Fluid Replacement in Sepsis

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Sepsis

- Sepsis is a complex syndrome induced by infection.
- Sepsis is a leading cause of mortality and critical illness worldwide.
- The pathobiology (changes in organ function, morphology, cell biology, biochemistry, immunology, & circulation) is continuing to advance, leading to increased knowledge related to diagnosis, treatment & management.

Singer M. et al. JAMA 2016;315:8:801-810
Sepsis initiates an excessive inflammatory response that is characterized by:
- Hemodynamic derangements including arterial hypotension, peripheral vasodilation, hypovolemia from capillary leak and myocardial depression

Endothelial damage  \[\uparrow\] Capillary permeability & edema formation  \[\rightarrow\] Organ system dysfunction

Waxman AB et al Crit Care 2014; 9:1; http://ccforum.coj/content/9/1E1
Sepsis Terms & Definitions

- Infection → SIRS → Sepsis →
- Severe Sepsis → MODS
Definition of Sepsis
Sepsis is defined as life-threatening organ dysfunction caused by a dysregulated host response to infection.
The current use of 2 or more SIRS criteria to identify sepsis was unanimously considered by the task force to be unhelpful.

SIRS criteria are present in many hospitalized patients, including those who never develop infection and never incur adverse outcomes (poor discriminant validity).
1 in 8 patients admitted with infection and new organ failure did not have the requisite minimum of 2 SIRS criteria to fulfill the definition of sepsis (poor concurrent validity) yet had protracted courses with significant morbidity and mortality.

Results: Of 1,171,797 patients, a total of 109,663 had infection and organ failure. Among these, 96,385 (87.9%) had ≥2 SIRS criteria and 13,278 (12.1%) did not.
The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3)

- Septic shock is a subset of sepsis in which underlying circulatory and cellular/metabolic abnormalities are profound enough to substantially increase mortality.

- Patients with septic shock can be identified with a clinical construct of sepsis with persisting hypotension requiring vasopressors to maintain MAP ≥65 mm Hg and having a serum lactate level >2 mmol/L (18 mg/dL) despite adequate volume resuscitation.

With these criteria, hospital mortality is in excess of 40%.
<table>
<thead>
<tr>
<th>System</th>
<th>Score</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>≥400 (53.3)</td>
<td>&lt;400 (53.3)</td>
<td>&lt;300 (40)</td>
<td>&lt;200 (26.7) with respiratory support</td>
<td>&lt;100 (13.3) with respiratory support</td>
</tr>
<tr>
<td>Respiration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pao₂/Fio₂, mm Hg (kPa)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coagulation</td>
<td></td>
<td>≥150</td>
<td>&lt;150</td>
<td>&lt;100</td>
<td>&lt;50</td>
<td>&lt;20</td>
</tr>
<tr>
<td>Platelets, ×10³/μL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liver</td>
<td></td>
<td>&lt;1.2 (20)</td>
<td>1.2-1.9 (20-32)</td>
<td>2.0-5.9 (33-101)</td>
<td>6.0-11.9 (102-204)</td>
<td>&gt;12.0 (204)</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>MAP ≥70 mm Hg</td>
<td>MAP &lt;70 mm Hg</td>
<td>Dopamine &lt;5 or dobutamine (any dose)</td>
<td>Dopamine 5.1-15 or epinephrine ≤0.1 or norepinephrine ≤0.1</td>
<td>Dopamine &gt;15 or epinephrine &gt;0.1</td>
<td>Dopamine &gt;15 or epinephrine &gt;0.1</td>
</tr>
<tr>
<td>Central nervous system</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glasgow Coma Scale score</td>
<td>15</td>
<td>13-14</td>
<td>10-12</td>
<td>6-9</td>
<td>&lt;6</td>
<td></td>
</tr>
<tr>
<td>Renal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creatinine, mg/dL (μmol/L)</td>
<td>&lt;1.2 (110)</td>
<td>1.2-1.9 (110-170)</td>
<td>2.0-3.4 (171-299)</td>
<td>3.5-4.9 (300-440)</td>
<td>&gt;5.0 (440)</td>
<td></td>
</tr>
<tr>
<td>Urine output, ml/d</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&lt;500</td>
<td>&lt;200</td>
</tr>
</tbody>
</table>

Abbreviations: Fio₂, fraction of inspired oxygen; MAP, mean arterial pressure; Pao₂, partial pressure of oxygen.

