Root Cause Analysis – A Mock Case Study

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Abstract

A percentage of Radiation Therapy treatments will result in an error, be it a treatment or planning error. These errors, or incidents, will range from the very insignificant to the very significant. Although some incidents may be able to be corrected in future treatments, in general it is not possible to completely correct an incorrect treatment. The one positive that can be taken from every incident is to learn from it, identifying the processes which failed and replacing these with more robust processes.

A root cause analysis (RCA) is a tool which focuses investigation of an incident onto processes and away from people. Incident analysis will only ever be successful if personal blame is removed.

This paper uses a mock case study to take the reader through the process of an RCA with the purpose of raising the appreciation of the value and benefits of such an analysis.

INTRODUCTION

Radiation Therapists constantly strive to deliver safe and accurate radiation therapy to their patients. Occasionally processes fail and an error, or incident, occurs. Most of these incidents are minor but a small proportion are more serious. It is important to not only take measures to minimise the impact of the error by making any treatment adjustments possible, but to also analyse what went wrong and to learn from it. A root cause analysis (RCA) is an extremely useful tool which allows a clinical incident to be studied and the issues underlying the incident to be brought to light. Among many other institutions the Veterans Affairs (VA) department in the USA has used this process extensively, to study all types of medical incidents.

This paper will present the Victorian guidelines around mandatory reporting of clinical incidents, the RCA process and who should participate will then be discussed. Finally a mock case study will be presented.

The aim of this paper is to introduce a valuable analysis tool to the radiation therapy community.

SENTINEL EVENTS

In Victoria there is mandatory reporting of certain serious clinical incidents, called sentinel events (Table 1). All incidents which fall into this category must be reported to the Department of Human Services (DHS) as soon as they occur, or it is realised they have occurred. The DHS requires that certain processes must be followed, and a final report is required within 45 days of reporting the event, these processes include the completion of a RCA. For further information see:


Of these events those applicable to Radiation Therapy and Radiation Therapists are:

a. Procedures involving the wrong patient or body part,

i. Other catastrophic event.

Table 1: DHS Reportable Sentinel Events in Victoria.

<table>
<thead>
<tr>
<th>Sentinel Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Procedures involving the wrong patient or body part.</td>
</tr>
<tr>
<td>b. Suicide in an inpatient unit.</td>
</tr>
<tr>
<td>c. Retained instruments or other material after surgery requiring re-operation or further surgical procedure.</td>
</tr>
<tr>
<td>d. Intravascular gas embolism resulting in death or neurological damage.</td>
</tr>
<tr>
<td>e. Haemolytic blood transfusion reaction resulting from ABO incompatibility.</td>
</tr>
<tr>
<td>f. Medication error leading to the death of patient reasonably believed to be due to incorrect administration of drugs.</td>
</tr>
<tr>
<td>g. Maternal death or serious morbidity associated with labour or delivery.</td>
</tr>
<tr>
<td>h. Infant discharged to wrong family.</td>
</tr>
<tr>
<td>i. Other catastrophic event.</td>
</tr>
</tbody>
</table>

Mandatory reporting and mandatory categories do raise some anomalies; treating the wrong patient may not be catastrophic, although it is definitely not to be recommended. Treating two women with left breast cancer using swapped treatment sheets would not be catastrophic but would need to be reported. Misplacement of a treatment beam and treating the lens of the eye would be catastrophic and would be reportable under category i, other catastrophic event.

Reporting an incident to the DHS and undertaking an RCA does not replace the requirements of the relevant safety authorities, the reporting requirements of these bodies must still be met.

OTHER INCIDENTS

Fortunately the vast majority of incidents do not fall into the above category and can be handled in house. Each Radiation Therapy department would have its own mechanism to report and analyse minor incidents such as reversing the field size on a (10 x 11)cm beam located away from critical structures.

DEFINITION OF RCAS

In any incident analysis it is essential that individual blame is not applied. Of course as professionals radiation therapists must take...
ROOT CAUSE ANALYSIS – A MOCK CASE STUDY

TABLE 2: EVENTS AND EXPLANATIONS OF INCIDENT

<table>
<thead>
<tr>
<th>USUAL PROCESS</th>
<th>ACTUAL PROCESS</th>
<th>VARIATION / WHY?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Simulation radiograph performed by Radiation Therapist-1 (RT-1).</td>
<td>One non standard beam positioning aid (Tegaderm over texta mark) used.</td>
<td>Patient refused standard beam positioning aids.</td>
</tr>
</tbody>
</table>

a. Standard beam positioning aids (three tattoos) used and their position recorded.  
   Relationship to the tattoo, which is called treatment reference point, (TRP).  
   Patient refused standard beam positioning aids.

b. Beam positioning landmarks recorded in relationship to the tattoo, which is called treatment reference point, (TRP).  
   Beam positioning landmarks recorded in relationship to palpated landmark, tip of coccyx, (TOC).  
   Bony landmark used as there were no tattoos, bony landmark considered superior to Tegaderm.

