Learning to make radiation therapy safer

Peter Dunscombe, Ph.D.
University of Calgary/
Tom Baker Cancer Centre

Refresher Course: RC222

IMRT: Patient Safety and Error Reduction

Radiological Society of North America Annual Meeting

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UNIVERSITY OF CALGARY

Alberta Cancer Board

Peter Dunscombe

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PI on collaborative research agreement with Varian

Acknowledgements

- Dr. David L. Cooke
- Amanda Korenowski

Learning to make radiation therapy safer

Who needs to learn?

- Individuals
- Institutions

Learning to make radiation therapy safer

Why learn?

- Individuals – so they can do their jobs better
- Institutions – so they can allocate resources appropriately

Learning to make radiation therapy safer

Where are the lessons?

- Local experience
- Global experience

Learning to make radiation therapy safer

Where are the lessons?

- Local experience

We need the local experience because institutional cultures vary widely, particularly in regards to risk management.

Learning to make radiation therapy safer

Where are the lessons?

- Global experience

We need the global experience because radiation therapy is very safe and accidents are infrequent.

Presentation Objectives

1. To analyze a real incident using a formalized Incident Learning System.
2. To summarize Basic Causes based on local, institutional experience.
3. To discuss a potentially global approach to incident learning

Presentation Outline

1. An Application of an Incident Learning System
2. Local Learning – An Analysis of Basic Causes
3. Global Learning – the AAPM Working Group on the Prevention of Errors and ROSIS
4. Local and Global Learning – are the lessons different?
5. Conclusions

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A Reference Guide for Learning from Incidents in Radiation Treatment

David L. Cooke, Meina Dubetz, Rahim Heshmati, Sandra Iftody, Erin McKimmon, Jodi Powers, Robert C. Lee, Peter Dunscombe

The Alberta Heritage Foundation for Medical Research

HTA Initiative #22

www.ihe.ca/hta/publications.html

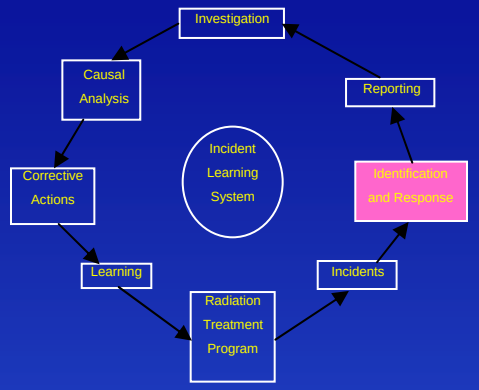
What is an Incident?

An incident is an unwanted or unexpected change from a normal system behavior, which causes, or has a potential to cause, an adverse effect to persons or equipment

The Incident Learning System

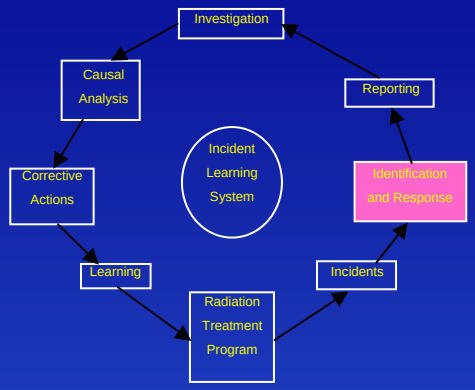
www.ihe.ca/hta/publications.html

Identification



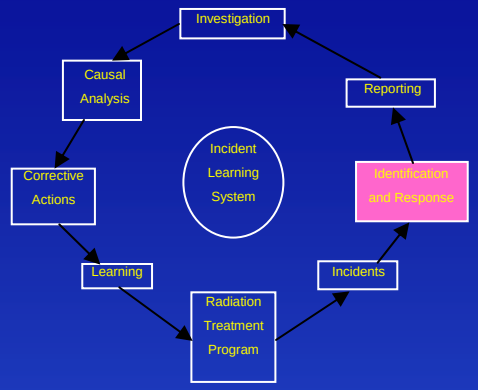
- An incident was first noted during a dynamic arc treatment (Day -3).
- An MLC collision interlock occurred during the first treatment of a patient
- Three days later a therapist on the unit reported to a physicist that he thought the leaves were not moving as they should during one of the dynamic arcs (Day 0).
- This observation was checked by a physicist and confirmed

