

Innovative Technology for the Development and Application of Living Evidence-based Guidelines

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McBRIDE STRATEGIC SERVICES

Personal Disclosures

Sandy Lewis:

I have no relevant COIs except:

- I am Chief Guidelines Officer at Doctor Evidence, a provider of technology solutions for EBGs
- I give public presentations on guideline development and implementation

Deb McBride:

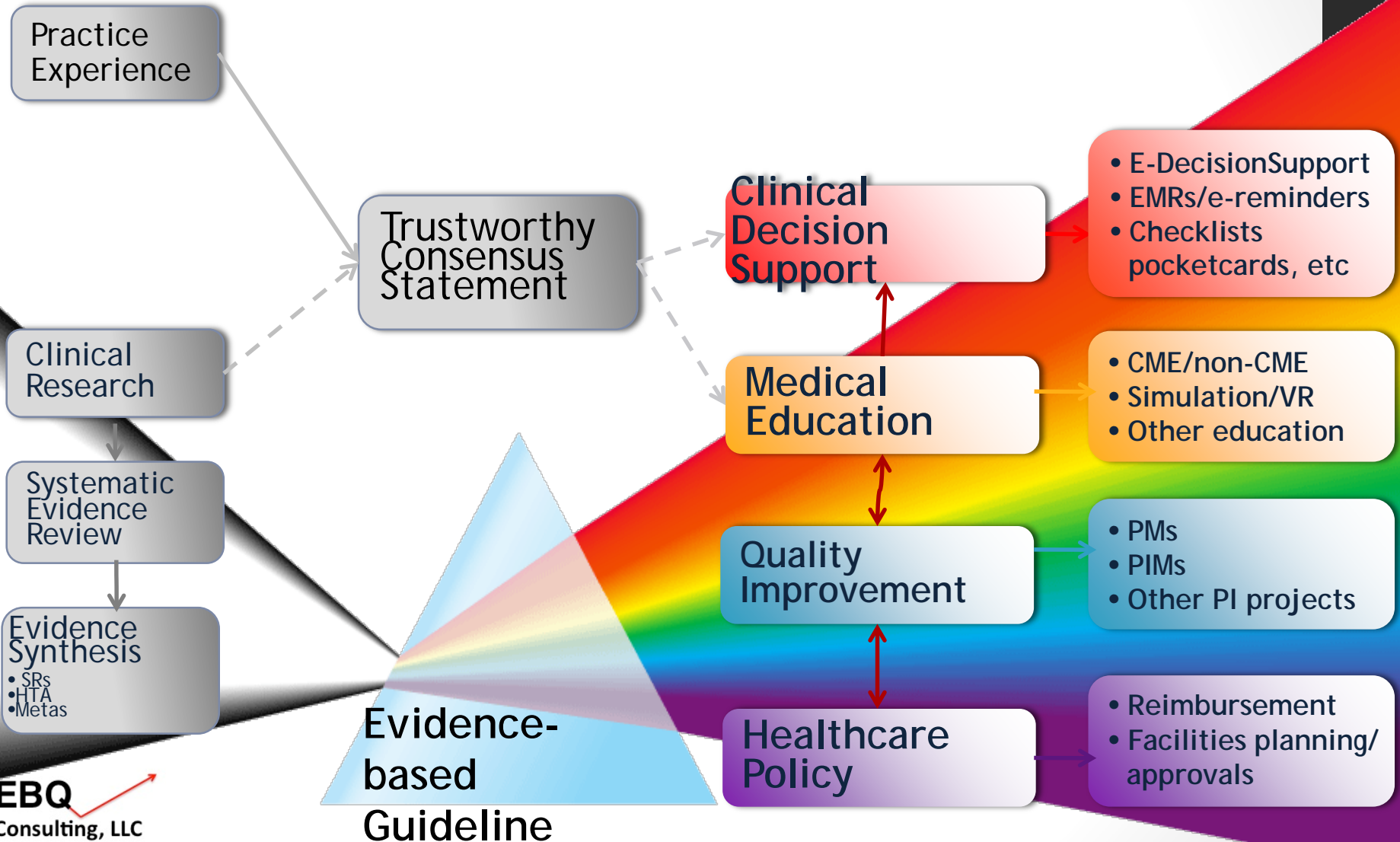
- I provide project management and editorial direction to organizations that develop and publish evidence-based guidelines

Presentation Outline

- Value of evidence-based guidelines (Our experience is in evidence-based medicine (EBM))
- Science of guideline development
- Steps in the guideline development process
- Technologies to support guideline development*
- Value of guidelines to publishers, librarians, subscription agents, and intermediaries

* Major focus of this presentation

Evidence-based Medicine Spectrum



Science of Guideline Development

Recent criteria memorialize the **scientific rigor** and establish a benchmark for **today's standards**:

