Principles of Business Continuity

R. Alfredo C. Siochi, PhD, DABR
Department of Radiation Oncology
West Virginia University
Conflicts of Interest

• Not related to this topic
  • Co-founder of Infondrian, LLC
    • Gap fund and Iowa based Grant to Infondrian
    • NIH phase I and phase II STTR grants
  • Various TG, committees, leadership positions in AAPM, ASTRO

• Related to topic
  • IHE-RO
Overview

• What is Business Continuity Management (BCM)
  • Event Lifecycle
  • Criticality and Severity
  • BC Lifecycle

• Patient Oriented BCM
  • Application to Radiotherapy
  • Physician Input
Main References for this talk

- Several Definitions, Figures, and Tables from this reference are included in this talk
- Red Journal Volume 100, issue no. 4
## Business Continuity Management – what is it?

<table>
<thead>
<tr>
<th>Manage the disruptions that prevent one from achieving the business goals</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Keep the enterprise running from a</em></td>
</tr>
<tr>
<td><em>Business perspective</em></td>
</tr>
<tr>
<td><em>Financial perspective</em></td>
</tr>
<tr>
<td><em>End-user / interested parties’ perspective</em></td>
</tr>
<tr>
<td><em>Internal processes</em></td>
</tr>
<tr>
<td><em>Reference 1 – ISO 22301</em></td>
</tr>
<tr>
<td>Manage the lifecycle of an event</td>
</tr>
</tbody>
</table>

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*West Virginia University School of Medicine*
Event Life Cycle*

Event
- Interruption
- Response

Impact
- Effect on Business

Recovery
- Restore Operations

*Reference 2
Event

Anything that can disrupt business operations

Similar to a Failure Mode in FMEA

Should prompt a planned response – e.g. how do I continue a patient’s treatment?
Event Scenarios

- Loss of Technology
- Loss of a Building
- Denial of Access to a building
- *Loss of Staff
- *Loss of a Supplier

*Some of these have longer lead times for responding, e.g. the loss is not immediate, you have some notice when an employee decides to leave.

Photos by Unknown Authors licensed under CC BY
Business Impact Analysis (BIA)

Understand the effect of the event upon the business

Similar to an Effect in FMEA
## Recovery

<table>
<thead>
<tr>
<th>Recovery Step</th>
<th>Example Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restore what was affected by the interruption</td>
<td>E.g. Patient Treatment – complete its delivery</td>
</tr>
<tr>
<td>Understand why the event happened</td>
<td>Root Cause Analysis</td>
</tr>
<tr>
<td></td>
<td>Or prospectively – Fault Tree Analysis</td>
</tr>
<tr>
<td>Reduce the likelihood of the event happening again</td>
<td>Hazard Mitigation</td>
</tr>
</tbody>
</table>
## Recovery Objectives

### Recovery Time Objective
- How quickly a system must be made available after it fails
- How quickly can we resume treatments?

### Recovery Point Objective
- The maximum amount of data loss that can be tolerated
- The maximum number of treatment fractions missed that can be tolerated?
*Business Continuity Process life cycle*

“Ensure critical activities are performed no matter what...”

This is a form of continuous improvement.

Reference 2
Background to do BCM

- similar to TG100 in a way
- Effects evaluated in terms of business continuity
- RISK MANAGEMENT EXPERIENCE* is very helpful

*Reference 3
Two Key Concepts in BCM

<table>
<thead>
<tr>
<th>1. Criticality – of activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>• If the activity is disrupted, what is its impact?</td>
</tr>
<tr>
<td>• How important is the activity to the business</td>
</tr>
<tr>
<td>• Need to develop some scheme for criticality levels</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Severity – of disruption</th>
</tr>
</thead>
<tbody>
<tr>
<td>• How significant is the event?</td>
</tr>
<tr>
<td>• Need a measure of severity – severity levels</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Concepts are related and can be mapped to each other</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Map severity levels to criticalities</td>
</tr>
</tbody>
</table>
Criticality - categories

High: If an activity is disrupted and it can cause a massive impact on the business

Medium: The activity is "merely" important.