Identification



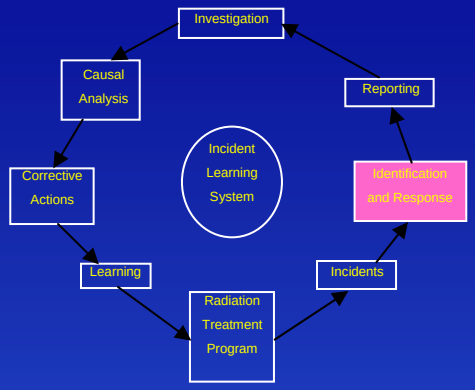
- The MLC leaves moved as planned in one quadrant of the gantry motion
- In the other quadrant the leaves were stationary until the end of the arc at which time they assumed the correct positions.
- This behaviour was reproducible.

Response



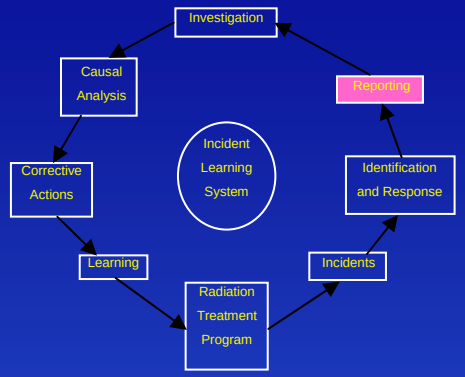
- Clinical Team notified on Day 0
- Over a weekend the 13 patients possibly affected were replanned (Day 2)
- Service engineers arrive on site (Days 2 and 3)
- Senior Management notified on Days 3 and 4

Response



- Unit returned to limited service (Day 4)
- Involved patients notified between Days 6 and 14.
- Independent Review Committee established on Day 14

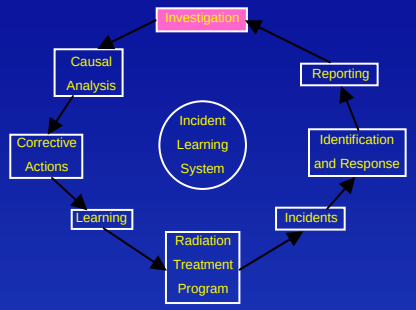
Reporting



The Incident was reported as

- Affecting patients
- Clinical
- Occurring during treatment
- Actual minor severity: potentially major severity

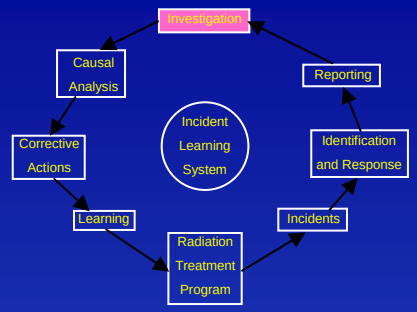
Investigation



- Review Committee comprised one Radiation Oncologist, three Patient Safety Experts and one Medical Physicist.
- Several patients were affected.
- The initial Incident classification was confirmed as occurring at Delivery, affecting the Volume prescription element, caused by an Infrastructure problem and was Systematic.

1. An Application of an Incident Learning System

Investigation



Assessment | Prescription | Preparation | Delivery | Follow up

- Delivery
  - Dose
    - Process
    - Infrastructure
  - Volume
    - Process
    - Infrastructure
      - Sporadic
      - Systematic

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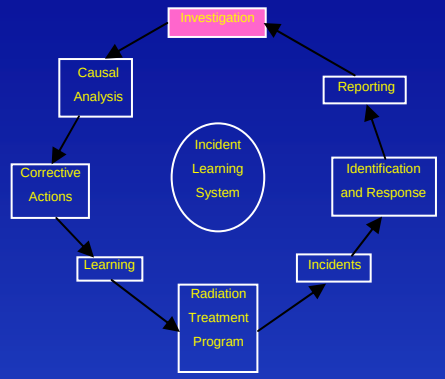
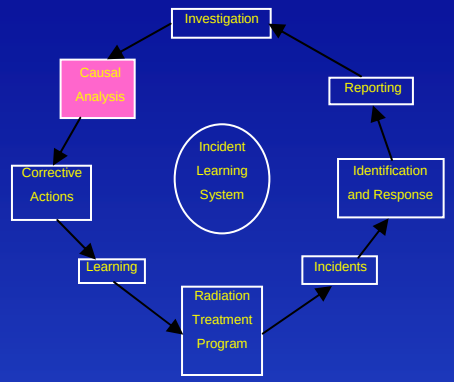
Investigation



- Replanning all patients indicated only minimal changes to doses to the target volumes and critical structures.
- Medical assessment concluded that no change in clinical outcome for any patient could be expected.