Adapted from Vincent et al.²⁷

Catecholamine doses are given as μg/kg/min for at least 1 hour.

Glasgow Coma Scale scores range from 3-15; higher score indicates better neurological function.
The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3)

- Organ dysfunction can be identified as an acute change in total SOFA score $\geq 2$ points consequent to the infection.

- A SOFA score $\geq 2$ reflects an overall mortality risk of approximately 10% in a general hospital population with suspected infection. Even patients presenting with modest dysfunction can deteriorate further, emphasizing the seriousness of this condition and the need for prompt and appropriate intervention, if not already being instituted.
Box 4. qSOFA (Quick SOFA) Criteria

Respiratory rate $\geq 22$/min
Altered mentation
Systolic blood pressure $\leq 100$ mm Hg
The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3)

**SOFA Variables**
- PaO$_2$/FiO$_2$ ratio
- Glasgow Coma Scale score
- Mean arterial pressure
- Administration of vasopressors with type and dose rate of infusion
- Serum creatinine or urine output
- Bilirubin
- Platelet count

**qSOFA Variables**
- Respiratory rate
- Mental status
- Systolic blood pressure
Operationalizing Clinical Criteria to Identify Patients With Sepsis & Septic Shock

Patient with suspected infection

qSOFA ≥ 2?

YES

Assess for Organ dysfunction

SOFA ≥ 2?

YES

SEPSIS

qSOFA Variables
Respiratory rate
Mental status
Systolic blood pressure

SOFA Variables
PaO₂/FIO₂
Glasgow Coma Scale Score
Mean arterial pressure
Vasopressor use
Serum creatinine or urine output
Bilirubin
Platelet count

Despite adequate fluid resuscitation, need vasopressor support for MAP >65 mm Hg + serum lactate >2 mmol/L?

YES

Septic Shock


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SURVIVING SEPSIS CAMPAIGN BUNDLES

TO BE COMPLETED WITHIN 3 HOURS:
1) Measure lactate level
2) Obtain blood cultures prior to administration of antibiotics
3) Administer broad spectrum antibiotics
4) Administer 30 mL/kg crystalloid for hypotension or lactate ≥4 mmol/L

TO BE COMPLETED WITHIN 6 HOURS:
5) Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation) to maintain a mean arterial pressure (MAP) ≥ 65 mm Hg
6) In the event of persistent arterial hypotension despite volume resuscitation (septic shock) or initial lactate ≥ 4 mmol/L (36 mg/dL):
   - Measure central venous pressure (CVP)*
   - Measure central venous oxygen saturation (ScvO₂)*
7) Remeasure lactate if initial lactate was elevated*

*Targets for quantitative resuscitation included in the guidelines are CVP of ≥ 8 mm Hg, ScvO₂ of ≥ 70%, and normalization of lactate.
Initial Resuscitation

1. We recommend the protocolized resuscitation of a patient with sepsis-induced shock, defined as tissue hypoperfusion (hypotension persisting after initial fluid challenge or blood lactate concentration 4 mmol/L).