Low: The activity can be suspended indefinitely.
## Example Criticality Levels

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Non-stop continuous operation</td>
</tr>
<tr>
<td>1</td>
<td>Recovery within 2 hours</td>
</tr>
<tr>
<td>2</td>
<td>Recovery within 4 hours</td>
</tr>
<tr>
<td>3</td>
<td>Recovery within 12 hours</td>
</tr>
<tr>
<td>4</td>
<td>Recovery within 24 hours</td>
</tr>
<tr>
<td>5</td>
<td>Recovery within 48 hours (about 2 days)</td>
</tr>
<tr>
<td>6</td>
<td>Recovery between 2 days and a week</td>
</tr>
<tr>
<td>7</td>
<td>Recovery between a week and a month</td>
</tr>
<tr>
<td>8</td>
<td>Recovery not required. To be reviewed if more than 4 weeks</td>
</tr>
</tbody>
</table>
## Severity Levels

<table>
<thead>
<tr>
<th>Severity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical</td>
<td>Significant risk to the continued operation of the whole enterprise</td>
</tr>
<tr>
<td>Severe</td>
<td>Significant risk to the continued operation of a business division or geographic region</td>
</tr>
<tr>
<td>Major</td>
<td>Risk to the continued operation of a major function, system or key location</td>
</tr>
<tr>
<td>Significant</td>
<td>Risk to the continued operation of a secondary site, function or system</td>
</tr>
<tr>
<td>Minor</td>
<td>Risk to the continued operation of a team, minor process or system</td>
</tr>
<tr>
<td>Non-Critical</td>
<td>Risk to non-critical activities, systems or individuals</td>
</tr>
</tbody>
</table>
# Severity / Criticality Mapping

<table>
<thead>
<tr>
<th>Severity</th>
<th>Criticality Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical</td>
<td>0-2 (Recovery Time Objective &lt; 4 hours)</td>
</tr>
<tr>
<td>Severe</td>
<td>0-2 (Recovery Time Objective &lt; 4 hours)</td>
</tr>
<tr>
<td>Major</td>
<td>2-4 (Recovery Time Objective &lt; 24 hours)</td>
</tr>
<tr>
<td>Significant</td>
<td>4-5 (Recovery Time Objective &lt; 48 hours)</td>
</tr>
<tr>
<td>Minor</td>
<td>5-6 (Recovery Time Objective &lt; 1 week)</td>
</tr>
<tr>
<td>Non-Critical</td>
<td>6-8 (Recovery Time Objective &gt; 1 week)</td>
</tr>
</tbody>
</table>
BCM - planning

**ANSWER THIS QUESTION:**
- What do you need to do if your activities are stopped in order to get them started again?

**Analyze event lifecycle for various types of events**
- Need to brainstorm the events
- For each event determine the impact
  - THE impact depends on your business goals
- For each impact determine how to recover
- Note that these also depend on the activity
Radiation Therapy – “Business” Goals

- Continuity of care for the patient
- Very Broad View
- Interfraction / Intrafraction
## Broad View

<table>
<thead>
<tr>
<th>Perspective of the Patient</th>
<th>Management of Recurrent Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Information from Prior RT</td>
</tr>
<tr>
<td></td>
<td>• Transfer of Care</td>
</tr>
</tbody>
</table>
## Interfraction / Intrafraction

<table>
<thead>
<tr>
<th>Clinic Perspective</th>
<th>Patient Perspective:</th>
<th>Subject of this session</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Linac uptime</td>
<td>• how does this impact the patient’s outcome?</td>
<td></td>
</tr>
<tr>
<td>• IT infrastructure uptime</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Is everything in place to treat the patient?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Criticality Levels in Radiotherapy?

CRITICALITY LEVELS are patient dependent

Primary GOAL
CURE the curable

Secondary GOAL
PALLIATE severe pain

Time is of the essence; curative patients may become incurable
Patient Dependent Criticality Levels for treatment activities

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Emergency patient – bleeding? SVC?</td>
</tr>
<tr>
<td>1</td>
<td>Curable BID patient with aggressive disease; Palliative patient in severe pain without other means of palliation.</td>
</tr>
<tr>
<td>2</td>
<td>Curable QOD patient with aggressive disease</td>
</tr>
<tr>
<td>3</td>
<td>Curable patient that could become palliative if they miss 3 fractions in a week</td>
</tr>
<tr>
<td>4</td>
<td>Palliative patient with tolerable pain</td>
</tr>
<tr>
<td>5</td>
<td>Recovery not required. Other non-radiation methods of palliation</td>
</tr>
</tbody>
</table>

These roughly map to the required recovery times from an event, e.g., Linac Down.
Continuity of Internal Processes

IDENTIFY

• MINIMUM RESOURCES FOR EACH PROCESS
• CRITICAL CLINICAL WORKFLOWS
Events – classified* - by extent of impact

<table>
<thead>
<tr>
<th>Disaster</th>
<th>System Wide</th>
<th>Regional</th>
<th>Local</th>
</tr>
</thead>
</table>
| • Failure of multiple critical resources | • Failure of single critical resource  
  • affects all patients and operations of the department | • Failure of one of several of a critical resource  | • Failure of a resource specific to a patient |

*This is my own classification – it helps prioritize business continuity planning
Prioritize BC Plan Development

- Consider events that affect the most patients (Severity)
  - Disasters
  - IT infrastructure
  - Linac Failure

- Consider the likelihood of the event (Occurrence)
  - Are Ransomware attacks more likely than a flood?