Basic Causes Table



Job Factors

1. Standards/Procedures/Practices
   - 1.1 Not developed
   - 1.2 Inadequate standard/ procedure/practice
   - 1.3 Standard/procedure/ practice not followed
   - 1.4 Inadequate communication of procedure
   - 1.5 Inadequate assessment of risk
   - 1.6 Not implemented
2. Materials/Tools/Equipment
   - 2.1 Availability
   - 2.2 Defective
   - 2.3 Inadequate maintenance
   - 2.4 Inspection
   - 2.5 Used incorrectly
   - 2.6 Inadequate assessment of material/tools/ equipment for task
3. Design
   - 3.1 Inadequate hazard assessment
   - 3.2 Inadequate design specification
   - 3.3 Design process not followed
   - 3.4 Inadequate assessment of ergonomic impact
   - 3.5 Inadequate assessment of operational capabilities
   - 3.6 Inadequate programming

Systemic/Management Factors

4. Planning
   - 4.1 Inadequate work planning
   - 4.2 Inadequate management of change
   - 4.3 Conflicting priorities/ planning/ programming
   - 4.4 Inadequate assessment of needs & risks
   - 4.5 Inadequate documentation
   - 4.6 Personnel availability
5. Communication
   - 5.1 Unclear roles, responsibilities, and accountabilities
   - 5.2 Lack of communications
   - 5.3 Inadequate direction/ information
   - 5.4 Misunderstood communications
6. Knowledge/Skill
   - 6.1 Inadequate training/orientation
   - 6.2 Training needs not identified
   - 6.3 Lack of coaching
   - 6.4 Failure to recognize hazard
   - 6.5 Inadequate assessment of needs and risks

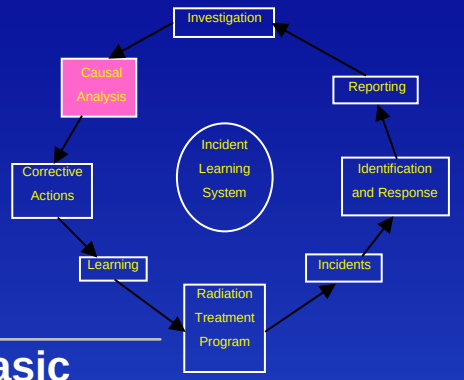
Personal Factors

7. Capabilities
   - 7.1 Physical capabilities (height, strength, weight, etc.)
   - 7.2 Sensory deficiencies (sight, sound, sense of smell, balance, etc.)
   - 7.3 Substance sensitivities/ allergies
8. Judgment
   - 8.1 Failure to address recognized hazard
   - 8.2 Conflicting demands/ priorities
   - 8.3 Emotional stress
   - 8.4 Fatigue
   - 8.5 Criminal intent
   - 8.6 Extreme judgment demands
   - 8.7 Substance abuse

Natural Factors

9. Natural Factors
   - 9.1 Fires
   - 9.2 Flood
   - 9.3 Earthquake
   - 9.4 Extreme weather
   - 9.5 Other

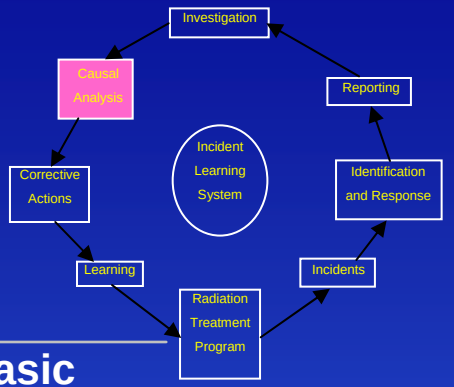
Causal Analysis



	Primary Level	Secondary Level	Tertiary Level	Basic Cause
Cause 1	Mismatched software	Installation procedures not followed		1.3 - Standard Procedure not followed by vendor
		Acceptance procedures did not check for software compatibility		1.2 - Inadequate Procedure supplied by vendor
		No knowledge of bulletin/alert	No management of bulletin/alert receipt or update of historical documents.	Unknown for vendors
			No ownership of bulletin/ alert dissemination/archive/ interpretation.	1.1 - Not developed by facility