- Institute of Medicine 2011
- Guidelines International Network 2012
- National Guidelines Clearinghouse revised inclusion criteria 2014

Methods and processes have developed to the point where an entire industry exists to support **trustworthy guideline development**

- Based on a systematic and comprehensive literature review
 - Precise analytics
- To support shared decision making at the point of care
 - Patient values and preferences
 - Around benefits and harms associated with optional interventions
 - And patient-important outcomes
- By a trusted panel of experts
 - Cleared for conflicts of interest (COIs)

Steps in Guideline Development

Submission and Approval of Proposed Topic

Panel construction: All Stakeholders

COIs Reviewed

Topic Narrowed and PICO Questions Refined

Literature Reviewed: Search, Screening

Literature Reviewed: Extractions, Grading, and Analyses

Writing and Grading Recommendations

Guideline Manuscript Drafting

Panel Conference/Voting

Review and Approval Process

Publication

Development of Derivative Products

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Technologies for Guideline Development

“Integration of the systems that automate systematic review tasks may lead to a revised systematic review workflow. We envisage the optimized workflow will lead to system in which each systematic review is described as a computer program that **automatically retrieves relevant trials, appraises them, extracts and synthesizes data, evaluates the risk of bias, performs meta-analysis calculations, and produces a report in real time.**”

Tsafnat G, et al. Systematic review automation technologies. *Systematic Reviews* 2014, 3:74
<http://www.systematicreviewsjournal.com/content/3/1/74>

Most of this exists today!

Technologies for Guideline Development

Literature Reviewed: Search, Screening

Distiller SR (Canada)

- User tools for systematic reviews and comparative effectiveness reviews
 - Reference management and form builder
- Service support
- Commercial pricing with student discounts

Covidence (Australia)

- Expanding internationally, Cochrane
- Only for systematic reviews
 - Screening
 - Double extraction adjudication
 - Methodological quality assessment
- Must export to RevMan for analyses
- Free first use. Unlimited use at \$20/month

EPPI Reviewer (UK)

- Search and saves PDFs
- Reference management
- Data extraction and analytics
- SR management
- Limited areas; “clunky”
- Limited service for support
- Commercial pricing

Technologies for Guideline Development

Literature Reviewed: Search, Screening

EndNote

- Reference management
- Library builder
- Download directly from PubMed
- No data extractions

Epistemonikos (Chile)

- Web searching for SRs, SR Overviews, & primary studies
- Matrix of studies across multiple SRs

Doctor Evidence (US/International)

(Refer to Slide 13)

Others: Rayyan (Qatar), **EROS – Early Review Organizing Software** (Argentina), **SUMARI – System for the Unified Management, Assessment and Review of Information** (Australia)

Technologies for Guideline Development

Literature Reviewed: Extractions, Analyses

SRDR – Systematic Review Data Repository (Brown University CEBM)

- Uses: creation, management, and archive searching of SRs
- Since 2012
- Open Access
- Certified data contributors (mostly EPCs now)
- Quickly create complex extraction forms, which can accommodate any study design or research question via the form design tool's powerful and flexible "question builder" capability
- Enabling easy comparison and reconciliation of double data extractions
- Seamlessly saving all data online.
- Export data in a variety of formats for local backup, printing, or analysis
- Downloading study information from PubMed® (and from other databases in the near future) automatically
- Future plans to integrate with Abstrackr and OpenMeta
- Online and direct support available without cost

Technologies for Guideline Development

Literature Reviewed: Extractions, Analyses

RevMan (Cochrane)

- Cochrane reviews, free use; Commercial enterprises pay
- Meta-analyses
- Graphical representations of results in Summary of Findings tables
- Virtual collaborative manuscript workspace

Archie (Cochrane)

- Internet repository of reviews

Abstrackr (Brown University CEBM)

- Software for semi-automatic citation screening
- Free, open-source, Web-based
- Still in development

OpenMeta (Brown University CEBM)

- Open source
- Step-by-step meta analysis software

Technologies for Guideline Development

Literature Reviewed: Extractions, Analyses

GDT – Guideline Development Tool (GRADE Working Group/GRADE Pro)

- Guideline management tool
- Steps in guideline development process
- Displays evidence profiles
- Import SoF tables from RevMan
- Does not offer digitized data or continuous upkeep

Development of Derivative Products

- Mobile application

Technologies for Guideline Development

Literature Reviewed: Search, Screening

Doctor Evidence (US/International)

- Since 2004
- Commercial but discounted nonprofit/governmental pricing
- More than tools/software, includes services
- Library searches (PICO-based) and screening
 - Medical Librarians

