Leveling the Evidence

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Clinical Nurse Specialist, Critical Care
Objectives

Upon completion of the session staff will be able to:

• Describe the basic approach to research and evidence based practice
• Define the levels of evidence as part of the research appraisal process
• Differentiate the different levels of evidence through clinical examples
Tradition & Authority

• Many questions are answered & decisions made based on customs or tradition
  – Individual not required to begin new to understand how to be a nurse
  – Facilitates communication => common foundation of accepted truth
  – May never have been validated
Tradition & Authority

• Information or Decisions can come from someone in Authority
  – A person with specialized expertise or training
  – Authorities are not infallible
  – Expertise could be based on personal experience
  – Leaders can be promoted based on experience
  – Knowledge can go unchallenged
Other Methods

Clinical Experience
• Is often too narrow
• Objective events are perceived differently

Trial & Error
• Alternatives are tried until one works
• Haphazard approach, often not recorded or shared generally

Intuition
• Working off a hunch
• Can not be explained by reasoning
• Can not be built into policies/procedures
Nursing Knowledge

• Previous studies showed a decline in best care knowledge related to the amount of information available and the limited time to absorb it.

• Knowledge of best care negatively correlates to year of graduation
  – Best care knowledge ↓ as years since graduation ↑

• Lack of knowledge of
  – EBP or think research is used in practice
  – Know how to search or use a database

Estabrooks 1998; Shin et al 1993; Pravikoff 2005
Evidence Based Practice

• Is a problem solving approach to clinical decision making that integrates the conscientious use of the best evidence in combination with a clinician’s expertise as well as patient preferences and values to make decisions.

• To produce high quality healthcare
EBP Key Assumptions

• Nursing is both a science and applied profession
• Knowledge is important to professional practice
  – Knowledge limits must be identified
• Evidence is not all equal
  – Use only the best available
• EBP -> to improved outcomes

• Increased consumer expectation to participate in care decisions and are researching treatment options on the internet. Push nurses to know the evidence
EBP

- Research
- Clinical experience
- Expert opinion
- Patient preferences
- Organization experience
  - QI data
  - Financial data

- Ensures
  - Efficacy
  - Efficiency
  - Effectiveness
Critical Thinking & EBP

- Critical thinking is a complex cognitive process that involves questioning, seeking information, analyzing, synthesizing, drawing conclusions from available information and transforming knowledge into action.

- Through the process of evidence based practice:
  - Nurses need to think critically about their practices, ask if practices are aligned with research and then work in teams and groups to change clinical practice standards.
EBP Clinical Decision Making

Evidence-Based Clinical Decision-Making

- Evidence from research/evidence-based theories, and opinion leaders/expert panels
- Evidence from patient assessment, H&P, PE, and availability of healthcare resources
- Clinical Expertise
- Information about patient preferences and values
# EBP Models

<table>
<thead>
<tr>
<th>Name of Model</th>
<th>Reference</th>
<th>Brief Description</th>
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<tbody>
<tr>
<td></td>
<td>Academic Center for Evidence-Based Practice. The University of Texas Health Science Center at San Antonio.</td>
<td>Circular model.</td>
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<td></td>
<td><a href="http://www.acestar.uthscsa.edu">www.acestar.uthscsa.edu</a></td>
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</tr>
<tr>
<td><strong>Iowa Model of Evidence-Based Practice to Promote Quality Care</strong></td>
<td>Titler, M.G., Kleiber, C., Steelman, V.J., Rakel, B.A., Budreau, G., Everett, L.Q., et al. (2001). The Iowa model of evidence-based practice to promote quality care.</td>
<td>Decision tree starting with triggers to action. Facilitates decisions to use the evidence or to conduct research.</td>
</tr>
<tr>
<td></td>
<td>Critical Care Nursing Clinics of North America, 13(4), 497–509.</td>
<td></td>
</tr>
<tr>
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<td>Indianapolis, IN: Sigma Theta Tau.</td>
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Clinical Process