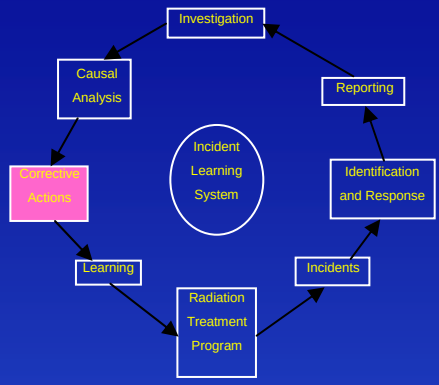
1. An Application of an Incident Learning System

Causal Analysis



	Primary Level	Secondary Level	Tertiary Level	Basic Cause
Cause 2	Lack of leaf motion not detected	Leaf positions only visually checked in start and final positions	We thought it was sufficient.	1.5 - Inadequate assessment of risk by facility
		Leaf motion not visible (scale problem)		3.1 - Inadequate hazard assessment by vendor
		No log analysis capability	Not available for this unit.	1.1 - Not developed by vendor

Corrective Actions



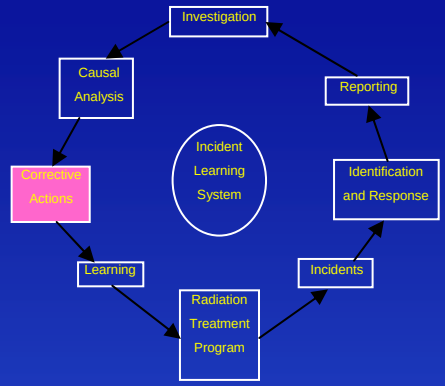
Basic Cause:

No ownership developed for dissemination/archiving/interpretation of bulletins and alerts – standards and procedures not developed by user

Corrective Action:

Develop procedures for managing and distributing vendor and regulatory alerts and bulletins.

Corrective Actions



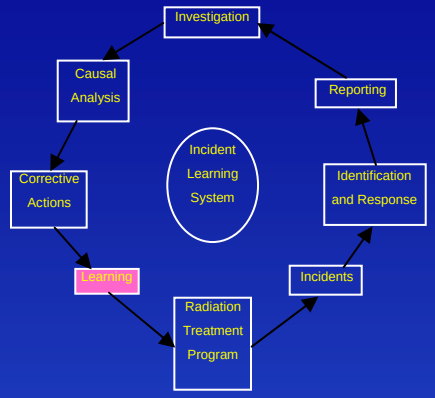
Basic Cause:

Leaf motion not visible – inadequate hazard assessment

Corrective Action:

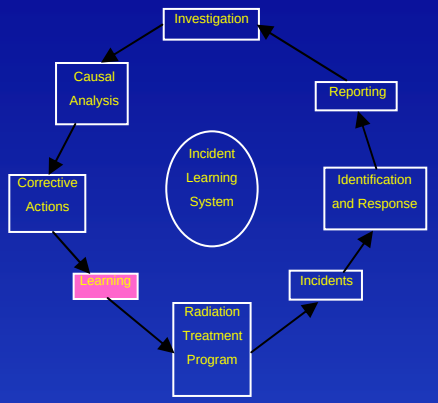
Recommend to a vendor that a certain functionality be improved.

Learning



- A brief description of the incident and the recommended corrective actions were available locally.
- Most of the learning took place within the specialist groups of physicists, electronics technologists and computer specialists responsible for radiation therapy infrastructure.

Learning



- Sharing detailed information even within the organization was not possible for legal reasons.
- Legal barriers to organizational learning may be compromising patient safety.

Closure

Ten Corrective Actions were recommended to address all the issues raised through the Basic Cause analysis.

Six Corrective Actions were the development of new Policies and Procedures.

PROBLEM SOLVED!

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Local Learning – An Analysis of Basic Causes

Data Source:

- Facility delivers 3,000 courses of radiation therapy per year on 10 machines
- The Radiation Treatment Program has a staff of 200
- 263 Incidents were reported over an 18 month period

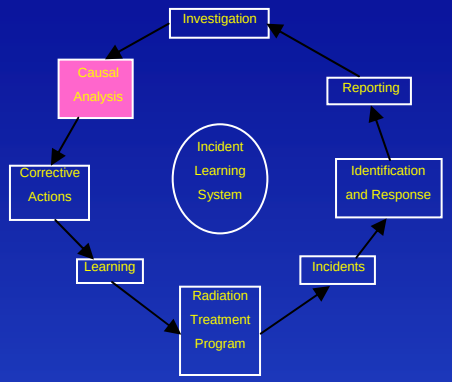
Local Learning – An Analysis of Basic Causes

Objective of this study:

To see if there are lessons for the institution from an analysis of the Basic Causes of these 263 Incidents.

