Defining Event-reporting in the Cell Processing Facility

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Background

• Laboratory “Events” go by different names in different laboratories
  - Accident
  - Complaint
  - Deviation
  - Occurrence
  - Reaction
  - Variance

• Reporting of Events, in the hospital setting are generally well defined
• Events occurring in the Cell Processing Facility are as yet not classified
• Some events are mandatory FDA-reportable
• Cell Processing Facilities are highly regulated.
  - FDA, FACT, AABB, CAP, CLIA, Joint Commission.

FACT-JACIE International Standards defines only four events.

1. Biological Product Deviation: Refers to Product Contamination
2. Errors and Accidents: Refer to Product Safety, Purity & Potency
3. Variance: Refers to Planned Deviation from Operating Procedure
4. Adverse Event: Refers to any Event related to an Intervention.

FDA’s Core Good Tissue Practice has only one broad concern: Complaint.

1. Complaint. HCT/P Deviation: Prevention of introduction, transmission, and spread of communicable disease through a Distributed HCT/P
2. Complaint. Adverse Reaction: Involving a Communicable disease, that is
   - Fatal
   - Life Threatening
   - Results in Permanent damage, or
   - Requires Intervention

Objectives

• To establish a system where the events are classified into different categories
• By categorizing the events we may be able to offer systematic solutions
• To eliminate the sense of guilt and discomfort in reporting the events without finger pointing
• To have a better understanding on the cause behind the problem

Materials and Methods

• A comparison was made of events reported in 2008 without the system being in place to events reported in 2009 under the new definitions
• The events of 2008 were reclassified using the new system
• In 2009, 663 HCT/P (458 Auto, 123 Allogeneic) were processed in the CTPF and 401 products infused (In House 280, CMH 49, MSC 27 and DCI 45)
CTPF Event Classification

1. HCT/P Deviation (Distributed Product Only)
   1.1 BPD: Contamination; Adverse Reaction; or Recall
   1.2 Improper Release: Without signature; w/o review; w/o UMN documentation
   1.3 Label related: Without adequate Label, Legend, Notice or Statement
   1.4 Bag related: Leaking, etc
   1.5 Patient/Donor Information related: Incomplete, inaccurate, etc

2. SOP Deviation
   2.1 Not per procedure: Outside of SOP; or No documented SOP
   2.2 Wrong SOP or Document: Followed archived or wrong version
   2.3 Label related: Non-distributed Product
   2.4 Data related: Wrong or inaccurate data or calculation; Lack of review or correction
   2.5 Lack of Notification: Physician, tech, participating program etc, not notified

3. Planned Deviation
   3.1 HCT/P related: Urgent Medical Need: Use of a Non-Conforming Product
   3.2 SOP related: Exceptional use of procedure, expired reagent lot, etc

4. Equipment or Supply related Event
   4.1 Recall or Notice
   4.2 Qualification, Calibration or Preventive Maintenance related
   4.3 Alarm or Monitor System related

5. Complaint
   5.1 Internal
   5.2 External

6. Other

CTPF Event Reporting System

1. Safe: Non-Punitive. Open to all.
3. Effective: Prompt investigation. Event Classification done by one person.

Comparison of Event Reporting

<table>
<thead>
<tr>
<th>Event Type</th>
<th>2008 (n=69)</th>
<th>2009 (n=188)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. HCTP deviation</td>
<td>2 (2.8%)</td>
<td>7 (3.7%)</td>
</tr>
<tr>
<td>2. SOP deviation</td>
<td>11 (15.9%)</td>
<td>50 (26.5%)</td>
</tr>
<tr>
<td>3. Planned deviation</td>
<td>40 (39.3%)</td>
<td>91 (48.4%)</td>
</tr>
<tr>
<td>4. Equipment</td>
<td>14 (20.2%)</td>
<td>30 (16.9%)</td>
</tr>
<tr>
<td>5. Complaint</td>
<td>0 (0%)</td>
<td>3 (2.5%)</td>
</tr>
<tr>
<td>6. Other (billing)</td>
<td>2 (2.8%)</td>
<td>7 (3.7%)</td>
</tr>
</tbody>
</table>

Discussion

Published Data on Hospital-wide Events concur that:

- Errors are much more frequent than reported Adverse Reactions; And result in substantial harm
- Humans are fallible and errors are to be expected
- Errors are consequences rather than cause
- Management at most times is unaware of the magnitude of the problem
- Event Reporting System may be able to produce valuable information to correct systems that could prevent errors

David W. Bates, et al.
Kohn LT, et al.
Bender NL.
Stanhope N, et al.
Discussion

• In all likelihood Cell Processing Facilities have many events which go unidentified and unreported in the absence of a standardized reporting system
• The number of events maybe over reported with a standardized reporting system
• We must create a culture that is willing to identify and accept errors
• The more events we report, we shall be better prepared to deal with them

An accurate Diagnosis is the key to effective therapy.

Barach Paul & Small Stephen.

Conclusion

• In a high volume and complex setting, events should be expected
• Reporting of events allow to establish corrective actions
• A system of reporting that categorizes events by type will be able focus on tracking and trending
• CTPF has developed a simplified and specific reporting system for cell processing labs and blood banks
• With the establishment of this system there has been an increase in the reporting of events in the CTPF, but the distribution is no different than that reported in 2008 when the system was not in place.

Future Directions

• To implement corrective and preventive actions for each reported event
• To validate the system
• To refine and fine-tune the CTPF Event Reporting system.

Acknowledgement

Thanks to Cell Therapy Processing Facility, Northwestern Memorial Hospital for sowing the seed which generated this abstract.

Thank you