During the first 6 hrs of resuscitation, the goals of initial resuscitation of sepsis-induced hypoperfusion should include all of the following as one part of a treatment protocol:

- Central venous pressure (CVP): 8–12mm Hg
- Mean arterial pressure (MAP) ≥ 65mm Hg
- Urine output ≥ 0.5mL.kg⁻¹.hr⁻¹
- Central venous (superior vena cava) or mixed venous oxygen saturation ≥ 70% or ≥ 65%, respectively (Grade 1C)

Dellinger RP et al. Critical Care Medicine 2013;41:580-637
A. Initial Resuscitation

1. Protocolized quantitative resuscitation of patients with sepsis-induced tissue hypoperfusion (defined in this document as hypotension persisting after initial fluid challenge or blood lactate concentration $\geq 4$ mmol/L). Goals during the first 6 hrs of resuscitation:

   a) Central venous pressure 8–12 mm Hg

   b) Mean arterial pressure (MAP) $\geq 65$ mm Hg

   c) Urine output $\geq 0.5$ mL/kg/hr

   d) Central venous (superior vena cava) or mixed venous oxygen saturation 70% or 65%, respectively (grade 1C).

2. In patients with elevated lactate levels targeting resuscitation to normalize lactate (grade 2C).
A Randomized Trial of Protocol-Based Care for Early Septic Shock

The PreCENSE Investigators

Trial of Early, Goal-Directed Resuscitation for Septic Shock

Paul R. Mouncey, M.Sc., Tiffany M. Osborn, M.D., G. Sarah Power, M.Sc.,
David A. Harrison, Ph.D., M. Zia Sadique, Ph.D., Richard D. Grieve, Ph.D.,
Rahil Jahan, B.A., Sheila E. Harvey, Ph.D., Derek Bell, M.D., Julian F. Bion, M.D.,
Timothy J. Coats, M.D., Mervyn Singer, M.D., J. Duncan Young, D.M.,
and Kathryn M. Rowan, Ph.D., for the ProMISE Trial Investigators

Goal-Directed Resuscitation for Patients with Early Septic Shock

The ARISE Investigators and the ANZICS Clinical Trials Group
## Differences Between Treatment and Control Groups in the ProCESS, ARISE, and ProMISE Trials

<table>
<thead>
<tr>
<th>Clinical Trial</th>
<th>Cohort</th>
<th>Intravenous Fluids (milliliters)</th>
<th>Central Line Placement</th>
<th>Vasopressor Utilization</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ProCESS</strong></td>
<td>EGDT</td>
<td>2805 +/- 1957</td>
<td>411/439 (93.6%)</td>
<td>241/439 (54.9%)</td>
</tr>
<tr>
<td>May 2014</td>
<td>Usual Care</td>
<td>2279 +/- 1881</td>
<td>264/456 (57.9%)</td>
<td>201/456 (44.1%)</td>
</tr>
<tr>
<td></td>
<td>Δ</td>
<td>526ml</td>
<td>35.7%</td>
<td>10.8%</td>
</tr>
<tr>
<td><strong>ARISE</strong></td>
<td>EGDT</td>
<td>1964 +/- 1415</td>
<td>714/793 (90%)</td>
<td>528/793 (66.6%)</td>
</tr>
<tr>
<td>October 2014</td>
<td>Usual Care</td>
<td>1713 +/- 1401</td>
<td>494/798 (61.9%)</td>
<td>461/798 (57.8%)</td>
</tr>
<tr>
<td></td>
<td>Δ</td>
<td>251ml</td>
<td>28.1%</td>
<td>8.8%</td>
</tr>
<tr>
<td><strong>ProMISE</strong></td>
<td>EGDT</td>
<td>2000 (1150-3000)</td>
<td>575/624 (92%)</td>
<td>332/623 (53.3%)</td>
</tr>
<tr>
<td>May 2015</td>
<td>Usual Care</td>
<td>1784 (1075-2775)</td>
<td>318/625 (50.9%)</td>
<td>291/625 (46.6%)</td>
</tr>
<tr>
<td></td>
<td>Δ</td>
<td>216ml</td>
<td>41.1%</td>
<td>6.7%</td>
</tr>
</tbody>
</table>


Conclusions

- Required monitoring of CVP and ScvO2 via a CVC as part of early resuscitation does not confer survival benefit in all patients with septic shock who have received timely antibiotics and fluid resuscitation compared with controls.