The Incident Learning System

Analysis



All 263 Incidents were entered into an Access® database for analysis

What Were The Basic Causes? (ILS)

Job Factors

1. Standards/Procedures/Practices
   - 1.1 Not developed
   - 1.2 Inadequate standard/ procedure/practice
   - 1.3 Standard/procedure/ practice not followed
   - 1.4 Inadequate communication of procedure
   - 1.5 Inadequate assessment of risk
   - 1.6 Not implemented

2. Materials/Tools/Equipment
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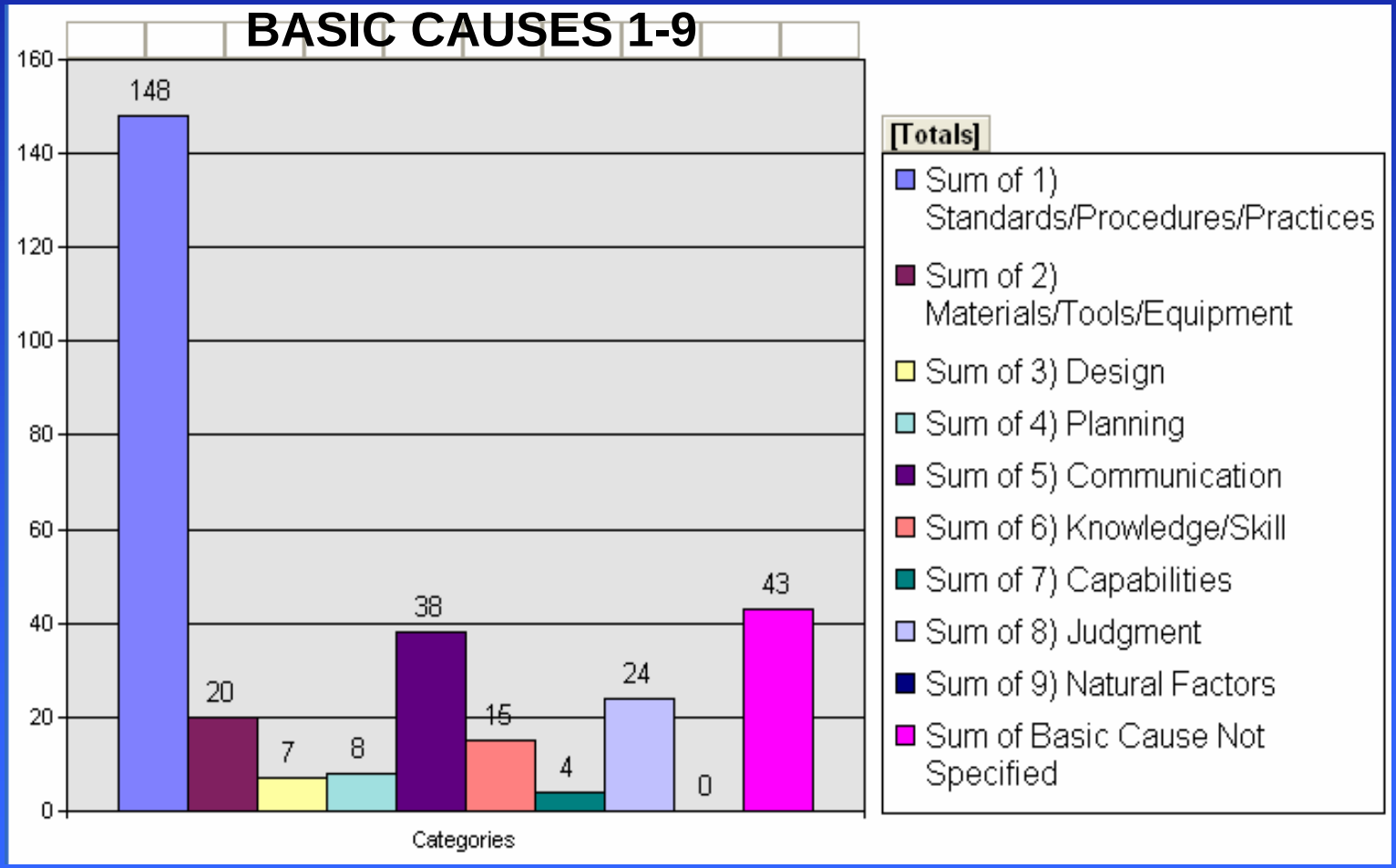
What Were The Basic Causes? (ILS)