Cultivate a spirit of inquiry and an EBP culture

1. Ask the PICO(T) question
2. Search for the best evidence
3. Critically appraise the evidence
4. Integrate the evidence with clinical experience & patient preferences to make the best clinical decision
5. Evaluate the outcome(s) of the EBP practice change
6. Disseminate the outcome(s)
Leveling the Evidence

• The challenge: combining the contributions of each type of evidence when making patient-care decisions
• How do we know how strong the evidence is?
• We appraise the research and non-research evidence to determine which is the strongest evidence to guide practice.
Systematic Reviews

Meta-Analysis (Level I)

- Scientific evidence that quantitatively synthesizes/analyzes the findings of multiple primary studies with similar research questions
  - Uses statistical procedures to pool results from independent primary studies
  - Usually includes experimental and/or quasi-experimental studies
Systematic Reviews

Meta-Synthesis (Level V)

- Qualitative research asks questions that draw on curiosity, involves flexible repetitive process, aims at reflecting diversity rather than representative characteristics and generates rather than collects data
  - Identification of key metaphors
  - Looks for relationships in the data
  - Interprets and translates findings
  - Limited to qualitative studies
Examples

• A Meta-Analysis of Studies of Nurses’ Job Satisfaction which looked at the strength of the relationship between the job satisfaction of staff nurses and three constructs: autonomy, job stress, and nurse-physician collaboration

• Parenting a Child with Chronic Illness which searched multiple databases to yield 11 qualitative studies focusing on parenting a child with chronic illness

Zangaro & Soeken, 2007
Coffey, 2006
- Systematic review or meta-analysis of all relevant randomized controlled trials (RCTs),
- Evidence-based clinical practice guidelines based on systematic reviews of RCTs
- Evidence obtained from at least one well-designed RCT
- Evidence obtained from well-designed controlled trials without randomization and from well-designed case-control and cohort studies
- Evidence from systematic reviews of descriptive and qualitative studies
- Evidence from a single descriptive or qualitative study
- Evidence from the opinion of authorities and/or reports of expert committees
Clinical Practice Guidelines (Level II)

- Specific practice recommendations that are based on methodologically rigorous reviews of best evidence on specific topic
- Group of experts combine evidence from research findings, clinician expertise, and patient preferences
- Have tremendous potential to improve quality of care, process of care, and patient outcomes
- Caution: Must meet level of rigor as defined by the National Guideline Clearinghouse
- The evidence can be limited to certain populations or conflicting.... Strength and quality of the guideline must be assessed
Clinical Practice Guidelines

• AGREE II Tool:
  – Appraisal of Guideline Research and Evaluation
  – http://www.agreetrust.org

• Ensures the guideline can be applied to disadvantaged populations
  – Some inequity noted between race, residence, occupation, gender, religion, education, socioeconomic status, social network and capital
AGREE II

- Assesses
  - Scope
  - Purpose
  - Stakeholder involvement
  - Rigor of development
  - Clarity & presentation
  - Applicability
  - Editorial independence

- Note potential conflicts of interest:
  - financial interests,
  - job descriptions,
  - personal research interests
  - previous experience
Applying Classifications of Recommendations and Levels of Evidence

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<tr>
<th>Class</th>
<th>Benefit Condition</th>
<th>Procedure/Treatment Suggestion</th>
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</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Benefit &gt;&gt;&gt; Risk</td>
<td>Procedure/treatment SHOULD be performed/ administered.</td>
</tr>
<tr>
<td>Class IIa</td>
<td>Benefit &gt;&gt; Risk</td>
<td>Additional studies with focused objectives needed. It is REASONABLE to perform procedure/administer treatment.</td>
</tr>
<tr>
<td>Class IIb</td>
<td>Benefit ≥ Risk</td>
<td>Additional studies with broad objectives needed. It is REASONABLE to perform procedure/administer treatment.</td>
</tr>
<tr>
<td>Class III</td>
<td>Risk ≥ Benefit</td>
<td>Procedure/treatment/ or diagnostic test/assessment should NOT be performed/administered. It is not helpful and may be harmful.</td>
</tr>
<tr>
<td>Class Indeterminate</td>
<td></td>
<td>Research is just getting started; continuing area of research; no recommendations until further research.</td>
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Strength of the Evidence