- Requiring measurement of CVP and ScvO2 in all patients with lactate >4 mmol/L and/or persistent hypotension after initial fluid challenge and timely antibiotics is not supported by available evidence.
FLUID RESUSCITATION WITH COLLOID AND CRYSTALLOID SOLUTIONS IS A ubiquitous intervention in acute medicine. The selection and use of resuscitation fluids is based on physiological principles, but clinical practice is determined largely by clinician preference, with marked regional variation. No ideal resuscitation fluid exists.
Plasma proteins

Damaged glycocalyx

Leaky

Endothelial cell
Balanced salt solutions are pragmatic initial resuscitation fluids, although there is little direct evidence regarding their comparative safety & efficacy.

The use of normal saline has been associated with the development of metabolic acidosis and kidney injury. The safety of hypertonic solutions has not been established.

All resuscitation fluids can contribute to the formation of interstitial edema particularly under inflammatory conditions in which resuscitation fluids are used excessively.

Critical care practitioners should consider the use of resuscitation fluids as they would the use of any other IV drug. The selection of the specific fluid should be based on indications, contraindications, and potential toxic effects in order to maximize efficacy & minimize toxicity.
What is the Role of Fluids in Sepsis Resuscitation?

Sodium chloride (saline) is the most commonly used crystalloid solution on a global basis, particularly in the United States.

Crystalloids with a chemical composition that approximates extracellular fluid have been termed “balanced” or “physiologic” solutions and are derivatives of the original Hartmann’s and Ringer’s solutions. However, none of the proprietary solutions are either truly balanced or physiologic.”
Fluid therapy

1. We recommend crystalloids be used in the initial fluid resuscitation in patients (Grade 1B).

2. We recommend that initial fluid challenge in patients with sepsis-induced tissue hypoperfusion with suspicion of hypovolemia to achieve a minimum of 30ml/kg. (Grade 1C).

Dellinger RP et al. Critical Care Medicine 2013;41:580-637
Controversies

• 30ml/kg may be too much volume for patients at risk for fluid overload:
  – CHF
  – Renal patients
How are you all working with your physicians to encourage the use of 30cc’s/kg? Especially in CHF and Renal patients?

Our intensivist has taken the position that you cannot resuscitate dead. When providers argue that the 30 cc/kg is too much for a CHF patient, he “tactfully” reminds the providers that we need a live patient to treat the CHF. If you don’t provide adequate fluid resuscitation, you don’t have to worry about fluid overload. We know that the sepsis mortality rate was 40% before the recent focus on sepsis care and bundled treatment.

Try giving them the evidence. I try to find a good study that is on point for their concern. They may review the evidence and reach their own conclusions. If they still pushback, ask them to share their studies (evidence) so that you can learn. If they do not have the evidence to back their assertion that 30 cc/kg is too much in a CHF patient, it makes it much more difficult to justify failure to follow internationally accepted standards.
Study aim: to determine differences between patients with pre-existing left ventricular dysfunction and those with normal ventricular function during sepsis in terms of mortality when treated in accordance with a sepsis treatment algorithm.

Results: In-hospital mortality rates (p=0.117) and intubation at 24 hours (p=0.687) were not significantly different. There was no correlation between the amount of intravenous fluid administration over the first 24 hours and the PaO2/FIO2 ratio at 24 hours.

Conclusions: Clinical outcomes were not different between septic patients with pre-existing left ventricular dysfunction and those with no cardiac disease. There was no correlation between fluid administration and oxygenation at 24 hours in either cohort.
Association Between the Choice of IV Crystalloid and In-Hospital Mortality Among Critically Ill Adults With Sepsis*

Karthik Raghunathan, MD, MPH1,2; Andrew Shaw, MB, FRCA, FFICM1, FFCCM11; Brian Nathanson, PhD3; Til Stürmer, MD, PhD4; Alan Brookhart, PhD4; Mihaela S. Stefan, MD5; Soko Setoguchi, MD, DrPH6; Chris Beadles, MD, PhD2; Peter K. Lindenauer, MD, MSc7

**Objective:** Isotonic saline is the most commonly used crystalloid in the ICU, but recent evidence suggests that balanced fluids like Lactated Ringer's solution may be preferable. We examined the association between choice of crystalloids and in-hospital mortality during the resuscitation of critically ill adults with sepsis.