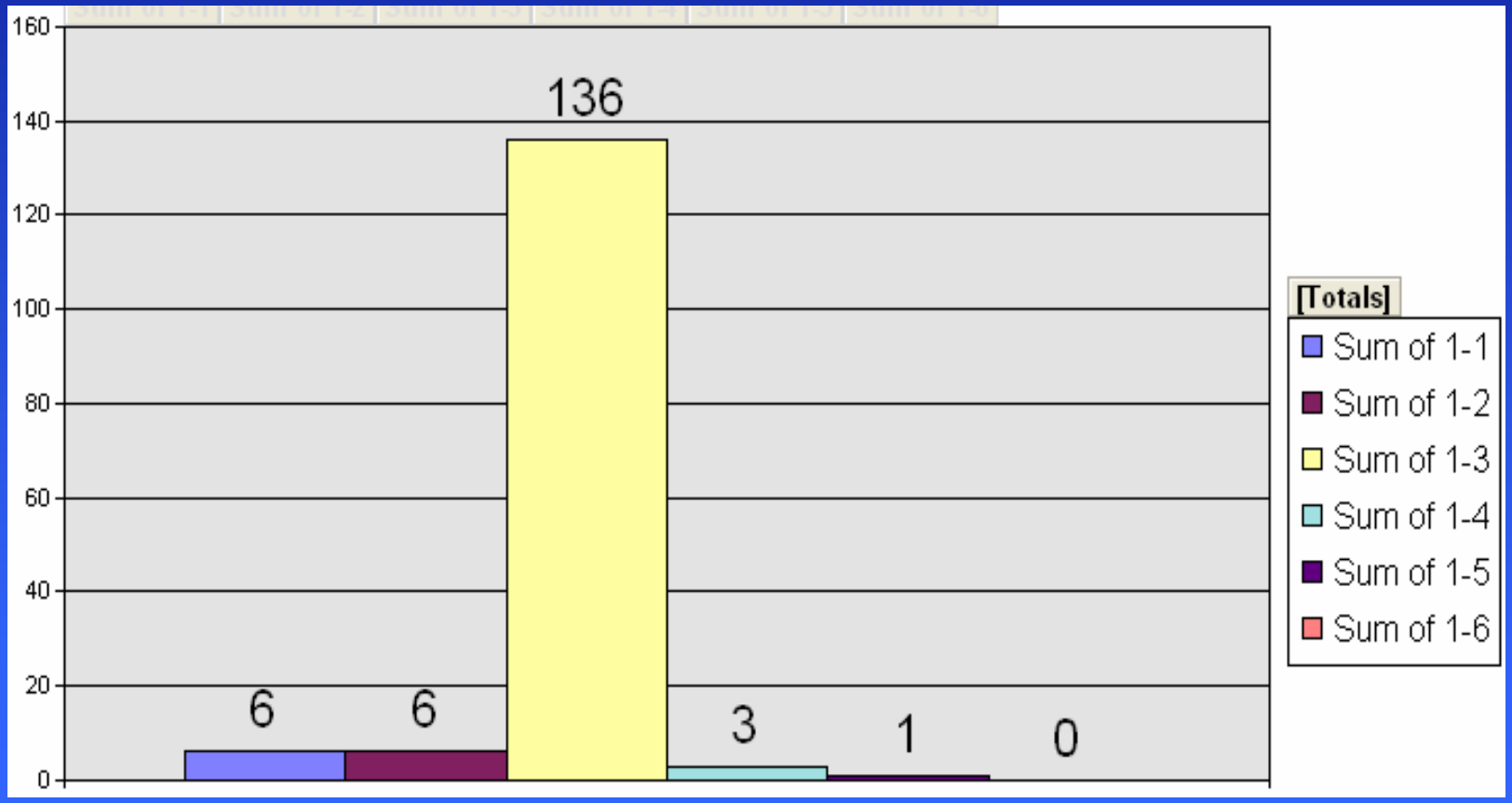
**TOTAL Incident Reports in this study = 263

What Were The Basic Causes? (ILS)

Standards/Procedures/Practices (~67%)
Communication (~17%)
Judgment (~11%)
Materials/Tools/Equipment (~9%)
Knowledge/Skill (~7%)
Planning (~4%)
Design (~3%)
Capabilities (~2%)
Natural Factors (0)
DID NOT SPECIFY: 43 / 263 = ~16%

**Percentages based on the reports that DID specify a basic cause (Total 220).

Why Was Basic Cause 1 So High?