• **Level A** — Data derived from multiple randomized clinical trials, directly relevant to the recommendation, yielded a consistent pattern of findings

• **Level B** — Some evidence from randomized clinical trials supported the recommendation, but scientific support was not optimal. Few randomized trials existed, the trials that did exist were somewhat inconsistent, or the trials were not directly relevant to the recommendation

• **Level C** — Reserved for important clinical situations where the panel achieved consensus on the recommendation in the absence of relevant randomized controlled trials
From Veteran's Health Administration, Office of Nursing Services, Evidence-Based Practice Resource Center. Clement J. Zablocki VA Medical Center, Milwaukee, WI.)
Primary Research

• Randomized Controlled Trials (Level II)
  – Use the traditional scientific manual
  – Three features
    • Randomization
    • Blind or Double Blind
    • Control
    • Manipulation

• Controlled Trials without Randomization Quasi-experimental (Level III)
  – Performed when not practical, ethical or possible to randomly assign subjects
  – Try to compensate by doing multiple groups or waves of measurement.
Examples

The Effect of Peer Councilors on Breastfeeding Rates in the Neonatal Intensive Care Unit: Results of a Randomized Controlled Trial

Effects of Stroke Rehabilitation Education Program for Nurses

• Non-equivalent comparison group design to study effects of rehab education on nursing practice in two stroke rehabilitation units.

Merewood et al. 2006

Booth et al. 2005
Primary Research

• Non-Experimental Designs
  – The study of naturally occurring phenomena
    • Groups
    • Treatments
    • Individuals
  – No intervention
  – Not randomly assigned
  – No manipulation of variables
  – Not always able to control the environment
  – Two types: descriptive & correlational
Non-Experimental Designs

- Descriptive Studies (Level VI)
  - Describes characteristics of phenomena
  - Ask who, what, when, & how of particular persons, places, or things
  - Analysis limited to frequencies & averages

- Types of Descriptive Studies
  - Exploratory
  - Descriptive Comparative
  - Time-Dimensional
    - Retrospective: events in the past
    - Prospective: events that may yet occur
    - Longitudinal: change over time
    - Cross-sectional: changes over different stages of development
    - Trends: changes in populations related to a phenomena
Non-Experimental Designs

- Correlational Designs (Level VI)
  - Examines relationship among variables (two)
  - Converts this into numbers for statistical analysis to obtain a correlation coefficient
    - -1 to 1
  - Magnitude: or the strength of the correlation
    - -1 negative correlation
    - 1 positive correlation

- Qualitative Designs (Level VI)
  - Design the study while conducting the study
  - Interpret data to develop insights into the meaning of life experiences
  - Types
    - Historical
    - Grounded
    - Ethnography
    - Hermeneutic phenomenology
Examples

• Sleep-Wake Disturbances and Quality of Life in Patients with Advanced Lung Cancer
  Vena, et al. 2006

• Perceived Readiness for Hospital Discharge in Adult Medical-Surgical Patients
  – Explored relationships among variables: nature of the transition, patient characteristics, nursing therapeutics, response to discharge
  Weiss, et al. 2007

• Empathy, Inclusion, and Enclaves: The Culture of Care of People with HIV/AIDS and Nursing Implications
  Hodgson, 2006
Tips for Reading Research

• The Title
  – Starting point should direct the reader to the type of study being reported

• The Effect of Peer Councilors on Breastfeeding Rates in the Neonatal Intensive Care Unit: Results of a Randomized Controlled Trial

• A Magnet Community Hospital: Fewer Barriers to Nursing Research Utilization
Tips for Reading Research

• The Abstract
  – Located after the title and author lines
  – Usually set apart in its own space or box
  – Contains the following:
    • Study’s purpose
    • Method
    • Results
    • Conclusions
    • Clinical relevance

• The Conclusion
  – Should contain a brief restatement of the experimental results & implications of the study
  – May not be labeled separately but placed at the end of the discussion section
Tips for Reading Research

• The Method
  – Described how the study was conducted
  – The population that was studied
  – The inclusion/exclusion criteria
  – Recruitment of subjects
  – Demographics
  – How data was collected and analyzed

• The Results
  – Findings of data analysis without commentary
  – Focus on figures and tables
  – Discussion of statistical vs clinical significance

• The Discussion
  – Results should be tied to material in the introduction
  – Caution: researchers can overstate their findings or use an assertive sentence suggesting the findings are a well-established fact…. “it is generally believed that ….”

