LEPS interviewed Dr. Roger Resar regarding quality improvement concepts in medicine and laboratory medicine. Dr. Resar is a national leader in the patient safety movement and has written and lectured extensively on realistic approaches to quality improvement. Dr. Resar’s work is informed by his 25 years of practice in internal medicine and pulmonology with a focus on critical care. In this interview, he focuses on understanding low reliability processes in healthcare, and realistic approaches to gradually improving them. Many thanks to Dr. James Hernandez, Assistant Professor, Laboratory Medicine, Mayo Clinic College of Medicine who helped conduct the interview.

LEPS: Why is healthcare less reliable than other industries?

Dr. Resar: The main reasons are:

- We rely too much on vigilance and hard work.
- Care providers are allowed too much autonomy, which leads to excessive variation.
- Benchmarking healthcare processes to mediocre patient outcomes gives a false sense of reliability.
- We fail to create systems specifically designed to reach realistic, well-defined goals for reliability.

continued on page 2
LEPS: Can you give an example in the laboratory domain of relying too much on vigilance and hard work?

Dr. Resar: We rely on a doctor’s vigilance regarding choosing the right test. For example, we expect a diabetic patient to be monitored twice annually with a hemoglobin A1C, and in many healthcare systems we rely on the doctor to be vigilant regarding accomplishing this. A better approach than vigilance would be to build multiple physician and patient reminders into the healthcare delivery system so that the diabetic is properly monitored.

LEPS: Shouldn’t a doctor be expected to know how frequently a diabetic should be monitored?

Dr. Resar: They generally do know. The problem comes when the diabetic patient comes in a context that is different than diabetes, for example for a vaccination or emergency room visit for a sprained ankle. Every doctor cannot be expected to remember every monitoring requirement at every visit for every disease. Reminders need to be designed into the system for delivering care.

LEPS: Why do we design systems that rely so much on a doctor’s vigilance?

Dr. Resar: This mystifies me. Vigilance and hard work are very admirable characteristics. Unfortunately, we emphasize them too much in physician training, and this has contributed to the attitude among health care leaders that vigilance and hard work is the answer to all our problems.

LEPS: Can you give an example of benchmarking healthcare processes to mediocre patient outcomes?

Dr. Resar: The processes underlying infection control include hand hy-
giene, waste disposal, facility and equipment disinfection, and patient isolation. Many hospitals benchmark these infection control processes to a patient outcome, which is the average nosocomial infection rate published by the Centers for Disease Control (CDC). Even if these processes fail, the patient’s resilience usually prevents infection. Thus, even though the handwashing rate may be an abysmal 50-60%, hospital leadership including front line managers are complacent about quality improvement because the overall nosocomial infection rate is not alarming relative to the mediocre CDC benchmark.

**LEPS:** In healthcare, process failures and patient outcomes are often not clearly connected. How does this hinder quality improvement?

**Dr. Resar:** Lack of clear connection between a particular process failure and a patient outcome prevents us from accepting the lack of reliability in our processes, and makes us complacent about improving quality. We falsely conclude that our processes are not that bad since we are unaware of specific cases where process failures caused harm. Using the example above, it is difficult to know if a patient’s infection was specifically due to inadequate hand washing. There are many other reasons a patient could become infected including their underlying medical condition.

**LEPS:** In a recent article, you emphasize choosing the correct reliability levels for a healthcare process. Isn’t six sigma (less than 3.4 defects per million opportunities) the correct reliability level for every process?

**Dr. Resar:** There are not sufficient resources to get every healthcare process to six-sigma reliability. Resource limitations dictate that you prioritize your battles. This means aiming for higher reliability for processes that are more likely to have catastrophic consequences if they are defective.

**LEPS:** What are the factors to consider when determining the reliability level for a particular process, such as calling a critical value to a care provider, or properly identifying a patient and collecting their specimen?

**Dr. Resar:** The factors to consider when determining a realistic reliability level are:

- Is the process potentially catastrophic for the patient immediately after it fails?
- If the process is potentially catastrophic, what is the likelihood of a catastrophic event if the process fails?
- What are the previous and current levels of performance for the process?
- What are the expectations of the users of the process?

Higher reliability levels are required if the process is catastrophic and likely to fail, and if users have high expectations for reliability. Obviously, the goal of quality improvement will be to surpass the current reliability level.

