the national scale of radiotherapy SUIs, we contacted the DH. From May 2000 to April 2006, IR(ME)R 2000 had been informed of 138 serious radiotherapy incidents unconnected with equipment failure.

The HSE was unable to tell us how many incidents due to equipment failure had been reported in the last 20 years: the cost of processing the information would have been too high.

By 31 March 2006, the National Patient Safety Agency (NPSA) (through the National Reporting and Learning System) had received notification of 66 incidents involving radiotherapy, seven reported as death and 59 as severe. It confirmed "the individual reports are not investigated or verified by the NPSA." Apparently, the incident report form does not enable bulk analysis of radiotherapy incidents since most of the description of each incident appears in a free text field.

We were told by Chris Ball at the National Cancer Services Analysis Team that the NHS-wide Radiotherapy Episode Statistics (RES) computerised system does not record SUIs, but does obtain data of both the planned and the actual dose of radiation given to each patient. Ball commented:

"However, if these two variables differ, there is no way of identifying whether this is a simple data entry error, a clinical decision, a machine transfer (for example, to avoid treatment delay) or a mistreatment and therefore we do not plan to analyse these variables."

The current NHS systems for reporting and learning from radiotherapy incidents are clearly not joined up and not accountable. So many bodies being responsible for parts of the problem – from the Royal College of Radiologists, Society of Radiographers, NCRAG, IR(ME)R Inspectorate, to the HSE and National Cancer Services Analysis Team – becomes part of the problem!

A Europe-wide system

There is a European radiotherapy incident reporting system, the Radiation Oncology Safety Information System (ROSIS)⁵, already used by five to 10 UK hospitals. This system, created by the European Society for Therapeutic Radiology (ESTRO), lists 726 incidents over three years and has a publicly-accessible database at www.rosis.info. Anonymous reports from staff involved in radiotherapy incidents are invited.

ROSIS describes incidents detected so far as:

"... breaks in the quality assurance process ... Such breaks, if allowed to go undetected, can result in accidents which put the lives of single or dozens of patients or their cure at risk. Only a minority of the incidents can be ascribed to technical or software problems. The reports are a graphic description of human failure and vulnerability, of shortcomings in communication, deviations from agreed procedure or just slips in attention."

Participating radiotherapy clinics receive a newsletter. There are plans to summarise the lessons learned.

We strongly urge the DH and the radiotherapy community to forge links with ESTRO and collaborate on the ROSIS project.

We also suggest that the DH examine the extensive research in risk management as applied to radiotherapy undertaken by Robert Lee and colleagues in Alberta, Canada⁶. They state that with "new technologies emerging at an exponential rate, the potential exists for new and highly uncertain risks".

In January 2006, 15-year-old Lisa Norris spoke out about the overdose of radiation to her brain tumour administered by a centre of excellence – Beatson Oncology Centre, Glasgow. Six months later, an FOI reply shows that the investigation into the incident is still incomplete. No interim safety alert has been circulated to other radiotherapy centres. There appears to be an unwritten pact of secrecy throughout the NHS to avoid litigation. In such a culture of institutional fear there can be no learning. Patients and staff continue to suffer.

To prevent repetition of the two accidents described in this article we offer the following recommendations. The DH should:

- apply the Manchester Patient Safety Framework to radiotherapy;
- immediately increase radiotherapy resources and improve working conditions;
- appoint a single, accountable head of radiotherapy;
- insist the NPSA make radiotherapy safety a priority;
- introduce a fit-for-purpose, unified mandatory radiotherapy incident reporting system;
- send feedback on near-misses and SUIs to radiotherapy centres;
- include ROSIS/Trinity College, Dublin's comprehensive four-day risk management course in all radiotherapy professionals' training⁷; and
- audit the implementation of Toft's safety recommendations as outlined in the Cookridge report.

Radiotherapy departments should:

- improve the supervision of trainees, particularly when working with rare or complex cases;
- employ extensive in vivo dosimetry checks, which will prevent most accidental overexposures;
- report anonymously to ROSIS and study its reports of near-misses and incidents;
- protect staff from "involuntary automaticity";
- photograph radiotherapy patients in order to prevent mistaken identification; and
- inform staff of their NHS trust's whistleblowing policy – the Public Interest disclosure Act 1998 and the guidance issued by the charity Public Concern at Work⁸. HCRB

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