ERROR POLICIES AND AUDIT SYSTEMS IN TRANSFUSION MEDICINE

K. Sazama

Introduction

About twenty years ago, the United States (US) government (through the efforts of the Food and Drug Administration (FDA)) published its regulations (Good Manufacturing Practices, or GMPs) for establishments providing blood components, among which are instructions for handling “errors and accidents” [1]. A curious omission from these regulations is the lack of definition of either “error” or “accident”. No further clarification of the intended meaning of these two terms has been made by the US government in any subsequently published guidance.

Using Merriam-Webster’s 1993 Collegiate Dictionary, 10th edition [2], several definitions for both “error” and “accident” can be found (Tables 1 and 2). With no single definition provided from the FDA to provide clarification, any or all may be assumed to be applicable. Also, something important can be appreciated from these definitions. Both terms encompass the ideas of no intent and of insufficient knowledge or ignorance leading to harm or injury. If accidents and

Table 1. An error is any of the following acts or conditions.
- Ignorant or imprudent deviation from a code of behavior.
- An unintentional deviation from truth or accuracy.
- Through ignorance, deficiency, or accident, departing from or failing to achieve what should be done.
- A mistake in the proceedings of a court of record in matters of law or of fact.

Table 2. An accident is
- An unforeseen and unplanned event or circumstance occurring with lack of intention or necessity.
- An unfortunate event resulting especially from carelessness or ignorance.
- An unexpected and medically important bodily event, especially when injurious.
- An unexpected happening causing loss or injury which is not due to any fault or misconduct on the part of the person injured but for which legal relief may be sought.

Accidents are “not amenable to planning or prediction”, and are chance events.
Table 3. An audit is
- A formal examination of an organization’s or individual’s accounts or financial situation.
- A methodical examination and review.

Table 4. Error rates for transfusion.

<table>
<thead>
<tr>
<th>Date</th>
<th>Author</th>
<th>Number of transfusions</th>
<th>Error rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1959</td>
<td>Binder [8]</td>
<td>81,392</td>
<td>1 in 2700</td>
</tr>
<tr>
<td>1963</td>
<td>Schmidt [10]</td>
<td>5,806</td>
<td>1 in 100</td>
</tr>
<tr>
<td>1972</td>
<td>Lacerte [12]</td>
<td></td>
<td>1 in 3</td>
</tr>
<tr>
<td>1984</td>
<td>Taswell [14]</td>
<td></td>
<td>1 in 100 to 1 in 1000</td>
</tr>
<tr>
<td>1992</td>
<td>Linden [15]</td>
<td>1,784,600</td>
<td>1/19,000</td>
</tr>
</tbody>
</table>

errors are unintended and unforeseen, then responses to them should emphasize changing human behaviour [3] but should focus instead on identifying and correcting system flaws [4] (only in some instances when either error or accident occurs through carelessness or dereliction would efforts to change human behaviour be appropriate). However, because even now the words “error”, “accident” and “audit” (Table 3) lack standard definition, published error reports lack comparability from institution to institution (Table 4). Perhaps the most consistent application of a single definition has been that of Taswell who has uniformly defined an error as “an inadvertent or unauthorized deviation from standard procedure” [5].

Focus on human error

The ultimate error in blood transfusion is fatality directly caused by the transfused component, virtually always attributable to human error. As late as 1956, ABO incompatible transfusions occurred with an incidence of 0.7% and mortality rates as high as 25% [6]. However, although overall risks of transfusion-associated fatality as high as 1/13,000 in Great Britain [7], and 1/11,000 in the US [8] have been reported in recent years, in the 1990s this risk in the US is probably closer to 1/250,000 [9].

To address this problem in 1953, a “... simple yet rigid system of check, check, and counter-check ...” was recommended in which only physicians were permitted to remove blood from the cold storage area and actually administer it to patients, with a second person (often a nurse) witnessing the event [7]. As recently as 1989, Australian transfusionists were advised “... to shift emphasis ... to the strict following of standard established protocols for transfusion ... to minimize the possibility of (ABO) accidents due to human error” [16].