**LEPS:** Can you give examples of a catastrophic healthcare process as opposed to a noncatastrophic process?

**Dr. Resar:** By catastrophic, we are referring to processes that would immediately cause serious harm if the process failed. An obvious example is the process for choosing the correct bodily site for a surgery. An example in clinical pathology is choosing ABO compatible blood for a transfusion.

continued on page 4}》
LEPS: What is an example of a noncatastrophic process?
Dr. Resar: Hand washing is a good example. Everybody would agree that is an important component of infection control, but failure in hand washing will not immediately cause a catastrophic event, and usually will not cause a bad outcome at all because of the patient’s host defenses.

LEPS: By these definitions, how would you characterize laboratory-testing processes?
Dr. Resar: With some exceptions, like the ABO example above and some testing in the emergency or critical care setting, most laboratory processes are not catastrophic in that they would rarely lead to immediate harm to the patient. For example, choosing the wrong test can harm a patient, but in most settings it does not cause serious harm, and it rarely causes immediate harm.

LEPS: Can you describe the reliability model now being used by IHI to help understand and improve low reliability, noncatastrophic processes like many of the processes involved in laboratory testing?
Dr. Resar: This model is outlined in table 1. The current state of healthcare is that we have a great number of processes at the $10^{-1}$ or $10^{-2}$ level of reliability, where we define $10^{-1}$ semi-quantitatively as 1 or 2 errors per 10 attempts at the process, and $10^{-2}$ is 1 to 5 failures per 100. This occurs because our most common approach to quality improvement is to develop a policy and procedure and then rely on staff education and vigilance for successful implementation.

LEPS: How do we move beyond this common and ineffective approach to quality improvement?
Dr. Resar: You have to walk before you can run. Many healthcare processes are at $10^{-1}$ reliability. We could get a tremendous boost in healthcare quality by making a great effort to get these processes to $10^{-2}$. This is done by designing processes that incorporate principles from the science of human factors and reliability. We call these principles “model $10^{-2}$ change concepts”.

LEPS: Can you give us an example of these concepts?
Dr. Resar: Examples of concepts that can help achieve the $10^{-2}$ or $10^{-3}$ level are:
- Build reminders and other decision aids into the system
- Make the desired action the default
- Incorporate methods for identifying failures and mitigating them.
- Design standardized systems compatible with the usual habits, patterns and abilities seen in the workplace.

LEPS: Can you give an example of design elements that are incompatible with the usual habits, patterns and abilities seen in the workplace.
Dr. Resar: A patient identification system that takes 10 minutes to properly identify a patient before performing phlebotomy will not work because it is too slow. Similarly, physicians who have to round on a large group of patients are not going to use an electronic medical record that has a lengthy login procedure for each patient.

LEPS: We have many processes in laboratory services stuck in the $10^{-3}$ range. This is especially true of processes that are not automated like patient identification and specimen collection, calling critical values, and collecting a technically adequate specimen. Why is it so hard for us to get beyond $10^{-2}$?
Dr. Resar: To get to $10^{-3}$ and beyond
nearly always requires technology and advanced design. This usually means making significant resource investments.

**LEPS:** When designed and implemented carefully, automation and computerization has helped the lab achieve $10^{-5}$ or $10^{-6}$ reliability for some aspects of laboratory testing. For example, automated specimen processing systems can achieve this level of reliability for the aliquotting of specimens. Similarly, transmission of data from the laboratory information system to electronic medical records can achieve this level of reliability. Can you comment on this?

**Dr. Resar:** These examples illustrate my point. These examples are achieved through successful technology design and implementation using human factors as the guide. It is hard to get beyond $10^{-3}$ without this technology. If technology does not exist to help you, you often have to be practical and aim at achieving a $10^{-3}$ reliability, until a helpful technology is available.

**LEPS:** How do previous and current levels of performance for a process influence the choice of reliability level?

**Dr. Resar:** If you are stumbling, you first have to learn to walk, and you have to be able walk before you can learn run. Therefore, if you have a process that is chaotic or at $10^{-1}$ reliability, it is most realistic to aim for the $10^{-2}$ reliability level. Similarly, if you are at $10^{-2}$, your next logical step is $10^{-3}$.

**LEPS:** How do you balance the investment of resources needed to improve noncatastrophic healthcare processes?

**Dr. Resar:** You must consider the cost of failure vs. the cost of going to the next reliability level. For noncatastrophic processes - and these are the majority of healthcare processes - it often takes a fair amount of investment in technology, design, and usability testing to go from $10^{-3}$ to $10^{-4}$. That same amount of investment might be better spent in bringing several chaotic processes to $10^{-2}$. Similarly, you might achieve better patient outcomes by spreading an investment to bring many $10^{-2}$ processes to $10^{-3}$, rather than concentrating the entire investment into driving one process to six sigma, (which equates to $10^{-6}$ reliability in the IHI model).