[Logo]
From Veteran's Health Administration, Office of Nursing Services, Evidence-Based Practice Resource Center. Clement J. Zablocki VA Medical Center, Milwaukee, WI.)
Non-Research Review

• Systematic review
• Clinical Practice Guidelines
• Questions for critiquing
Expert Opinion

• Case Studies
  – An in depth look at a single patient or group for descriptive data of the phenomena

• Narrative Literature Reviews
  – Description of the scientific and non-scientific literature
  – May or may not include an appraisal of the literature

• Advice of Individual Experts
  – Could be commentary, position statements, case reports, letters to the editor
  – Could be written or verbal (presentation)
Organizational Experience

• Quality Improvement Reports
• Financial Data
  – Cost analysis
  – Cost-benefit
  – Cost-utility
• Program Evaluations
• Practitioner Experience & Expertise
• Patient Experience
Critically Appraise the Evidence

• Can be exhaustive and time consuming
• But answers to critical appraisal questions ensure relevance and transferability to specific population you are providing care for
  – Are the results of the study or systematic review valid?
  – What are the results? Are they meaningful/reliable? If applied, can I get the same results?
  – Are the findings clinically relevant to patients?
Sufficient Evidence

• Implement
  – There is sufficient evidence
  – Incorporate clinical expertise and patient preferences & values

• Do Not Implement
  – No evidence or not enough... Generate evidence
    • Internal evidence through outcomes management
    • External evidence through rigorous research
Integrate the Evidence

• Integrate evidence from literature search/critical appraisal with clinician’s expertise, clinical assessment and available health resources

• In addition to patient preferences and values to implement a decision
Evaluate the Outcomes

• Evaluation of the intervention includes:
  – How treatment worked?
  – How effective clinical decision was with particular patient or practice setting?
  – *Did the change based on evidence result in expected outcomes?*
Disseminating Results

- Targeted dissemination efforts must use multifaceted dissemination strategies
- Emphasis on channels and media that are most effective for particular user segments or stakeholders
Examples
Objective: To provide an update to “Surviving Sepsis Campaign Guidelines for Management of Sepsis and Septic Shock: 2012.”

Design: A consensus committee of 55 international experts representing 25 international organizations was convened. Nominal groups were assembled at key international meetings (for those committee members attending the conference). A formal conflict-of-interest (COI) policy was developed at the onset of the process and enforced throughout. A stand-alone meeting was held for all panel members in December 2015. Teleconferences and electronic-based discussion among subgroups and among the entire committee served as an integral part of the development.

Methods: The panel consisted of five sections: hemodynamics, infection, adjunctive therapies, metabolic, and ventilation. Population, intervention, comparison, and outcomes (PICO) questions were reviewed and updated as needed, and evidence profiles were generated. Each subgroup generated a list of questions, searched for best available evidence, and then followed the principles of the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system to assess the quality of evidence from high to very low, and to formulate recommendations as strong or weak, or best practice statement when applicable.

Results: The Surviving Sepsis Guideline panel provided 93 statements on early management and resuscitation of patients with sepsis or septic shock. Overall, 32 were strong recommendations, 39 were weak recommendations, and 18 were best-practice statements. No recommendation was provided for four questions.