**Setting:** Three hundred sixty U.S. hospitals that were members of the Premier Healthcare alliance between November 2005 and December 2010.

**Patients:** A total of 53,448 patients with sepsis, treated with vaso-pressors and crystalloids in an ICU by hospital day 2 including 3,396 (6.4%) that received balanced fluids.
<table>
<thead>
<tr>
<th>Outcome</th>
<th>Balanced Fluid–Matched Cohort</th>
<th>No-Balanced Fluid–Matched Cohort</th>
<th>Effect Estimate</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absolute in-hospital mortality</td>
<td>19.6% (659 of 3,365)</td>
<td>22.8% (768 of 3,365)</td>
<td>Relative risk, 0.86</td>
<td>0.78, 0.94; p = 0.001</td>
</tr>
<tr>
<td>ARF with dialysis</td>
<td>4.52% (142 of 3,144)</td>
<td>4.74% (149 of 3,144)</td>
<td>Relative risk, 0.953</td>
<td>0.761, 1.194</td>
</tr>
<tr>
<td>ARF without dialysis</td>
<td>7.12% (159 of 2,655)</td>
<td>7.50% (199 of 2,655)</td>
<td>Relative risk, 0.950</td>
<td>0.784, 1.150</td>
</tr>
<tr>
<td>Hospital LOS in days (survivors)</td>
<td>11.26</td>
<td>11.37</td>
<td>Absolute difference,</td>
<td>−0.55, 0.34</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>−0.11</td>
<td></td>
</tr>
<tr>
<td>ICU LOS in days (survivors)</td>
<td>5.39</td>
<td>5.50</td>
<td>Absolute difference,</td>
<td>−0.37, 0.15</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>−0.11</td>
<td></td>
</tr>
</tbody>
</table>

ARF = acute renal failure, LOS = lengths of stay.
Fluid resuscitation should be guided by assessment of fluid responsiveness.
Fig 2 Fluid administered between enrolment and 72 h and 90-day mortality in the control arm of the Early Goal Directed Therapy (EGDT) Studies performed between 2001 and 2015. APACHE II = APACHE II Severity of illness scoring system (0–71).
Fig 3 Fluid administered between enrolment and 6 h and central venous pressure (CVP) at h in the Early Goal Directed arm of the EGDT studies performed between 2001 and 2015.
Fluid therapy

3. We suggest adding albumin in the initial fluid resuscitation regimen of severe sepsis and septic shock when patients require substantial amounts of crystalloids (Grade 2C).

4. We recommend against the use of hydroxyethyl starches (HES) for fluid resuscitation of severe sepsis and septic shock (Grade 1B).

Dellinger RP et al. Critical Care Medicine 2013;41:580-637
“Our analyses suggest that balanced solutions may be preferable to unbalanced solutions if crystalloids are used and that, in sepsis, albumin may be a reasonable alternative to other resuscitation fluids. However, relative to balanced crystalloids, albumin confers a small risk associated with transfusion of blood products and costs markedly more.”
Early Management Bundle, Severe Sepsis/Septic Shock

New Bundles & CMS “Core Measures” to Begin October 2015
SEP-1

TO BE COMPLETED WITHIN 3 HOURS OF TIME OF PRESENTATION †:

1. Measure lactate level
2. Obtain blood cultures prior to administration of antibiotics
3. Administer broad spectrum antibiotics
4. Administer 30ml/kg crystalloid for hypotension or lactate ≥4mmol/L

† “time of presentation” is defined as the time of earliest chart annotation consistent with all elements severe sepsis or septic shock ascertained through chart review.
TO BE COMPLETED WITHIN 6 HOURS OF TIME OF PRESENTATION:

5. Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation) to maintain a mean arterial pressure (MAP) \( \geq 65\text{mmHg} \)

6. In the event of persistent hypotension after initial fluid administration (MAP < 65 mm Hg) or if initial lactate was \( \geq 4 \text{mmol/L} \), re-assess volume status and tissue perfusion and document findings according to table 1.