**LEPS:** We would like you to apply these concepts to a specific example. Should we be pushing for six sigma reliability for patient identification and specimen collection since there is so much at stake regarding misidentifying a lab specimen?

**Dr. Resar:** I agree that this is an important problem but the context is important. The likelihood of a catastrophic episode occurring as a result of mislabeling is actually quite small. However, the other factors - like the reputation of the institution, the expectation of the users of the process, and previous levels of performance - may push the desired reliability into the $10^{-6}$. But there is not currently a realistic solution with $10^{-6}$ reliability. If we are currently at $10^{-3}$ reliability for proper labeling in most hospitals, the next step is to try to apply technology and advanced concepts from reliability science to get to $10^{-4}$.
LEPS: What is a laboratory example of putting a high level of resources toward achieving high reliability for a catastrophic process?

Dr. Resar: As I mentioned before, the transfusion of ABO compatible blood is potentially catastrophic. A significant amount of resources have gone into improving this process, and currently, the chance of death from receiving a mismatched unit of blood is about 1 in $10^5$.

LEPS: Can we end the interview with a take home message?

Dr. Resar: Designing a process is not simply making a policy and asking staff to be vigilant in applying it. Process design incorporates basic principles of reliability science to increase the likelihood of success. For noncatastrophic processes, it is often a wise to use available resources to bring a variety of chaotic or $10^{-1}$ processes to the $10^{-3}$ reliability level.

LEPS: Many thanks for some useful advice.

References

1. Resar RK. Making noncatastrophic health care processes more reliable: learning to walk before running in creating high-reliability organizations. Health Serv Res. 2006; 41:1677-1689.


<table>
<thead>
<tr>
<th>Definition</th>
<th>Defect Rate</th>
<th>Characteristics of Process</th>
<th>Examples in Laboratory Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chaos</td>
<td>&gt; 2 defects out of 10 opportunities</td>
<td>Absence of any well articulated process</td>
<td></td>
</tr>
</tbody>
</table>
| $10^{-1}$   | 1 or 2 failures per 10 | Articulated process with reliance on staff education, hard work and vigilance to achieve standardization | • Properly filling out a manual requisition  
• Identifying the current direct care provider associated with a hospitalized patient  
• Hand washing |
| $10^{-2}$   | <5 failures per 100 (>95% success) | Articulated process implemented using some basic human factors principles | • Notifying ambulatory patients of their test results  
• Adequate specimen (quantity sufficient, not contaminated or hemolyzed)  
• Properly logging in a manual requisition into the laboratory information system |
| $10^{-3}$   | <5 failures per 1000 (>99.5% success) | Articulated process implemented using human factors principles, and systems for failure detection and mitigation | • Patient identification and specimen labeling  
• Critical value notification |

Table 1. Overview of reliability labels used to describe many noncatastrophic healthcare processes. The examples are provided by LEPS editorial staff based on their opinions. Despite some notable exceptions, most organizations have not achieved higher reliability for these processes. The table is adapted from reference 1.
Question: Why can’t I get my nurses to consistently ask for two identifiers?

Answer: This topic is briefly discussed in the interview with Dr. Roger Resar in this issue. It is hard to get your nurses excited about quality improvement regarding specimen labeling because they do not clearly see the link between failure to properly label the specimen and poor patient outcomes. One of the reasons for not seeing this connection is a phenomenon referred to as the tyranny of small numbers. Let me illustrate using the following theoretical but realistic data:

- Mislabling rate in a hospital: 0.2%
- Blood draws in 1 year by a nurse: 500 specimens
- Mislables by nurse in 1 year: 0.2% x 500 = 1
- % of mislabels that lead to any patient harm: 5%
- % of mislabels that lead to serious patient harm (loss of life or limb): 0.1%

These numbers cannot be found in the literature, but I think they are realistic based on experience and personal communications with front line quality improvement specialists. My view is that the scientific literature, with some notable exceptions, shows a publication bias against the reporting of actual error rates, and therefore underestimates laboratory error.

Using the data shown, the nurse above would mislabel 1 specimen each year (which is 0.2% of 500 draws) and harm no patients. If the nurse had a mislabeling rate of 0.8%, the nurse would mislabel 4 specimens per year (0.8% x 500 draws), and would be unlikely to harm a single patient (probability = 4 x 5% = 0.2).

It is going to be hard to convince those nurses that there is a patient safety problem here. What is their motivation to be vigilant regarding the two-identifier rule? From the perspective of the individual nurse, this is not a crisis.