**TOTAL Incident Reports in this study = 263

Why Was Basic Cause 1 So High?

1. Standards/Procedures/Practices
   - 1.1 Not developed (<3%)
   - 1.2 Inadequate standard/ procedure/practice (<3%)
   - 1.3 Standard/procedure/ practice not followed (~62%)
   - 1.4 Inadequate communication of procedure (~1%)
   - 1.5 Inadequate assessment of risk (<1%)
   - 1.6 Not implemented (0)

**Percentages based on the reports that DID specify a basic cause (Total 220).

An Observation

Writing Policies and Procedures in response to an Incident may not solve the problem at all.

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Global Learning –the AAPM Working Group on the Prevention of Errors and ROSIS

- The AAPM established a Working Group on the Prevention of Errors in Radiotherapy in 2005
- In recognition of the importance of learning from the experience of others, a recurring theme of discussions has been the establishment of a shared database of Incidents.
- As such a database (ROSIS) already exists, it makes sense to explore possible collaboration.

Introduction to ROSIS

- Radiation Oncology Safety Information System
- http://www.rosis.info
- ROSIS began in 2001, funded by ESTRO – European Society for Therapeutic Radiology and Oncology

Introduction to ROSIS

The architects of ROSIS are:

Dr Ola Holmberg, Copenhagen, Denmark,

Dr Tommy Knöös, Lund, Sweden,

Mrs Mary Coffey, Dublin, Ireland

Ms Joanne Cunningham, Dublin, Ireland

Introduction to ROSIS

- Voluntary, anonymous, web-based reporting system
- ~75 participating centres, over 1000 incidents reported
- Newsletters sent out with “spotlight cases”. Anyone can search the database by keyword or view all reports

ROSIS
Radiation Oncology Safety Information System

Global Learning –the AAPM Working Group on the Prevention of Errors and ROSIS

- The WGPE and ROSIS are currently exploring the possibility of collaborating on an Incident Database which would meet both European and North American needs.

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Local and Global Learning – are the lessons different?

Data Sources:

- The Incident Learning System
- The ROSIS database
- Over 250 reported Incidents to each data base were analyzed

Local and Global Learning – are the lessons different?

Objective of this study:

To compare the Basic Causes of Incidents reported to the Incident Learning System and the ROSIS database.

ROSIS Data Analysis

- Randomly started at ROSIS IncidentID number 600, until there were no more reports (IncidentID number 884)
- TOTAL = 276
- Incident reports were only grouped into a Basic Cause category if details on the ROSIS form could clearly support the choice