- Develop plans to respond to the most severe and likely events.
  - Plans should consider the workflows that will be affected the most
  - Plans should also consider realistic recovery times
Consider outcomes first, causes second

There can be several causes leading to the same outcome

• Example: outcome = Data Loss. Causes: Ransomware, Floods, Fire....

The response to, and preparedness for, the outcome largely depends on the outcome, not so much the cause

• Example:
  • IT infrastructure not available
  • Response – switch to failover site
  • Causes – ransomware, disaster
Parts of Response Plans can be shared - maybe

- Ransomware
- Loss of IT infrastructure
- Flood
- Loss of Linac and IT Infrastructure

Recovery of IT
Critical Workflows / States

- **CRITICAL** – from the viewpoint of the department goal
  - PROVIDE BEST QUALITY CARE – WORK TOWARDS CURE

- **Patients under treatment**
  - Curative, at risk of not being curative if treatment interrupted
  - Palliative, without other means of pain control

- **Patients in planning with aggressive disease**
  - Need to start right away
# Example Critical Resources

<table>
<thead>
<tr>
<th>Derived from Critical workflows</th>
<th>Linear Accelerator</th>
<th>Know the modality and energy that is used for the majority of patients</th>
<th>6 MV Higher energy photon</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Source for treatment parameters</td>
<td>Could be Aria or Mosaiq</td>
<td>Could be a DICOM File</td>
<td></td>
</tr>
<tr>
<td>Therapists – you can’t turn on the machine without them!</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Note that you also need resources to respond to the disruption</td>
<td>Leadership – someone to coordinate the response</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Know your processes. Which ones are important? What would disrupt these processes?

- Process Improvement
- Peer Review
- IMRT QA
- Linac QA
- Treatment Planning
- Treatment Delivery
- Treatment Management
- Documentation
EXAMPLE EVENTS – Loss of an Office

Steam Pipe Leak in a radiation oncologist’s office

Impact
- delays in physician’s work
- Similar to the impact of a loss of staff.

Response:
- (1) Relocated the oncologist’s workspace
- (2) Moved back everything once repairs to office were complete
Example Event – Loss of Staff

SNOWSTORM → ROADS BLOCKED → Reduction in available staff
- reassign staff
- postpone less critical activities
Example Events – Loss of Technology

TrueBeam went down

- Didn’t know when it was going to be back up
- Supply chain issues for parts
- OBJECTIVE WAS FOR PATIENTS TO GET AT LEAST 2 FRACTIONS THAT WEEK.

COMMENT: SOMEWHAT AD HOC RESPONSE.
Comment on Extreme Downtime

- Down to one machine
- Our recovery plan kept changing.
- Several replans made, but not used.

This prompted the development of a policy specific to machine downtime and the decision making involved in the replanning.
Example of high priority event: Ransomware

High likelihood.

Large Impact.
- Affects almost all processes.
- Spreads over network.
- Stop it as soon as it is recognized.
- Can affect the entire hospital

To be discussed by other speakers in this session
Business Continuity is Continuity of Patient Care

- Requires MD input
- State the recovery objective in the patient’s chart:
  - E.g., patient should not miss more than $x$ fractions per week
  - Or patient should finish by original final treatment date
  - May have to treat on the weekend
- Consider different scenarios:
  - A machine goes down, but at least another machine is available
  - IT infrastructure unavailable
  - Clinic not available (fire, flood)
EDITORIAL

Radiation Therapy in a Time of Disaster

Sue S. Yom, MD, PhD, MAS,* and Anthony L. Zietman, MD

*Department of Radiation Oncology, University of California San Francisco, San Francisco, California; and 1Department of Radiation Oncology, Massachusetts General Hospital, Boston, Massachusetts

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This edition of the Red Journal was inspired by the sheer accumulation of recent disasters around the world and our acknowledgment that, in a time of climate uncertainty, terrorism, and an aging electrical grid, we are each and all vulnerable. We are presenting this collection not to pass out easy answers but in hopes of starting a conversation about how these events affect our profession and our patients. Sharing experiences and recommendations is a necessary first step on our path to preparation.