Conclusions: Substantial agreement exists among a large cohort of international experts regarding many strong recommendations for the best care of patients with sepsis. Although a significant number of aspects of care have relatively weak support, evidence-based recommendations regarding the acute management of sepsis and septic shock are the foundation of improved outcomes for these critically ill patients with high mortality. (Crit Care Med 2017; 45:486–552)

Key Words: evidence-based medicine; Grading of Recommendations Assessment, Development, and Evaluation criteria; guidelines; infection; sepsis; sepsis bundles; sepsis syndrome; septic shock; Surviving Sepsis Campaign
Time to Treatment and Mortality during Mandated Emergency Care for Sepsis

Christopher W. Seymour, M.D., Foster Gesten, M.D., Hallie C. Prescott, M.D.,
Marcus E. Friedrich, M.D., Theodore J. Iwashyna, M.D., Ph.D.,
Gary S. Phillips, M.A.S., Stanley Lemeshow, Ph.D., Tiffany Osborn, M.D., M.P.H.,
Kathleen M. Terry, Ph.D., and Mitchell M. Levy, M.D.

ABSTRACT

BACKGROUND
In 2013, New York began requiring hospitals to follow protocols for the early identification and treatment of sepsis. However, there is controversy about whether more rapid treatment of sepsis improves outcomes in patients.

METHODS
We studied data from patients with sepsis and septic shock that were reported to the New York State Department of Health from April 1, 2014, to June 30, 2016. Patients had a sepsis protocol initiated within 6 hours after arrival in the emergency department and had all items in a 3-hour bundle of care for patients with sepsis (i.e., blood cultures, broad-spectrum antibiotic agents, and lactate measurement) completed within 12 hours. Multilevel models were used to assess the associations between the time until completion of the 3-hour bundle and risk-adjusted mortality. We also examined the times to the administration of antibiotics and to the completion of an initial bolus of intravenous fluid.

RESULTS
Among 49,331 patients at 149 hospitals, 40,696 (82.5%) had the 3-hour bundle completed within 3 hours. The median time to completion of the 3-hour bundle was 1.30 hours (interquartile range, 0.65 to 2.35), the median time to the administration of antibiotics was 0.95 hours (interquartile range, 0.35 to 1.95), and the median time to completion of the fluid bolus was 2.56 hours (interquartile range, 1.33 to 4.20). Among patients who had the 3-hour bundle completed within 12 hours, a longer time to the completion of the bundle was associated with higher risk-adjusted in-hospital mortality (odds ratio, 1.04 per hour; 95% confidence interval [CI], 1.02 to 1.05; P<0.001), as was a longer time to the administration of antibiotics (odds ratio, 1.04 per hour; 95% CI, 1.03 to 1.06; P<0.001) but not a longer time to the completion of a bolus of intravenous fluids (odds ratio, 1.01 per hour; 95% CI, 0.99 to 1.02; P=0.21).

CONCLUSIONS
More rapid completion of a 3-hour bundle of sepsis care and rapid administration of antibiotics, but not rapid completion of an initial bolus of intravenous fluids, were associated with lower risk-adjusted in-hospital mortality. (Funded by the National Institutes of Health and others.)
ABSTRACT

Objective: Lactate levels are increasingly used to guide resuscitation efforts. Some surgical literature suggests that tourniquet use during phlebotomy falsely elevates results, although studies in healthy volunteers have not demonstrated this. The purpose of this study was to determine in clinical practice whether tourniquet use during the drawing of a lactate results in significantly altered levels compared to the result of a level drawn without a tourniquet.

Methods: A prospective cohort study was carried out on emergency department patients whose clinical presentation led a physician to order a lactate level. Written informed consent was obtained from patients or their proxies. Study lactates were obtained using a tourniquet during the draw sequence of other laboratory studies. Lactate levels for clinical use were drawn per hospital protocol with no tourniquet. The time of lactate measurements and patient demographic information were recorded. Lactate levels for each patient were compared with the Wilcoxon Rank-Sum Test.

Results: 40 patients were consented and enrolled. The median clinical lactate level was 1.9 (interquartile range 1.5-2.6), and the median study lactate level was 1.9 (interquartile range 1.4-2.7). There was no difference between paired lactate values ($p = 0.95$).

