Guidelines Based on Fear of Type II (False-Negative) Errors
Why We Dropped the Pulse Check for Lay Rescuers

Richard O. Cummins, MD; Mary Fran Hazinski, RN, MSN

The new guidelines for CPR and ECC strongly emphasize evidence as the basis for all new clinical recommendations. The level of evidence may range from a high of Level 1 (one or more randomized, controlled clinical trials) to a low of Level 8 (rational conjecture, common sense, or accepted historically as standard practice). Nonevidence factors can influence the selection of the final class of recommendation, such as the expense of interventions, the ease of teaching, and the consequences of error. A technique that might improve resuscitation outcomes based on animal evidence, eg, open-chest CPR, turns out to be complex, difficult to learn, and difficult to implement. Such a technique would not merit as strong a recommendation as a technique that produced more modest improvements in survival but did so with superior ease of teaching, learning, and implementing.

Two principles that were less familiar to the International Guidelines 2000 experts came into play in several of the debates over the final class of recommendation:

- Avoid “false-negative” (type II) errors in patient assessment.
- Keep any risks from the interventions as close to zero as possible.

We have followed these principles in developing 3 new guidelines recommendations:

- Elimination of the pulse check for lay rescuers.
- Secondary confirmation techniques for tracheal tube placement. These are additions to current overreliance on physical examination as the best confirmation technique.
- More specific methods to prevent tracheal tube dislodgment.

As a general rule clinicians develop a strong imperative always to avoid what are called type II errors or the error of accepting false-negatives.1–6 This imperative has been a clinical heuristic (decision-making principle) for many decades. Simply stated, whenever a clinician ponders a differential diagnosis, he or she makes 1 of 2 diagnoses: either the disease is present or disease absent—and the physician’s clinical diagnosis—disease present or disease absent (see Table 1).3,7

The classic 2×2 matrix has many uses in clinical epidemiology and diagnostic decision making. Clinicians, researchers, and epidemiologists use the 2×2 matrix to calculate the sensitivity, specificity, and accuracy of diagnostic tests as well as probability, odds ratios, and likelihood for positive or negative treatment outcomes. In statistics the 2×2 matrix enters into calculations for testing the “null” hypothesis, sample size, study power, and probability value related to the probability of α and β errors.7 (Statisticians and others will recognize that a type II or false-negative error rate is the same dilemma statisticians face when they calculate probability value: the probability of accepting the “null hypothesis” when, in fact, the null hypothesis is wrong. The use of double negatives [“yes, the null hypothesis is of no benefit”] can make this a confusing topic.)

No clinician, however, considers false-negative and false-positive (type I and type II) errors to be equivalent in importance or concern. If a clinician has the misfortune to make a wrong clinical diagnosis, which of the following would be a more grievous error: (a) to tell a patient that he or she is well when in truth the patient has a serious illness (false-negative or type II error) or (b) to tell the patient that he or she is ill with a serious condition when in reality the patient is in glowing health (false-positive or type I error)?

The false-negative (type II) error causes an opportunity for a “cure” to be missed. Most clinicians would contend that this is a much more severe mistake than a false-positive (type I) error, ie, thinking a disease is present when it is not. False-positive mistakes have the negative consequences of producing worry, concern, and unnecessary treatment. If the treatment itself lacks serious side effects and poses no harm to the patient, retracting a negative diagnosis and replacing it with a clean bill of health would have few if any negative consequences.

The Pulse Check: A Diagnostic Test

The pulse check, under scrutiny by a number of researchers in the 1990s, is in reality a diagnostic test.8–23
TABLE 1. 2×2 Table That Compares the Results of a Diagnostic Test With the “True” Status of the Patient

<table>
<thead>
<tr>
<th>“TRUE” Status of the Patient</th>
<th>Disease Present</th>
<th>Disease Absent</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test positive: disease present</td>
<td>A</td>
<td>B</td>
<td>A+B</td>
</tr>
<tr>
<td>Correct diagnosis: disease present</td>
<td>Type I error: false positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test negative: disease absent</td>
<td>C</td>
<td>D</td>
<td>C+D</td>
</tr>
<tr>
<td>Type II error: false negative</td>
<td>Correct diagnosis: disease absent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A+C</td>
<td></td>
<td>B+D</td>
<td>Total Number</td>
</tr>
</tbody>
</table>

The palpation of the carotid artery “tests” for the “diagnosis” of cardiac arrest. If this “disease” is present and the rescuer correctly diagnoses “no pulse,” the rescuer starts CPR and (frequently) attaches an AED and delivers shocks.

If the pulseless state is present and the rescuer, in error, states that he or she feels a pulse (false-negative), then the rescuer fails to provide CPR and neglects to check for VF with an AED. This type of false-negative error yields considerable negative consequences, the most telling being the loss of a chance to save a life.

One of the more important pulse check studies was first presented in 1994 at the Scientific Congress of the European Resuscitation Council, in Mainz, Germany. This simple but elegant study alerted resuscitation experts to the danger of false-positive errors. The authors noted that when rescuers thought a pulse was absent, they were correct most of the time (60%) and started their CPR and AED protocols. For the other 40% of patients about whom the rescuers were in error (60%), we can calculate the sensitivity (53/59=90%). This meant, however, that 10% of the time (100% minus 90%) the victim was falsely diagnosed as having a pulse (n=6) when in fact the pulse was absent (n=59).