Volume 100, no.4 of the Red Journal has a collection of experiences with providing continuity of care to patients in the midst of disasters.
Puerto Rico: After María
Angélica Pérez-Andújar
Published in issue: March 15, 2018
p834-835

Radiation Oncology in the Face of Natural Disaster: The Experience of Houston Methodist Hospital
Matthew Mireles, Ramiro Pino, Bin S. Teh, Andrew Farach, Adrienne Joseph, E. Brian Butler
Published in issue: March 15, 2018
p843-844

Our Role in Radiation Disaster Preparedness
Andrew L. Salner
Published in issue: March 15, 2018
p849-850

Radiation Oncology and Related Oncology Fields in the Face of the 2011 “Triple Disaster” in Fukushima, Japan
Akihiko Ozaki, Masaharu Tsubokura
Published in issue: March 15, 2018
p845-848

When Disaster Strikes: Mitigating the Adverse Impact on Head and Neck Cancer Patients
Sue S. Yom, Paul M. Harari
Published in issue: March 15, 2018
p836-840

Natural Disasters and the Importance of Minimizing Subsequent Radiation Therapy Interruptions for Locally Advanced Lung Cancer
Michael C. Roach, Cliff G. Robinson, Jeffrey D. Bradley
Published in issue: March 15, 2018
p836-837

Role of Overall Treatment Time in the Management of Prostate Cancer Patients: How to Manage Unscheduled Treatment Interruptions
Howard M. Sandler
Published in issue: March 15, 2018
p841-842
Business Impact Analysis and Recovery for Radiotherapy: Analyze the outcomes. How is tumor control affected?
Locally Advanced Lung Cancer
(Red Journal V100 no 4)

A recent analysis of 14,154 patients in the National Cancer Database with stage III non-small cell lung carcinoma (NSCLC) treated with concurrent chemotherapy and fractionated radiation therapy showed that treatment delays during radiation were significantly associated with inferior overall survival (1). The median overall survival for treatment without break versus prolonging treatment by 1 to 2 days, 3 to 5 days, 6 to 9 days, and >9 days was 22.7 months, 20.5 months, 17.9 months, 17.7 months, and 17.1 months, respectively (P<.0001).

“...RadiationTherapy Oncology Group studies, which showed a 2% increase in the risk of death for each day of treatment prolongation in patients with inoperable stage II or III NSCLC treated with concurrent chemotherapy and fractionated radiation therapy in the 1990s (2).”

In practical terms, for patients who have received only 1 week (approximately 10 Gy) of radiation and then a 2- to 3-week break or longer, the tumor impact of the initial 10 Gy is essentially lost. In such cases, we would recommend delivering the full prescription dose of 60-70 Gy without reduction once the patient is able to resume therapy. On the other hand, when patients have received more than a few weeks of treatment and then undergo treatment interruption, there may be value to consider accelerated and/or hyperfractionated schedules to try to maintain the overall total treatment time, if feasible to deliver (22, 23).

A less preferred alternative is to simply deliver the remaining standard fractions when delivery becomes possible again. In this case, the anticipated loss in tumor control may be substantial, because a break of 1 week may be associated with an absolute reduction in the local control rate of 10-14% (1, 6).

For treatment delays <1 week, no need for corrective action would be required. For longer delays, one might consider that androgen ablation, if being used along with RT, might mitigate the adverse impact of treatment delays and thus patients who received ADT might tolerate longer breaks in OTT, perhaps safely for up to 2 weeks. For those receiving RT alone and for whom a long break is anticipated because of natural disasters or other unforeseen issues, such as major machine downtime, one might consider starting ADT for its cytostatic effect.