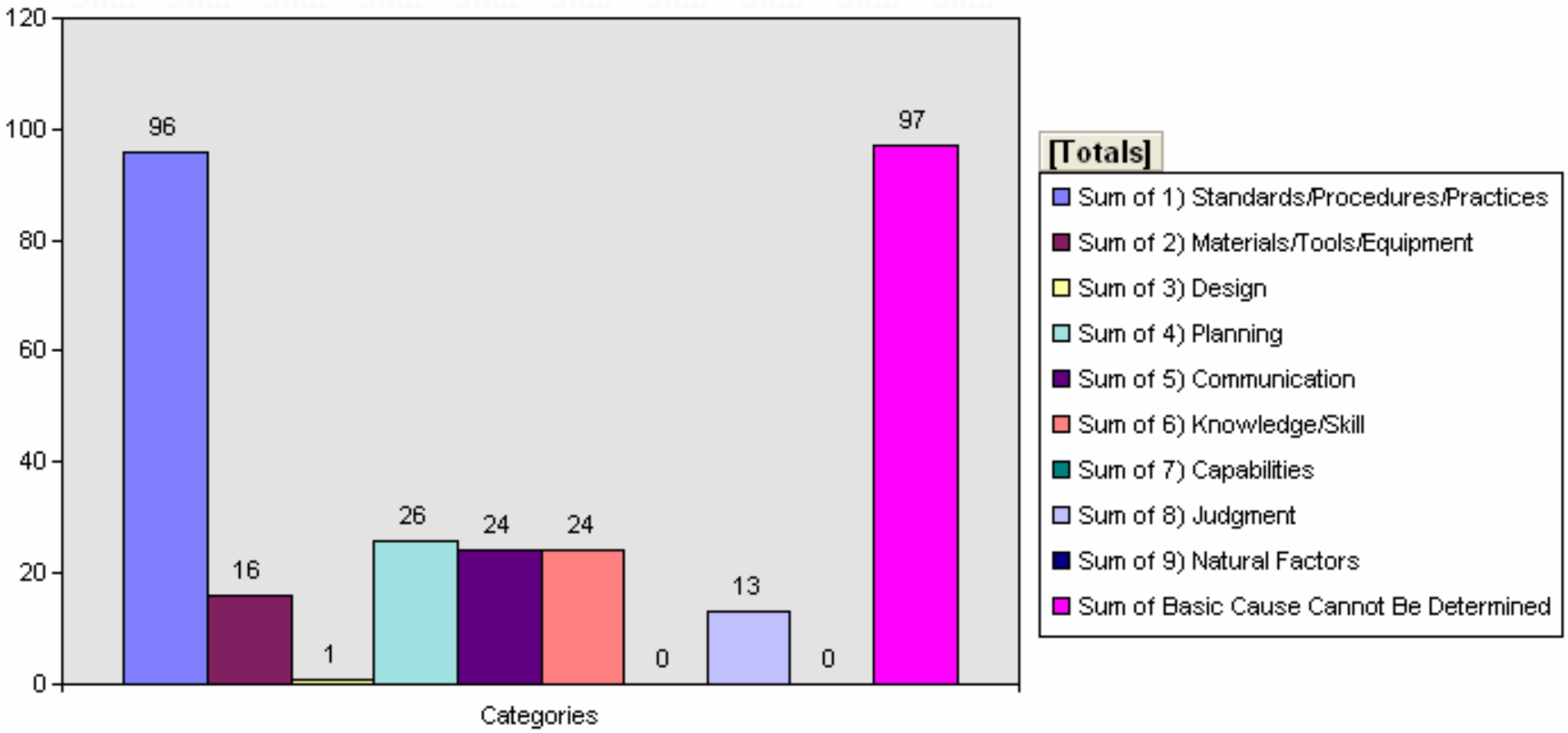
ROSIS Data Analysis

- Incidents were only grouped into the general Basic Cause categories, 1 – 9

1. Standards/Procedures/Practices
2. Materials/Tools/Equipment
3. Design
4. Planning
5. Communication
6. Knowledge/Skill
7. Capabilities
8. Judgment
9. Natural Factors

4. Local and Global Learning – are the lessons different?

What Were The Basic Causes? (ROSIS)



TOTAL Incident Reports in this study = 276

What Were The Basic Causes? (ROSIS)

Standards/Procedures/Practices (~54%)
Planning (~16%)
Communication (~13%)
Knowledge/Skill (~13%)
Materials/Tools/Equipment (~9%)
Judgment (~7%)
Design (<1%)
Capabilities (0)
Natural Factors (0)
Basic Cause not determined, 97 / 276 = ~35%

**Percentages based on the reports where a Basic Cause was evident (Total 179)

4. Local and Global Learning – are the lessons different?

Basic Cause Comparison

Incident Learning System	ROSIS
Standards/Procedures/ Practices (~67%)	Standards/Procedures/ Practices (~54%)
Communication (~17%)	Planning (~16%)
Judgment (~11%)	Communication (~13%)
Materials/Tools/Equipment (~9%)	Knowledge/Skill (~13%)
Knowledge/Skill (~7%)	Materials/Tools/Equipment (~9%)
Planning (~4%)	Judgment (~7%)
Design (~3%)	Design (<1%)
Capabilities (~2%)	Capabilities (0)

Local and Global Learning – are the lessons different?

An Observation

Both local experience and global experience suggest that more than half of all incidents are related to Standards/Practices and Procedures

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Conclusions

- A formal structured Incident Learning System can make radiation therapy safer
- Local experience suggests that most incidents result from procedures not being followed
- ROSIS data also suggest procedure related issues result in the greatest number of incidents
- Full effective implementation of an Incident Learning System requires significant resources