

Chapter X

What went wrong at the Beatson Oncology Centre?

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A parable

A man tried on a suit in a clothing store. Looking at himself in the mirror, the man observed that the jacket was too long in the back. “No problem,” said the salesman. “Just bend forward a little at the waist.” The man bent forward. The back of the suit now looked fine but he now saw that the left sleeve was a little too short and the right one a little too long. “No problem,” said the salesman again. “Just lift up your left shoulder and lower your right shoulder a little bit.” The man lifted the one shoulder and lowered the other. Now the sleeve lengths were correct but he could see that the right pant leg was too short. “No problem,” said the salesman. “Just lift your right hip up an inch or two.” The man did this and it made the pants perfect. The man bought the suit. One day he walked, in his contorted, twisted posture, past two old ladies sitting on a bench. One of the ladies nudged the other and said quietly, “Did you see that cripple? Oh, how sad.” The other replied, “Yes, but didn't his suit fit well?”

Background

Radiation cancer treatment is the most computationally complex individual patient activity in healthcare. It is a useful means for treating certain types of localized cancers. It is the oldest form of non-surgical treatment of cancer and one of the earliest uses of artificially or naturally produced ionizing radiation (Bernier, 2004).

A radiation beam, usually produced by a linear electron accelerator (often called a *linac* or *lineac*) is directed at the tumor and the energy transferred to the cancer cells destroys them. The goal of therapy is to provide the highest possible radiation dose to the tumor while limiting the dose to non-tumor cells. In practice, this is accomplished by

delivering the radiation through a daily series of small doses (called fractionation) and by irradiating the tumor volume from different directions to maximize the total dose to tumor while simultaneously distributing that dose among different healthy cells.

Because the tumor type, location, and extent and the patient size, age, and medical condition vary, the treatment for each patient is unique. By shaping the beam of radiation (using metal shapes to block portions of the beam) and irradiating from different angles the radiation oncologist can maximize the radiation delivered to the target (the tumor) while limiting the damage to the rest of the patient. A series of radiation fields Some tissues (e.g., brain and spinal cord) are particularly sensitive to radiation while others (e.g., muscle) are relatively tolerant to it.

Treatment planning is the process that determines how to irradiate a particular patient (Smith et al., 2006). The purpose of treatment planning is to insure that the tumor volume receives a uniformly high dose of radiation while other tissues receive only tolerable amounts of radiation. Planning relies on detailed three-dimensional geometric modeling and simulation that incorporate complex algorithms, often with direct image guidance. Graphical computational tools are used iteratively to generate and refine candidate plans. The result is a treatment plan that specifies the sequence of irradiation episodes called treatments.

Historically, treatment planning was carried by hand computation and treatment plans were relatively crude but simple. Because of its inherently geometric character, treatment planning was one of the earliest clinical computing applications. Treatment planning computers were in use as early as 1968. Early treatment planning computation was carried out with stand-alone computer programs running on commercially available hardware. These programs allowed radiation physicists to calculate the effect of proposed radiation fields and, by iterative adjustment, to optimize the radiation treatment. Until the 1980's, metal field blocks were used to sculpt crisply defined radiation fields for individual patients. Individual treatment was provided by placing these metal blocks in the radiation delivery path before exposing the patient. Therapy was a fairly mechanical process that

involved selecting and placing blocks and precisely positioning the patient to receive the beam.

The advent of minicomputers and, later, microcomputers allowed more complicated plans. Now the beam could be shaped in real-time and varied as the radiation generator moved around the patient. By replacing the static cutout blocks with a continuously variable shutter system and placing the exposure under computer control a more sophisticated and more efficient treatment was possible. Moreover, therapy device operation was treatment records themselves. The sophistication of radiation device control and treatment planning computation grew in parallel.

Radiation therapy is typically carried out in a facility separate from the acute care hospital. The need for elaborate shielding structures, the size and power requirements of the array of therapy machines and computers, the repetitive nature of the treatments, the manner of financing and reimbursement for care, and the specialized nature of the work itself all promote the development of freestanding clinics. Even when physically co-located with a hospital, a radiation therapy unit is likely to be organized, operated, and managed as an independent unit.

The equipment for radiation therapy is marvelously complicated, big, and expensive to purchase and maintain. As in other areas of medicine, the technology is in flux, with new devices and techniques being introduced at short intervals. Two manufacturers of *linac*-type radiation therapy machines are Varian in the U.S. and Siemens in Europe. There is only a small market for devices. The huge costs of research, manufacturing, and maintenance have virtually eliminated all but these two companies from the marketplace. The situation is comparable to that found in commercial aviation.