2. RT 1 measures up and marks simulation radiographs.  
   Beam positioning landmarks are recorded on the simulation radiograph in relationship to the tip of coccyx (TOC).  
   No tattoo present and see point 1.b.

3. Patient is contacted with treatment appointment, this appointment is made with allowance for adequate time for all pre treatment planning processes.  
   The treatment start date needed to be brought forward unexpectedly and urgently.  
   Change in patient’s condition.

4. RT-1 generates planning computer data and constructs treatment sheet.  
   RT-2 generates planning computer data and constructs treatment sheet.  
   RT-1 was not on duty, therefore RT-2 needed to perform task due to urgency of treatment.

5. Beam positioning landmarks are recorded in relationship to the tattoo (TRP).  
   Beam positioning landmarks are recorded on the treatment sheet in relationship to the tip of coccyx (TOC).  
   Work completed under pressure due to need to push this in amongst already heavy workload due to urgency of treatment.

As the tattoo (TRP) and the tip of coccyx (TOC) are separated by a distance of 10cm, the beam positioning landmarks on the treatment sheet describe a beam 10cm from the intended position.

6. RT-3 checks all data relating to patient’s radiation therapy treatment.  
   Sufficient time is allowed for a check with no undue pressure to complete the task.  
   The patient was due in 1 hour for treatment and competing demands for RT-3’s time led to a fragmented check.

a. This check was performed with a sense of urgency.

The discrepancy between simulation radiograph and treatment sheet beam positioning landmarks was not detected.

7. Patient arrives at appointment time.  
   Several phone calls are received from the patient and medical staff regarding whether or not the radiation therapy treatment will begin at the expected time.  
   RTs and patient all confused as to whether treatment is continuing and if so when.

8. An RT on the radiation therapy treatment unit overviews the treatment plan.  
   RT-4 began an overview of the treatment plan but did not complete it.  
   RT-4 was called away from check to perform other duties as it was now believed the patient was not coming for radiation therapy treatment that day.

The part of the overview not completed was the section relating to the beam positioning landmarks.

a. Patient arrives at designated appointment time.  
   Patient arrives later in the day, not at appointment time.  
   Due to confusion about whether treatment beginning or not.

   Patient arrives and receives radiation treatment. This coincides with the arrival of an urgent ambulance patient, creating a degree of stress.  
   Ambulance patient kept waiting the previous day. RTs keen not to keep either patient waiting.

CONTINUED ON THE NEXT PAGE
responsibility when errors occur, but analysis must be into the processes not people. Those involved in the incident must feel confident and supported to discuss what occurred openly, honestly and constructively. If blame is being laid this will not occur.

RCAs are conducted by a facilitator and team members, as discussed below. Three meetings are usually held, again, as discussed below. The method being presented in this paper is one of many models of an RCA which can be used.

The Facilitator
The first step in a RCA is to appoint a facilitator, often the hospital’s Clinical Risk Manager, but any person who understands the RCA process can be the facilitator. The facilitator must speak with each person involved in the incident and complete a two sided table with the usual steps in the process on one side and what happened in this case on the other. This will show what steps were at variance to the normal. The discussion between the facilitator and those involved can be in a group but is ideally done on a one to one basis. The facilitator must be someone who people feel they can trust.

The Team
An RCA team usually consists of six to eight people, including the facilitator. There should be one person who has little understanding of or experience with Radiation Therapy, as this person sees things with no preconceived ideas or prejudices and can often challenge our intrinsic beliefs in a positive way. There must also be someone with the authority to action or champion change. Although the RCA team usually restricts itself to recommendations they have more weight if supported by someone in authority. A clinician who knows the patient involved is a useful team member as they can add the clinical perspective. Last, but definitely not least, at least two Radiation Therapists who were involved in the incident must be included. These people clearly have the most difficult role and they must be supported through the process and never blamed.