7. Re-measure lactate if initial lactate elevated.
SEP-1

TABLE 1
DOCUMENT REASSESSMENT OF VOLUME STATUS
AND TISSUE PERFUSION WITH:

• Either
  – Repeat focused exam (after initial fluid resuscitation)
    by licensed independent practitioner including vital
    signs, cardiopulmonary, capillary refill, pulse and skin
    findings

• Or two of the following:
  – Measure CVP
  – Measure ScvO2
  – Bedside cardiovascular ultrasound
  – Dynamic assessment of fluid responsiveness with
    passive leg raise or fluid challenge
**Definition: Bedside Cardiovascular Ultrasound**

**Criteria for Data Abstraction**
- Expected response: yes/no ("yes" meaning an appropriate ultrasound was done)
- Requirements – Ultrasound occurs within six hours of the presentation of septic shock
- Appropriate exams to qualify for a "yes" include:
  - TTE (trans-thoracic echocardiogram)
  - TEE (trans-esophageal echocardiogram)
  - IVC US (Inferior Vena Cava ultrasound)
  - Esophageal Doppler monitoring

**Physician Reference**
- Clinically Necessary or definitional, but documentation not required
- Definitional: Caval index: IVC expiratory diameter - IVC inspiratory diameter, divided by IVC expiratory diameter × 100 = caval index (%).
- Definitional: The caval index is written as a percentage, where a number close to 100% is indicative of...

<table>
<thead>
<tr>
<th>Inferior Vena Cava Size (cm)</th>
<th>Respiratory Change</th>
<th>Central Venous Pressure (cm H₂O)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1.5</td>
<td>Total collapse</td>
<td>0–05</td>
</tr>
<tr>
<td>1.5 – 2.5</td>
<td>&gt; 50% collapse</td>
<td>6–10</td>
</tr>
<tr>
<td>1.5 – 2.5</td>
<td>&lt; 50% collapse</td>
<td>11–15</td>
</tr>
<tr>
<td>&gt;2.5</td>
<td>&lt; 50% collapse</td>
<td>16–20</td>
</tr>
<tr>
<td>&gt;2.5</td>
<td>No change</td>
<td>&gt;20</td>
</tr>
</tbody>
</table>
**Definition: Passive Leg Raise**

**Criteria for Data Abstraction**

- **Expected response:** yes/no ("yes" meaning a passive leg raise is documented or administration of a fluid challenge is documented)
- **Requirements:**
  - Passive leg raise or fluid challenge occurs within six hours of the presentation of septic shock
  - No documentation of lower extremity amputation in the case of passive leg raise
  - Presence of a passive leg raise test typically documented as “PASSIVE LEG RAISE (PLR):” with findings “positive,” “negative,” “fluid responsive,” “not fluid responsive,” or other language
Definition: Repeat Physical Exam

Criteria for Data Abstraction

- Expected response: yes/no ("yes" meaning a complete exam is recorded)
- Requirements: Clinical exam components within 6 hours of the presentation of septic shock and must include each of the following:
  - **Vital signs** (including temperature, heart rate, blood pressure, respiratory rate: all four must be present)

  and

  - Presence of a **cardiopulmonary exam**: typically documented as "HEART:" and "LUNGS:"
    - **Documentation examples**: HEART- "RRR," "Irregular," "S1, S2, S3, S4," "murmur," or other LUNG - "clear," "crackles," "diminished," "dull," or other language

  and

  - Presence of **peripheral pulses** examination typically "PULSES:" with findings
    - **Documentation examples**: "1+," or "2+," or "absent," or other language

  and

  - Presence of documentation of **capillary refill**
    - **Documentation examples**: "brisk," "< 2 seconds," "> 2 seconds," or other language

  and

  - Presence of a **skin examination**
    - **Documentation examples**: "mottled," "not mottled," "knee caps clear/mottled," or other language