In addition, one might consider increasing the overall dose of RT. For example, the data of Thames et al (3) suggest that each additional 2-Gy fraction adds roughly 5% to biochemical control, and thus an overall 6% negative impact of a 1-week treatment delay might be overcome by 1 or 2 additional treatment fractions if safely deliverable. Finally, one might consider, once treatment resumes, an acceleration in the remaining treatment in an attempt to minimize OTT with either selected twice-daily fractionation, such as 6 fractions in 5 days, or a moderate increase in the dose per fraction, as in recent hypofractionation experiences.
See table 3 – how do you compensate for the missed treatments?
Recommendations are very specific to the clinical scenario

**NSCLC** locally advanced, postop vs definitive

**SCLC** limited vs extensive stage

**Head and Neck** – dependence on when interruption happens

**Uterine Cervix** – Definitive vs postop

**Breast** – site? Chest wall? Nodes?

**Prostate**
Planning for a Disaster
1. Ensure you have a plan in place to deal with the loss of key utilities at home and your facility.
2. If your facility is in an area that floods and your department is in the basement, ensure there is a flood mitigation plan in place (e.g., flood gates).
3. Where feasible, twin your machines to minimize the need to rerun plans if you lose a machine owing to loss of cooling or other issues.
4. Ensure that you plan for an extended disaster. Our personnel had homes that were livable but were without power for 3 weeks’ duration.
5. These times are psychologically and physically difficult, and encouragement and support are needed for the members of the department; never underestimate the power of good morale.
6. One can never truly predict when a disaster will occur; we had 3 serious events in 16 years. Our goal is to be perpetually prepared because we cannot predict whether a disaster will occur in any given time period.
7. You need to be aware of the psychological and physical impacts on your team and help guide them through the event. “Leadership at the front lines” is critical.
8. Maintain a positive attitude: You will recover!
9. Communication is essential to the leadership of your department, and coordinating your plan with that of your facility is vital to ensure your operation resumes as quickly as possible.
10. Protect your power generators from flooding.
11. Ensure that you have a process in place to back up your patient data.
Conference aims to close radiation treatment gaps in disasters

Jim Ware StarNews Correspondent
Published 6:00 a.m. ET July 16, 2019 | Updated 12:57 p.m. ET July 15, 2019

It didn’t take long for New Hanover Regional Medical Center to get its radiation oncology program back on track after Hurricane Florence’s initial blows in September, but flooding and closed roads kept some cancer patients from receiving scheduled treatments.

While interruption of a treatment plan might not be critical in some fields, it can have a negative impact on the effectiveness of radiation therapy for patients, said Dr. Michael Papagikos, a radiation oncologist at NHRMC.

“When Hurricane Florence came in, we had a significant gap interruption in our patients’ treatment,” Papagikos said. “Through a lot of hard work and dedication of our staff and through the collegiality of the North Carolina radiation oncology community, we were able to get a number of our patients transferred out and have their care resumed at outside facilities until we were back up and running.”
Advances in Radiation Oncology – Letter to the editor – university of Vermont Larner College of Medicine (2021 V6, Carl Nelson etal)

• Patients triaged
  • Immediate resumption based on tumor biology and anticipated effects of tx delays
  • 3 Groups:
    • Squamous cell cancer (H&N, cervical, anal)
    • Non-Squamous cancer with concurrent chemoradiation
    • Tumors with slower cell repopulation (breast, prostate, benign brain tumors)
Example of treatment continuity process – decision is per patient. Scenario requiring replanning.
## IT Disaster Recovery (DR)

### Part of Business Continuity Plan

- Recovery times normally > 4 hours; typically, 8-12 hours.
- Recovery Point? No more than a day’s worth of generated data?
- From a patient viewpoint, this is at least one missed fraction (2 if BID).

### MAKE A DATA FLOW DIAGRAM
Add IP addresses

Identify network(s) in the route from one device to another.

Perform a tracert for each arrow in the diagram.
Report of TG201. Distributed Data repository.
IT DR Planning

<table>
<thead>
<tr>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duplicates of data sources?</td>
</tr>
<tr>
<td>Mirror site(s)?</td>
</tr>
<tr>
<td>How often is the data duplicated?</td>
</tr>
<tr>
<td>Alternative routing between devices?</td>
</tr>
<tr>
<td>Topics from last 2 speakers in session</td>
</tr>
</tbody>
</table>
Conclusion

• Business Continuity is Continuity of Care
• Business Impact Analysis: Impact on Patient Outcomes
• Plan for
  • Equipment being Down (Linacs, CT, etc)
  • Data unavailable for treatment
  • Network unavailable (loss of communication amongst devices)
  • Disaster – long term unavailability
    • Partner with other clinics
    • Safe copy of treatment data
PLUG FOR IHE-RO

• Integrating the Healthcare Enterprise – Radiation Oncology
• Use Case: Radiation Oncology Treatment History
  • Addresses continuity of patient care
• Encourage your vendors to participate
• Volunteer (Planning Committee)
References


• (4) – Red Journal, Volume 100 no 4 – several articles in special section on disasters