Meanwhile the healthcare system in which the nurses work has a serious patient safety problem. If there are 500,000 blood draws each year in the system, then 1000 specimens per year are mislabeled (0.2% x 500,000 draws) and 50 patients are harmed each year.

continued on page 8
(5% x 1000), one very seriously (0.1% x 1000). So what is not perceived as a problem by each individual nurse in a healthcare system is a huge problem for the healthcare system.

To summarize:
**Individual Nurse perspective:** I never harm anybody, what is the big deal. If my labeling of specimens was a test in school, I would be getting an A or A+. I achieve a reliability level of $10^{-3}$, and that is very good for a manual process.

**Health system perspective.** We are mislabeling lots of specimens and harming quite a few patients. An A for individual performance on an exam is a C for this health system. An A on this exam is a score of 99.99999%, not 99.8%.

**Solution to problem:** There is no simple solution. The solution involves a culture change that promotes understanding of the tyranny of small numbers. This culture change can be hastened through nursing education and through clearly communicating - to the entire nursing staff - information about actual adverse events due to mislabeling.

LEPS would love to hear from readers who have complimentary, supplementary, or alternative ideas.

**References:**

---

**Proper Use of Consultants**

**Expert:** Michael Astion, M.D., Ph.D.,
Editor-in-Chief,
Laboratory Errors and Patient Safety
University of Washington Department of Laboratory Medicine

**Question:** Our hospital executives love consultants and force them upon us. Many times they have minimal laboratory experience. Aren’t I competent to do the job that I was trained to do? Ironically, I have helped outside laboratories to do just the thing that consultants are being asked to do for me.

**Answer:** The love of consulting is the business manifestation of what author Frank Furedi calls the “Therapy Culture”¹. He used this term to refer to western culture’s current framework for understanding and addressing personal problems. This framework emphasizes the need for permanent, outside, professional help and de-emphasizes our own ability to transcend our problems through self-study, and through our own rich network of personal and business contacts.

With regard to your question whether you can get the job done, therapy culture would say no you cannot because:

- You are a diminished, damaged person, a weakling in need of formal help.
- The damage is permanent, based on wounds from your upbringing. These wounds have left you with a dysfunctional approach to your work.
- The damage cannot be overcome through self-study, personal ingenuity, or through collaboration with friends, coworkers, business colleagues— including vendors, and contacts in professional groups like the AACC, CAP, CLMA, or ASCLS.
Therefore:

- You will need outside professional help from a consultant (therapist).
- Your need for consulting (therapy) could last quite a long time. You will probably need it repetitively, although the consultant (therapist) may change over time.
- The consultant (therapist) will be expensive, and you should assume that they are competent, even though their credentials might be significantly diminished relative to yours.
- If the suggestions of the consultant do not work it will be your fault. You are inflexible. You are not hip to current trends and particular methods, some of which are proprietary.

My belief is the exact opposite of the therapy culture. You can transcend the vast majority of your work problems through study and the help of your conventional, support systems and business relationships such as friends, family, spiritual communities, coworkers, colleagues outside your institution, and professional groups.

Am I ruling out the use of consultants? Absolutely not. Just as it is true that some of life’s problems require professional therapeutic help, it is also true that some professional problems require outside help. But these are not the typical day-to-day problems that afflict laboratories. In addition, even for large problems, it is usually wise to first use your professional contacts—and then perhaps experienced consultants—to teach you methods that would help you overcome your problems.

Teach a man to fish. The LEPS philosophy is that you can do it, especially when you collaborate with your colleagues.

In summary:

- The overuse of consultants is a result of the current therapy culture. It is just the business manifestation of the current approach to personal problems.
- Consultants are needed far less than they are used.
- Experienced consultants, along with professional contacts and organizations, can be useful in an educational role to help you overcome your problems.
- When consultants are needed, choose an experienced one and verify this experience.

References:

Question: According to material presented in LEPS, we are not supposed to punish people who commit honest human errors in the context of an error prone environment, and this includes most examples of mislabeling blood tubes by busy nurses, and data entry errors by busy technologists. We are supposed to pursue “systems fixes”. But what am I supposed to do with the nurse who mislabels blood tubes at a rate of 15 times that of his or her peers, when our overall “system” for phlebotomy is reasonable and comparable to our peers?

Answer: For teaching purposes, I have created a theoretical table below that illustrates the nature of the problem you present. The error-prone nurse in your example is Nurse A in the table.