TABLE 2: EVENTS AND EXPLANATIONS OF INCIDENT, CONTINUED

<table>
<thead>
<tr>
<th>No.</th>
<th>Event</th>
<th>Explanations</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>RT - 4 who had performed the overview treats the patient.</td>
<td>RT-5 and RT-6 begin to set the patient up for treatment.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>RT-4 was not rostered to duty at the time when the patient ultimately arrived.</td>
</tr>
<tr>
<td>b.</td>
<td>RT - 5&amp;6 check there is an overview signature.</td>
<td>No check made.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Assumption made that check complete as RT-4 had been seen doing the check earlier in the day.</td>
</tr>
<tr>
<td>c.</td>
<td>Patient set up to tattoo at TRP.</td>
<td>RT - 5 &amp; 6 noted the lack of tattoo and saw the Tegaderm. Noted that there was no reference to it on the treatment sheet and went to consult with colleagues.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>RT-1 not rostered for duty. RT-2 not available. RT-3 &amp; 4 had left the building. RT - 7 was consulted and confirmed positioning of the Tegaderm and that it had been placed there by RT-1.</td>
</tr>
<tr>
<td>d.</td>
<td>RT 5&amp;6 believed the radiation beam should be placed in relationship to the Tegaderm which was replacing the refused tattoo as the TRP. This was also the instruction written on the treatment sheet.</td>
<td>Tegaderm in TRP position, therefore assumption made that tegaderm was replacing tattoo.</td>
</tr>
<tr>
<td>10.</td>
<td>Patient’s family waits in waiting room while treatment delivered.</td>
<td>Patients family at the treatment console.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Family very close to staff at console leading to a feeling of inhibition.</td>
</tr>
<tr>
<td></td>
<td>Verification x-rays are processed and checked by two RTs. Discrepancy noted and acted upon.</td>
<td>Situation is disclosed to patient, no late sequelae envisaged by RO.</td>
</tr>
</tbody>
</table>

Meeting 1
At the first meeting of the team a third column is added to the two columns, in which the reason for any variance is recorded. At this stage no attempt to analyse the variance occurs.

Meeting 2
At this meeting analysis of the variations occurs and recommendations for changes in processes are made. It is extremely important to put time lines and attach names to recommendations so all members of the team understand their respective responsibilities.

Documentation
In the formal RCA mandated by the DHS specific deidentified documentation must be returned to the DHS in a timely fashion. The DHS is not interested in personal blame, rather they need to know that suspect processes and procedures have been addressed.

When to undertake a RCA
As previously discussed, in some instances in Victoria RCAs are mandatory, however there is a lot to be learned even in non mandatory situations. In general a RCA is useful in any situation where there are multiple levels or processes involved in an incident.

RCAs encourage us to look beyond the obvious cause of an incident and consider all factors involved.

MOCK CASE STUDY

Background
Patient was a 57-year-old male with rectal cancer. The radiation...
therapy treatment was prescribed as 50.4 Gy in 28 fractions at 5 fractions per week, the technique used was a posterior and two lateral beams, the patient was lying prone on a belly board.

Incident
The first treatment fraction was delivered 10 cm superior to the prescribed area. This discrepancy was noted on port films.

If this treatment was delivered in Victoria it may come under the DHS category of “wrong body part” and a RCA would be mandatory. Even in other states a RCA would be desirable to test which processes failed.

Facilitator
The facilitator would begin the process by speaking to each person involved in the treatment and planning of this patient.

After these interviews a table (Column 1 & 2, Table 2) would be completed with “usual” events on one side and “actual” events on the other.

Team
The RCA team would be recruited, it would consist of the facilitator with staff from Radiation Therapy and Radiation Oncology.

Meeting 1
At this meeting a third column would be added to the table (Column 3, Table 2) asking the question why the variations occurred.

Meeting 2
Another table would be constructed detailing actions to prevent the same situation occurring again, or handling the situation more safely if it could not be avoided.

Actions
All actions would be allocated to a person who would be responsible for them and a time line would be attached (Table 3).

CONCLUSION
In this paper the Victorian guidelines around mandatory reporting of clinical incidents have been discussed, the RCA process and who should participate has also been discussed. A mock case study of a RCA was also presented.

The only positive that can come out of an incident is the opportunity to learn from it and improve processes. An RCA is a valuable analysis tool for the radiation therapy community to become aware of and use.

REFERENCES

Peer Reviewed
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TABLE 3: ACTION PLAN

<table>
<thead>
<tr>
<th>ACTION</th>
<th>RESPONSIBLE</th>
<th>DATE DUE</th>
<th>DATE COMPLETED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tegaderm to replace all tattoos, not just one.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acronym “TRP” to be written full to avoid confusion with others such as “TOC”.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reproritising workload to accommodate urgent patients rather than just fitting them in.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Checking time be sacrosanct with no interruptions.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General discussions regarding handling the prioritisation of patients into the treatment room in a non stressful manner when two “urgent” patients arrive at the same time.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discussion to occur with all staff on how to manage open communication between staff, patients and their carers.</td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>