Conclusions: Tourniquet use appears to have no impact on measured lactate levels. Our findings suggest that current practices at many institutions regarding lactate collection are likely too stringent and should be changed.
Clinical trial of a novel surface cooling system for fever control in neurocritical care patients

Stephan A. Mayer, MD; Robert G. Kowalski, BS; Mary Presciutti, RN; Noeleen D. Ostapkovich, MS; Elaine McGann, RN; Brian-Fred Fitzsimmons, MD; Dileep R. Yavagal, MD; Y. Evelyn Du, PhD; Andrew M. Naidech, MD; Nazli A. Janjua, MD; Jan Claassen, MD; Kurt T. Kreiter, PhD; Augusto Parra, MD; Christopher Commichau, MD

Objective: To compare the efficacy of a novel water-circulating surface cooling system with conventional measures for treating fever in neuro-intensive care unit patients.

Design: Prospective, unblinded, randomized controlled trial.

Setting: Neurologic intensive care unit in an urban teaching hospital.

Patients: Forty-seven patients, the majority of whom were mechanically ventilated and sedated, with fever ≥38.3°C for >2 consecutive hours after receiving 650 mg of acetaminophen.

Interventions: Subjects were randomly assigned to 24 hrs of treatment with a conventional water-circulating cooling blanket placed over the patient (Cincinnati SubZero, Cincinnati OH) or the Arctic Sun Temperature Management System (Medivance, Louisville CO), which employs hydrogel-coated water-circulating energy transfer pads applied directly to the trunk and thighs.

Measurements and Main Results: Diagnoses included subarachnoid hemorrhage (60%), cerebral infarction (23%), intracerebral hemorrhage (11%), and traumatic brain injury (4%). The groups were matched in terms of baseline variables, although mean temperature was slightly higher at baseline in the Arctic Sun group (38.8 vs. 38.3°C, p = .046). Compared with patients treated with the SubZero blanket (n = 24), Arctic Sun-treated patients (n = 23) experienced a 75% reduction in fever burden (median 4.1 vs. 16.1 °C°-hrs, p = .001). Arctic Sun-treated patients also spent less percent time febrile (T ≥38.3°C, 8% vs. 42%, p < .001), spent more percent time normothermic (T ≤37.2°C, 59% vs. 3%, p < .001), and attained normothermia faster than the SubZero group median (2.4 vs. 8.9 hrs, p = .008). Shivering occurred more frequently in the Arctic Sun group (39% vs. 8%, p = .013).

Conclusion: The Arctic Sun Temperature Management System is superior to conventional cooling-blanket therapy for controlling fever in critically ill neurologic patients. (Crit Care Med 2004; 32:2508–2515)

Key Words: fever; cooling blankets; intracerebral hemorrhage; subarachnoid hemorrhage; stroke
A randomized controlled trial comparing the Arctic Sun to standard cooling for induction of hypothermia after cardiac arrest

Article history:
abstract
Context: Hypothermia improves neurological outcome for comatose survivors of out-of-hospital cardiac arrest. Use of computer controlled high surface area devices for cooling may lead to faster cooling rates and potentially improve patient outcome.
Objective: To compare the effectiveness of surface cooling with the standard blankets and ice packs to the Arctic Sun, a mechanical device used for temperature management.
Intervention: Standard post-resuscitative care inducing hypothermia using cooling blankets and ice (n = 30) or the Arctic Sun (n = 34).
Main outcome measures: The primary end point was the proportion of subjects who reached a target temperature within 4 h of beginning cooling. The secondary end points were time interval to achieve target temperature (34 °C) and survival to 3 months.
Results: The proportion of subjects cooled below the 34 °C target at 4 h was 71% for the Arctic Sun group and 50% for the standard cooling group (p = 0.12). The median time to target was 54 min faster for cooled patients in the Arctic Sun group than the standard cooling group (p < 0.01). Survival rates with good neurological outcome were similar; 46% of Arctic Sun patients and 38% of standard patients had a cerebral performance category of 1 or 2 at 30 days (p = 0.6).
Conclusions: While the proportion of subjects reaching target temperature within 4 h was not significantly different, the Arctic Sun cooled patients to a temperature of 34 °C more rapidly than standard cooling blankets.
Trial registration: ClinicalTrials.gov NCT00282373, registered January 24, 2006.
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