Although the radiation generating device is a core resource, the creating and carrying out a treatment plan is an intensely information processing activity. Device manufacturers offer complete systems that include software and hardware intended to integrate the entire patient care process including record keeping and billing, financial support, and architectural support for the design of buildings to house the facilities. Although multi-vendor radiation therapy centers are not unheard of, the scale and complexity of treatment processes and the need for

efficient use of these expensive systems create strong incentives for treatment centers to obtain their software and hardware from a single source. VARiS™ (VARian Information System) is an example of such a system (Varian, 2007a). It includes the Eclipse™ treatment planning module (Varian, 2007b).

The high cost and rapid obsolescence of the technology puts a premium on treatment efficiency. On any day a radiation therapy unit may provide treatments or treatment planning to a hundred patients or more. In the U.S. and Europe, reimbursement from third party payers for treatments is more or less fixed by external factors. The high fixed-costs and more or less fixed reimbursement per patient combine to create strong incentives to treat large numbers of patients, to minimize the number and duration of treatments, and to minimize the delay between patients. The variable costs of radiation therapy operations are mainly the labor of physicians, radiation physicists, nurses, treatment technicians, and clerical staff. This is reflected in concern about appropriate staffing levels and staff planning (cf. Potters et al., 2004).

The Event and its Formal Investigation

LN, then 15 years old, underwent radiation treatment for a pineoblastoma at the Beatson Oncology Center (BOC) in Glasgow, Scotland. The treatment of choice for such a tumor is chemotherapy followed by radiation therapy. She underwent chemotherapy and then received 19 of 20 or 21 planned treatments before it was discovered that each treatment had delivered a dose 57% greater than intended. The fault reported to have caused the event was the failure of a relatively inexperienced operator to enter the scaling factor needed to convert a generic set of dosing parameters to values appropriate to individual. The overdose was discovered when a supervisor checking the treatment plan for another patient found that the planner had failed to enter the correct scaling factor for that patient. LN died nine months later. It is reported that, at autopsy, residual cancer was present (Williams, 2007).

Pineoblastoma is a rare but vicious tumor of the central nervous system. This rapidly progressive PNET (“primitive neuroendocrine tumor”) is deadly if untreated. Current aggressive therapy (a

combination of surgery, chemotherapy, radiation therapy, and bone marrow transplant) may produce “progression free survival” in perhaps 50% of pediatric patients 5 yrs after diagnosis (Reddy et al., 2000; Lee et al., 2005; Frim, 2007). Treatment effects are routinely severe. Survivors have long-term neurological deficits that may include poor school performance, memory deficits, and neuroendocrine dysfunction including short stature. Long term survival is exceptional. Patients with disseminated cancer uniformly die within 5 yrs of diagnosis; 50% of these are dead within two years (Reddy, 2000). LN’s reported residual cancer at autopsy suggests that her prognosis was poor. Paradoxically, it is possible that the overdose actually prolonged her survival by destroying more tumor than the intended dose would have done.

The Johnston report (Johnston, 2006) describes an investigation by the Scottish Executive’s health department that began on February 10, 2007, nine days after the overdose was recognized and at least 57 days after the relevant form was filled out (at the latest, December 16, 2005). The initial investigation of the event (between February 1, 2006 and February 10, 2006) was undertaken by facility management. Dr. Johnston is an employee of the Scottish Executive, which is the regulator and authority under which the BOC operates. The Johnston report focuses heavily on staffing and quality assurance matters. The report summary notes that Dr. Johnston did not examine the devices involved in the event because “the error...was procedural and was not associated in any way with faults or deficiencies in the Varis 7 computer system” (Johnston, 2006;ii). Perhaps more to the point, the report itself sets the stage for its contents in §2.7:

...at no point in the investigation was it deemed necessary to discuss the incident with the suppliers of this equipment since there was no suggestion that these products contributed to the error. (Johnston, 2006; 2)

The decision to ignore machines and their interactions with humans is typical of novice inquiries into accidents that involve human operators. The resulting narrowness is characteristic of stakeholder investigations and the Scottish Executive is an important stakeholder. The findings of the report are little more than the usual “blame-and-train” response that is the staple of medical accident investigations (Cook et al., 2000, 2005; Norman, 2005).

