Sample Rejection

How you reject unsuitable specimens is an important part of your laboratory quality system.

By Scott Warner, MLT(ASCP)

Your laboratory is a busy place, with specimens arriving from outpatient draw stations, inpatient wards, and drop offs from patients and doctor offices. Inevitably, specimens unsuitable for testing are received. How you reject these is an important part of your laboratory quality system. This article considers the elements of a workable specimen rejection policy.

Garbage In, Garbage Out

GIGO, a computer acronym for "garbage in, garbage out," coined by a programming instructor at IBM nearly 50 years ago, reminds us that output quality equals input quality. If incorrect data is fed into a program, the computer correctly spews out nonsense. The term is now widely used in many settings, but a core concept remains: a correctly functioning system will automatically process bad as easily as good data, and we may not know the difference.

Similarly, your techs may be trained, instruments calibrated, and kits validated. Your testing system functions correctly. But if the specimen is damaged, mislabeled, or no longer usable (garbage in), your system will always produce erroneous results (garbage out). Your system may not detect these kinds of errors, which although rare, may create a tendency to add disclaimers or an interpretation of the results.

Subpart K of the Clinical Laboratory Improvement Amendments (CLIA) requires that laboratories "must establish and follow written policies and procedures" for specimen acceptance and rejection. The GIGO concept should drive your rejection policy, just as computer scientist concerns about dirty data govern database stewardship, in eliminating unusable specimens before they are analyzed.

How Much Rejection?

Your current policy may or may not be effective. How do you know? While patients are identified prior to collection and specimens are inspected before testing, these preanalytical processes may not be documented. A literature search can provide a sense of how much rejection your laboratory should expect.

A 2008 study at a 600-bed tertiary care hospital in India’s Delhi territory identified an overall rejection rate of 1.52 percent, with 53.2 percent of samples collected from outpatients. Rejection causes included hemolysis (0.74 percent), improper requisitions (0.47 percent), and quantity not sufficient (QNS) (0.23 percent). For this hospital chemistry laboratory, the average was a little over four rejections per day.

A broader College of American Pathologists Q-Probes study of 453 laboratories collected information on chemistry specimens with an overall rejection rate of 0.35 percent. The 10th percentile of the study was 1.35 percent. The most common cause of rejection was hemolysis, which was five times greater than QNS, the second most common. Laboratory personnel submitted fewer rejected specimens than other groups.

Another Q-Probes study of 703 laboratories considered hematology specimens, finding that 0.45 percent were rejected. The most frequent reason for rejection was a clotted specimen, which was six times more common than QNS. Again, laboratory personnel performed better than other personnel.
Also, smaller hospitals had lower rejection rates. Both Q-Probe studies recommend monitoring rejection rates regularly and setting active thresholds for quality improvement. Based on the above, for example, your laboratory might conservatively choose 0.4 percent as an expected average, or about one a day for a volume of 100,000 tests per year; if you tally significantly fewer rejections, it's possible your techs are not reporting or rejecting aggressively enough.

**Policy Elements**

A rejection policy defines the following elements:

- **Retrievable vs. Irretrievable**--specimens divided by which can easily be recollected from the patient (e.g., a lavender top tube) or not (e.g., cerebrospinal fluid). Irretrievable specimens may also be rare enough to be identified by other means. Examples are in Table 1.

- **Categories of Error**--errors and responses can fall into categories (labeling, storage, volume, etc.) as summarized in Table 2. For example, transposed letters in a name should not be treated the same as the wrong name altogether.

- **Laboratory Responsibility**--your policy should clearly spell out what happens when a specimen is rejected, including who is called, an expected time period, who recollects if indicated, and how the event is documented.

- **Mitigating Errors**-- laboratory rules are ineffective if no one knows about them. Including how data is fed back to collectors with education (e.g., annual competency for collectors) is good quality improvement.

**TABLE 1: RETRIEVABLE VS. IRRETRIEVABLE SPECIMENS**

<table>
<thead>
<tr>
<th>Retrievable</th>
<th>Irretrievable</th>
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<tbody>
<tr>
<td>A recollected specimen does not harm the patient and is diagnostically equivalent to the original. Examples:</td>
<td>A recollected specimen has a potential to negatively impact care or will not represent the original (e.g., unique collections). Examples:</td>
</tr>
<tr>
<td>- throat swab</td>
<td>- cerebrospinal fluid</td>
</tr>
<tr>
<td>- urine</td>
<td>- cord blood</td>
</tr>
<tr>
<td>- stool</td>
<td>- bone marrow</td>
</tr>
<tr>
<td>- sputum</td>
<td>- pathology specimens</td>
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</tbody>
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**TABLE 2: CATEGORIES OF ERROR**

<table>
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<tr>
<th>Priority</th>
<th>Error</th>
<th>Example</th>
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| Level 1--minimally process and hold until problem is resolved | Minor labeling error | • incorrect date  
• incorrect initials |
| Level 2--reject specimen(s) and hold requisition until recollected | Specimen integrity | • hemolysis  
• contaminated or diluted  
• improper storage or handling  
• QNS |
| Label integrity | | • no label  
• wrong label  
• only one identifier on the label |
| Level 3--do not process and hold until provider or pathologist makes decision | Level 2 errors with irretrievable specimen | • unlabeled CSF  
• placenta with wrong patient |
Manufacturer package inserts are a primary source for specimen requirements. But it's also a good idea to develop rules of thumb for non-technical staff, including phlebotomists and nursing staff. Adding a prominent "Specimen Rejection Criteria" section to each procedure can provide more specific information, especially if these are available online.

Quality Improvement

A rejection policy that includes an expectation of results, education and implementation, data gathering, and periodic review is a model of quality improvement that you can take advantage of. Deming's PDSA cycle describes this process:

- **Plan** -- Plan ahead for change; analyze and predict the outcome.
- **Do** -- Implement your plan using small steps in controlled circumstances.
- **Study (or check)** -- Gather data on the process and study the results.
- **Act** -- Take steps to standardize or improve the process.

Laboratory staff can help review package inserts, make a list of retrievable and irretrievable specimens, and update procedures (Plan). Implementation can include a "roll out" to your collectors by presenting your plan and the reasons why specimens are rejected; doing this in person, such as at a nursing staff meeting, gives collectors a chance to ask questions (Do). Gathering data can help you measure your process against a threshold as suggested above (Study). This data can be used to improve your process (Act).

If, for example, your statistics show an increase in hemolyzed specimens collected by your ED staff, this is a "win-win" opportunity for a joint departmental team to work together to examine the process, including needle choice, order of tube draw, staff competency, etc.

Ultimately, the goal of a specimen rejection policy is to not just avoid GIGO-type errors but to reduce the number of rejected specimens. Roll-out and education to collecting staff will help avoid rejection being seen as arbitrary, leading to better patient care.

Scott Warner is lab manager at Penobscot Valley Hospital, Lincoln, ME.

References