<table>
<thead>
<tr>
<th></th>
<th>Mislabeled Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average nurse</td>
<td>0.2%</td>
</tr>
<tr>
<td>Nurse A</td>
<td>3.0%</td>
</tr>
<tr>
<td>Next poorest</td>
<td>0.6%</td>
</tr>
</tbody>
</table>

Table 1. Mislabeled data for nurses in one nursing unit. Unfortunately, Nurse A is incompetent.

There are a few points to consider regarding Nurse A’s performance. The first point is that Nurse A is incompetent. For those who prefer a more euphemistic term, we can say that Nurse A’s skill set is mismatched with the job. An equally important point is Nurse A’s performance is unlikely to respond sufficiently to systems fixes. There is only so much error proofing that can be done regarding phlebotomy, and the current system, described in the table, produces an average mislabeling rate of 0.2%, which is an order of magnitude below that of Nurse A’s error rate. Clearly Nurse A is an outlier.

Although incompetence is not particularly common, it is common enough to make the concept of “blame-free” great in principle, but difficult in practice. Front line managers understand this, and that is why there is a movement among many healthcare facilities toward adopting the concept of a “just work culture”, rather than a “blame-free culture”. Just culture acknowledges that most errors are honest human errors where blaming has no role, but it also acknowledges that incompetence occurs and when it does there must be accountability.

The intervention for this problem is to stiffen your backbone and confront the employee using the human resource policies and procedures of your institution. The toolkit for this problem has no flow charts, process maps, automated devices or books about moving cheese and tipping points. None of these will make Nurse A an acceptable phlebotomist. The toolkit merely contains a working backbone, a healthy dose of perseverance, and your local human resource rules.

Once you have adapted the correct toolkit, the most important decision to make is whether this is temporary or chronic incompetence. If the error rate is chronic, the
employee has to be terminated or
transferred to a job that is a better fit. There is no way around this.

The case of temporary incompetence is more difficult. Temporary incompetence happens when workers are ill, bereaved, or otherwise temporarily overcome by life circumstances so they are unable to adequately perform their job. This happens to many if not most people over the course of a career, and it is likely becoming more common as the average age of laboratory personnel increases. For example, treatment of a newly diagnosed chronic illness often has a number of temporary side effects until the treatment is optimized, and these side effects - such as confusion, difficulties with vision, and depression - makes it difficult to perform laboratory procedures. Similarly, loss of a loved one can also temporarily render somebody incapable of performing his or her job.

Ideally, the response to temporary mismatch is a leave of absence or transfer to duties that cannot adversely impact patients. However, the main guiding principle is that these employees cannot be put in a position to harm patients, no matter how nice the employee or unfortunate their circumstance. That is true even if the employee is you, me or somebody we like.

The discussion above generalizes to errors throughout the total testing process. If the system in place for a laboratory task produces an acceptable error rate relative to peers or a standard, and an employee’s performance is well beyond that error rate, break out your backbone and get working on the problem. The guiding themes at that point are not “blame-free” and “error-proofing”, but rather “accountability” and “humane confrontation”, utilizing the policies and procedures present in nearly every healthcare workplace.

References
### Subscription Form

**SUBSCRIPTION**

<table>
<thead>
<tr>
<th></th>
<th>RATE</th>
<th>QTY.</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1-YEAR PDF SUBSCRIPTION</strong> (6 issues in Electronic Adobe Reader format)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Institutional*</td>
<td>$225</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individual</td>
<td>$125</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MTS Lab Training Library Subscribers</td>
<td>$95</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AACC Member Rate (Discounted Rate)</td>
<td>$95</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**All Archive Issues** (Since July 2004)

<table>
<thead>
<tr>
<th></th>
<th>RATE</th>
<th>QTY.</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutional*</td>
<td>$350</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individual</td>
<td>$150</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Institutional subscribers can share LEPS with colleagues at their institution via email or by posting on their facility’s internal website. For more information on which sets are available, visit our website: [www.LaboratoryErrors.org](http://www.LaboratoryErrors.org)*

### Payment Information

- Make checks payable to: Medical Training Solutions
- Tax ID#: 91-2137002
- Washington State subscribers add 8.8% sales tax
- Check enclosed
- Please invoice
- PO#
- VISA#
- Exp. date
- MC#
- Exp. date

### Ordering Information

- **By phone:** 866-681-6700
- **By fax:** 206-299-3005
- **By mail:** Medical Training Solutions
  - PO Box 17349
  - Seattle, WA 98127

---

MTS
Medical Training Solutions
PO Box 17349
Seattle, WA 98127