Literature Reviewed: Extractions, Analyses

- Data extractions/digitizations, evidence grading, and analyses
 - Clinical Data Analysts & QC Analysts (double blinded extractions + adjudication (CMO))
 - User-defined binding to ontologies, project-specific rules
 - Meta-analyses (indirect, NMA), Bayesian, other R stats package
 - Graphical presentations: instantaneous plots, graphs, tables
 - Dynamic digital systematic reviews, enables living guidelines

Guideline Manuscript Drafting

- Virtual collaborative work environment
 - Easy import of graphs, charts, tables, reference lists
 - Cite While You Write

Technologies for Guideline Development

Development of Derivative Products

MAGICapp (Norway/International)

- GRADE guideline authoring
- Point of care access to recommendations
 - Integration into EMRs
- Mobile application
- Partnership with Doctor Evidence provides drill back to see substantiating evidence (tables, graphs, analyses, libraries of studies supporting individual recommendations)

SHARE-It

- Shared decision-making at the point of care
- Visualizations of magnitude of benefits and harms
- Integration into MAGICapp/Doctor Evidence partnership

Technologies for Guideline Development

Summary Points:

- Usability remains an issue for many of the options
- Few provide full end-to-end solution for systematic reviews/health technology assessments and guidelines
 - A patchwork of software products is not very efficient
 - Fully integrated technologies are maximally expedient
- Most do not provide services to accompany the tools
- Some are not freely available
- Non-digital data are insufficient for today's analytics and inhibit the ability to maintain current evidence for living guidelines.
 - All guidelines should use high-quality digital, updatable data with robust analytics to support living guidelines.

From the Publisher's Perspective

- Opportunity to increase impact factor
- Opportunity to increase academic standing
- Opportunity to generate revenues
 - Licensing for translations
 - Reprints
 - Derivative products
 - apps
 - educational materials
 - live programs
- Opportunity to increase submissions on related topics

Publication Access Throughout the Process of Guideline Development and Dissemination

- Original literature searches
- Citations in document
- As updated
- As read
- As cited
- As disseminated
- As applied
- As derivative materials are generated and used


Librarians' Involvement

- Original literature searches in guideline development
- As methodologist
- Authorship as appropriate
- Specialized activities
 - Grading of evidence
 - Training panel members

Case Study of Surviving Sepsis Campaign Guidelines



Case Study of SSC Guidelines


Special Articles

Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2012

R. Phillip Dellinger, MD¹; Mitchell M. Levy, MD²; Andrew Rhodes, MB BS³; Djillali Annane, MD⁴; Herwig Gerlach, MD, PhD⁵; Steven M. Opal, MD⁶; Jonathan E. Sevransky, MD⁷; Charles L. Sprung, MD⁸; Ivor S. Douglas, MD⁹; Roman Jaeschke, MD¹⁰; Tiffany M. Osborn, MD, MPH¹¹; Mark E. Nunnally, MD¹²; Sean R. Townsend, MD¹³; Konrad Reinhart, MD¹⁴; Ruth M. Kleinpell, PhD, RN-CS¹⁵; Derek C. Angus, MD, MPH¹⁶; Clifford S. Deutschman, MD, MS¹⁷; Flavia R. Machado, MD, PhD¹⁸; Gordon D. Rubenfeld, MD¹⁹; Steven A. Webb, MB BS, PhD²⁰; Richard J. Beale, MB BS²¹; Jean-Louis Vincent, MD, PhD²²; Rui Moreno, MD, PhD²³; and the Surviving Sepsis Campaign Guidelines Committee including the Pediatric Subgroup*

Objective: To provide an update to the "Surviving Sepsis Campaign Guidelines for Management of Severe Sepsis and Septic Shock" last published in 2008.

Design: A consensus committee of 68 international experts representing 30 international organizations was convened. Nominal groups were assembled at key international meetings (for those committee members attending the conference). A formal conflict of interest policy was developed at the onset of the process and enforced throughout. The entire guidelines process was conducted independent of any industry funding. A stand-alone meeting was held for all subgroup heads, co- and vice-chairs, and selected individuals. Teleconferences and electronic-based discussion among subgroups and among the entire committee served as an integral part of the development.

Methods: The authors were advised to follow the principles of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system to guide assessment of quality of evidence from high (A) to very low (D) and to determine the strength of recommendations as strong (1) or weak (2). The potential drawbacks of making strong recommendations in the presence of low-quality evidence were emphasized. Some recommendations were ungraded (UG). Recommendations were classified into three groups: 1) those directly targeting severe sepsis; 2) those targeting general care of the critically ill patient and considered high priority in severe sepsis; and 3) pediatric considerations.