If we make several assumptions, we can see the consequences of this 10% type II error rate for the pulse check. Consider a person who suddenly collapses in a cardiac arrest. The nearest witness is a CPR-trained family friend or relative. After checking unresponsiveness and calling the emergency response system, the rescuer would perform steps “A” and “B” and arrive at the “C” of the ABCs. The rescuer needs to check for a pulse. With a false-negative error rate of 10%, the person doing the pulse check will state the equivalent of “I feel a pulse: we do not need chest compressions” approximately 1 out of every 10 witnessed arrests. The consequence for that victim is that the rescuer will withhold CPR and AED application inappropriately.

If we consider a hypothetical population of 100 people who experience a sudden, witnessed collapse, 70 to 80 people will be in VF. We know that with early defibrillation, the rate of survival to hospital discharge for the VF victims could be 50% to 70%. A range of 35 to 56 people (50% of 70 to 70% of 80) should have been discharged alive. With the 10% false-negative rate, however, approximately 4 to 6 potential survivors will not survive because CPR and early defibrillation have been withheld.

This possibility for such a severe problem arises because healthcare providers assume that lay rescuers can attend a basic life support course and leave with the ability to accurately detect both the absence of a pulse and the presence of a pulse. The positive consequences of the plan to drop the pulse check for the lay rescuer is that now the rescuer will start CPR on the basis of unresponsiveness and the absence of any signs of life. All of our hypothetical 100 people in cardiac arrest will receive the positive benefits of early CPR. This avoids having CPR omitted for 10 out of 100 people in need of the intervention.

What are the major consequences of dropping the pulse check for lay responders? What benefits are being sacrificed? What harm may ensue? Elimination of the pulse check should simplify CPR training because rescuers must learn fewer action steps and because the pulse check is the most difficult CPR action to master. Simple training for a simple skill

TABLE 2. 2×2 Table That Compares the Results of a Diagnostic Test of Carotid Pulse Check With the “True” Status of the Patient

<table>
<thead>
<tr>
<th>“TRUE” Status of the Patient</th>
<th>Disease Present (&quot;No Pulse: Cardiac Arrest!&quot;)</th>
<th>Disease Absent (&quot;Good Pulse!&quot;)</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rescuer thinks DISEASE PRESENT (&quot;no pulse: cardiac arrest!&quot;)</td>
<td>53 Sensitivity: number of times rescuer thinks no pulse/number of times there is no pulse: 53/59=90%</td>
<td>66 Type I error: number of times rescuer thinks there is no pulse/number of times there is pulse</td>
<td>119</td>
</tr>
<tr>
<td>Rescuer thinks DISEASE ABSENT (&quot;good pulse: no CPR, no AED&quot;)</td>
<td>6 Type II error (false negative): a cardiac arrest but rescuer thinks pulse present</td>
<td>81 Specificity: times rescuer thinks disease absent/times disease really is absent</td>
<td>87</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>206</td>
</tr>
</tbody>
</table>

Modified from Reference 24. Based on data from Reference 8.
increases the probability that a lay responder will perform successfully some time in the future.

In addition, the data suggests that of 100 people who collapse but still maintain a pulse, lay responders will "diagnose" the disease of "no pulse" up to 40 times. Thus, a rather high number of people will receive unnecessary ventilations and chest compressions. We must remember, however, that the guidelines still direct the lay rescuer to "check for signs of life" and avoid depending on just the pulse check. Experts speculate that these people diagnosed falsely as "cardiac arrest: begin chest compression" will begin to display other signs of life when the mouth-to-mask ventilations and the forceful chest compressions begin. Attempts to perform unnecessary CPR on people who need it probably will not continue for more than 1 or 2 cycles.

The widespread expectation that public access defibrillation (PAD) will continue to expand over the next decade led to a final concern expressed at the Guidelines 2000 Conference. Will dropping the pulse check for lay rescuers produce a conflict with currently accepted indications for attaching and activating an AED? AED instructions provided by AED manufacturers state that AEDs should be attached and placed in assess-and-treat mode only for people in cardiac arrest. The pulse check is necessary to determine cardiac arrest and be consistent with the labeling from AED manufacturers. Does dropping the pulse check for lay responders mean they will be unable to participate in PAD programs? Participation could be denied because lay responders will not be trained to perform the essential step required for AED attachment. This sounds like speculation on a conundrum based on semantics. Eliminating the pulse check should not develop into an obstacle to PAD expansion. The FDA and the AED manufacturers have begun very reasonable dialogue on this issue, which should be resolved in a short time.

In conclusion, the International Guidelines 2000 recommend elimination of the pulse check for lay rescuers as a Class IIa recommendation. When the question of the accuracy and validity of the pulse check was raised, we had to adjust our perspective in two ways. First, it was critical to begin to evaluate the pulse check as exactly what it is—a diagnostic test. Once analyzed in this way the shortcomings of the pulse check became glaringly apparent. The pulse check performs poorly when used as a diagnostic tool by lay responders.

The most significant error that could result from continued use of the pulse check would be a type II error—belief in a false-negative result. Such an error will lead at once to failure to diagnose cardiac arrest, failure to start CPR, and failure to assess the arrest rhythm for VF for approximately 10% of victims of cardiac arrest. A diagnostic test with life or death consequences that has an overall accuracy of only 75% (90% sensitivity; 60% specificity) is unacceptable and must be discontinued. This new guideline should eliminate an inaccurate test and increase the number of victims of cardiac arrest who receive chest compressions and early defibrillation.

Finally, we must add the benefits that come from simplifying CPR teaching. Elimination of the pulse check will reduce the number of CPR steps and the skills that the rescuer must learn, remember, and do. Such simplification will increase the likelihood that lay rescuers will learn CPR, perform CPR, and save more lives.

References

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