The blame-and-train focus of this and other investigations serves bureaucratic, organizational, and psychological purposes. By concentrating on the sharp end practitioner (Cook & Woods, 1994) the possible causes are constrained in ways that serve stakeholder needs. Stakeholder investigations are driven by stakeholder needs. The most pressing needs for the Scottish Executive's health department are to demonstrate and justify its singular, vested authority. The investigation proceeds along pathways that localize the failure in individuals at the facility, rather than in the authority itself or in other factors that would be disruptive to the needs of the authority. The reference to ISO 9000 document control is particularly significant in this respect. The facility failed to update its ISO 9000 controlled documents and this is identified as a contributing factor to the event. But the documents were so far out of date that it is certain that they played little or no role in the daily operations that produced the LN case. The emphasis on staffing relative to guidelines and document control serves to direct attention away from a detailed investigation of the event and towards familiar, bureaucratically comfortable territory. The Johnston report is an effective document from the perspective of the stakeholder that created it. The report lodges failure in a few individuals while keeping the expensive and complicated machinery and procedures out of view.

What is Missing?

The account of the BOC event lacks any real attention to the complexity of the processes required to carry out mass scale, individualized, high risk activities. The investigation entirely misses the significance of the system that has been created to deliver radiation treatments and ignores the experience from other domains regarding the nature of human-computer interaction, human factors, and the management of hazardous processes.

The VARiS 7 computing system is a large distributed computing network with multiple programs that are coordinated through references to a common, shared database. The patients and treatments are objects in the database and these objects are manipulated by the code of the various modules. The purpose of this complex system is to

integrate treatment planning, treatment, and record keeping into a seamless process in which all relevant information is passed through the database objects. Current systems for radiation therapy are workable largely because the complexity of treatment planning and delivery is managed using a computer agent. While the predecessor systems were workable assemblies of discrete programs, machines, and procedures, the complexity of treatment planning and the need to use these enormously expensive machines efficiently has made integration of the information infrastructure the core of the system. In the past, information technology was one peripheral component of many that literally and figuratively surrounded the treatment machines. In the modern setting, the information technology is the core and the machines are peripheral elements.

Making automation a team player in complex work settings has proven to be considerably harder to do than to imagine. Despite experiences with automation failures in multiple domains and a good deal of talk about user-centered automation, very little attention has been paid to the creation of useful automation for healthcare. As Woods (reference?) has said, “the road to technology centered systems is paved with user centered intentions.” Klein et al. (2004) identified ten key features of team player automation. These are:

1. Fulfill the requirements of a Basic Compact to engage in common grounding activities
2. Able to adequately model other participants’ actions vis-à-vis the joint activity’s state and evolution
3. Be mutually predictable
4. Be directable
5. Able to make pertinent aspects of their status and intentions obvious to their teammates
6. Able to observe and interpret signals of status and intentions
7. Able to engage in negotiation
8. Enable a collaborative approach
9. Able to participate in managing attention
10. Help to control the costs of coordinated activity

What prompted the experts at the BOC to conclude that the LN treatment plan was too complicated to allow it to be generated on the Eclipsis module and sent directly to RTChart? What sort of integration is it when the easy plans are left to the computer but the hard (and more complicated) ones require manual entry? Reviewing the list of requirements for making automation a team player suggests that the BOC system failed in multiple ways. Why is it that there is no independent representation of the total dose being delivered by a plan? Why is it that there are no independent measurements of radiation delivery to a given patient? Why is there so little feedback about planning and data entry consequences? We might venture a hypothesis that the entire system is rigged to make planning and treatment efficient and that the information technology makes it difficult to detect the sort of failure that led to the overdose of LN. The problem that occurred during LN's treatment planning was, in review, surprisingly common but it is clear that no one in the facility had considered this particular type of failure a possibility prior to the discovery of the overdose. What other kinds of problems had occurred here? The organization had apparently been dysfunctional since the late 1990's – at least as far as its performance according to ISO 9000. But if this is true, why was that never recognized? If the ISO 9000 yearly audit is actually valuable we would expect that ignoring it for 6 or 7 years would create all sorts of problems. Conversely, if the only thing that happens when ISO 9000 requirements are not adhered to is that once every 6 or 7 years one patient gets an overdose, is there really much value in ISO 9000?

We also know very little about the context of work in which this even occurred. We know, for example, that the treatments for LN were recognized by some senior technical people as being importantly different from those applied to other patients. This led them to try to use what may be politely called an out-of-date method for planning. But there is nothing in the report about how this particular vulnerability was recognized and why it was that these particular cases required a resort to the “old way” of doing things. What, precisely, are the complexities that the Eclipsis planning programs do not handle?