Results: Key recommendations and suggestions, listed by category, include: early quantitative resuscitation of the septic patient during the first 6 hrs after recognition (1C); blood cultures

* Members of the 2012 SSC Guidelines Committee and Pediatric Subgroup are listed in **Appendix A** at the end of this article. Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this on the journal's Web site (<http://journals.lww.com/ccmjournal>). Complete author and committee disclosures are listed in **Supplemental Digital Content 1** (<http://links.lww.com/CCM4615>). This article is being simultaneously published in *Critical Care Medicine* and *Intensive Care Medicine*. For additional information regarding this article, contact R.P. Dellinger (Dellinger-Phil@CooperHealth.edu). Copyright © 2013 by the Society of Critical Care Medicine and the European Society of Intensive Care Medicine
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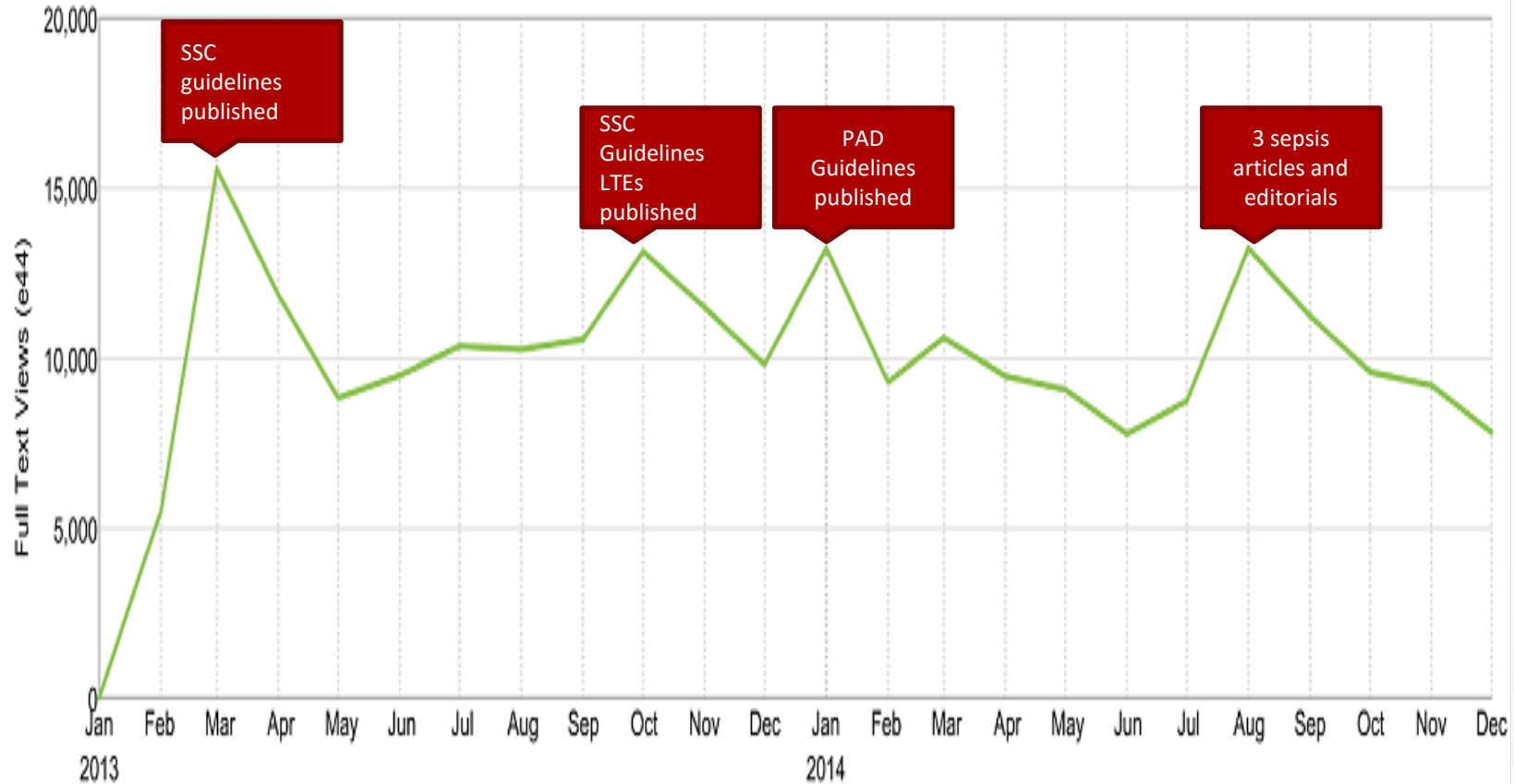
Development of Derivative Products

Case Study of SSC Guidelines

- Literature search resulting in 636 published references
- Access from multiple sites—for better or worse
- More than 12 million hits on all sites
- Increase in journal access
- 163 citations from *Critical Care Medicine*
- Fourth edition in development now
- Derivative products
 - App
 - Quality improvement programs
 - Educational sessions
 - Checklists, protocols, point-of-care tools

Case Study of SSC Guidelines

— Critical Care Medicine



What's Next for SSC Guidelines

- Living Guidelines !!!!

Questions and Comments



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