From a slightly different perspective, it seems that the problem at the BOC arose from the difficulty that accompanies introducing new,

highly automated technology into a fast paced, high hazard process control setting. In past systems, technology was machines, blocks of metal, and paper printouts from computers. In the new systems the newness is the information technology itself. Moreover, the nature of information technology means that it is constantly changing. VARiS & was preceded by VARiS 6. Within the major version changes are multiple upgrades and updates and the configurations of these systems is constantly changing. Predecessor systems were bulky, awkward, and crude and changed slowly. Current systems change quickly and constantly and the impact of these changes is often difficult for operators to appreciate.

It is clear that the professionals at the BOC recognized that LN was a special patient and they sought to return to an older way of doing things in order to obtain high confidence in the treatment plan. But modern systems make such retreats more and more difficult. It is clear that the new automation does not smoothly adapt to a hybrid approach – part computer with database, part human with planning form. The complexity of current systems tends to make their use an all-or-nothing proposition. The ability to manage complexity with computers leads to the development of more complex systems. It is actually quite hard to retreat to the old way of doing things and the systems and processes that gave those methods their robustness are hard to maintain when the old way has been replaced. The new way of doing things is more reliable, more efficient and, critically, more economical but its use carries with it a host of hazards that are hard to appreciate until something goes wrong.

The complexity and complications of advanced information technology are not widely appreciated. After accidents the reconstruction of events tends to make it seem that the human performance was bad while the technology performed well. Closer examination, however, demonstrates that the human performance was awkward because the humans involved were the adaptable elements of the system. To make the technology work requires a variety of adaptations and workarounds in order to get the job done. When the limits of adaptation are reached and failure occurs, the human performance is evaluated and found wanting. After accidents the adaptations are found to be vulnerable and

the workarounds are treated as violations. But these findings are more reflections of the naivete of the finders than a meaningful assessment of the system itself. Technology is like the suit the contorted practitioners make fit and we are the two old ladies: “Oh, look at that poor man”, “Yes, but doesn’t his suit fit well.”

• 5. What should happen?

The LN overdose and the similar cases identified at the BOC raise concerns about how radiation therapy is managed within the U.K. that are unanswered by the Johnston report. Rather than being the last work on what happened at the BOC, the report is a single stakeholder perspective on a complex event.

There are in Scotland, the U.K., and the U.S., no independent investigations of significant medical events that result in a public report. Every accident investigation is carried out by stakeholders. The result is that there no regular supply of reliable, authoritative, scientifically grounded investigations of medical accidents. This is in stark contrast with transportation accidents which are, in the U.S., investigated by an authority without stakeholder interest. The National Transportation Safety Board (NTSB) is an agency of the government that is carefully distanced from the regulator (the various highway and aviation administrations) and from the other stakeholders. The result is a steady stream of accident reports that serve both technical and social needs. The NTSB reports are derived from immediate first-hand investigation by professionals, are highly technical and technically vetted, and are recognizably free from stakeholder control. The immediacy, technical grounding, and stakeholder independence are the essential elements that make the NTSB the relevant source of information about specific transportation accidents. Significantly, it is because the NTSB reports may identify the failure of regulatory agencies to perform effectively and make recommendations that cut against the institutional grain that its investigations are so widely regarded and relied upon for the technical understanding of the causes of accidents. It is inconceivable, for example, that the investigation of a transportation accident involving complex, computer controlled machinery would have ignored the machines and interactions between them and their operators.

Why is there no such body for healthcare? There are a number of reasons but the primary one is that, in the final analysis, stakeholders control the information at every stage and do so in ways that make their pronouncements about the underlying events less than satisfying. Although the stakeholders are often at odds with each other in the courts and the court of public opinion, they agree that the handling of these sorts of events is best managed by themselves. We have only just completed a project to test the feasibility of an “NTSB for healthcare” in the U.S. It demonstrated that such investigations can be undertaken and that the findings they produce are not generated through the normal channels of response to accidents. We believe that such a body would be useful.

It is also clear that the oversight and evaluation of large healthcare information technology systems is in disarray. These systems are being developed and implemented throughout healthcare with little thought being given to their potential for harm or the difficulties associated with their use. The enthusiasm for new technology as a means to save money and rationalize care is not matched by the performance of these systems. With a detailed investigation, the event at the BOC might have shed some light on the medico-industrial complex that produces and markets these systems. The failure to do so is not a great loss. One thing that experience shows is that there will be other events like the overdose of LN and other opportunities to do more detailed investigations of ways in which human-computer interactions create new forms of failure.

The most disturbing thing to us is the ease with which events like the LN overdose are forgotten. Just over a year later, the BOC radiation therapy website contains nothing about LN or the event, nothing about other accidents that have happened there. Ironically, the most recent Scottish Executive website posting related to the BOC was the announcement that a minister was soon to travel there in order to announce the funding of more new technology (Scottish Executive, 2007).

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