

From Evidence  **To EMS Practice:**

Building the National Model

Evidence-Based Medicine in EMS

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Building the National Model

History and Development of EBM

- Historical assumption
 - Medical education, CME, experience, and interaction with colleagues are adequate to lead to good clinical decisions

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Early 1970's: Destroying the assumption

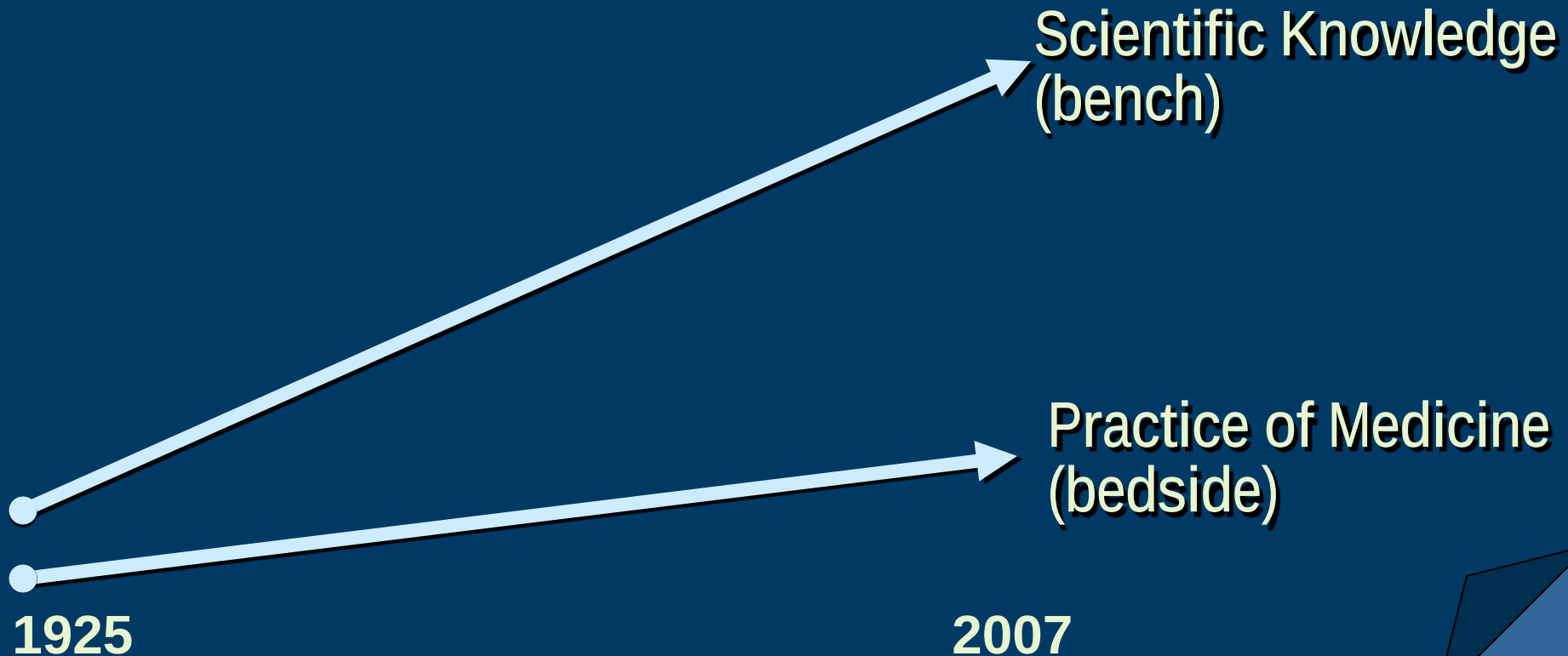
- Documentation of wide variation in practice patterns (Wennberg, 1973)
 - Dramatic procedural variation (RAND)
- Most medical practice was founded on tradition/experience rather than evidence.
 - Cochrane-1972: Many standards of care were found to be ineffective...or even dangerous.
 - IOM Report-1985: Estimate: Only 15% of medical practices based upon solid evidence.
- Enormous lag-time from new research findings to practice.
 - Dutton-1988: "Worse than the Disease: Pitfalls of Medical Progress."

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The ever widening gap

> 100 new articles related to EM/day (Medline)



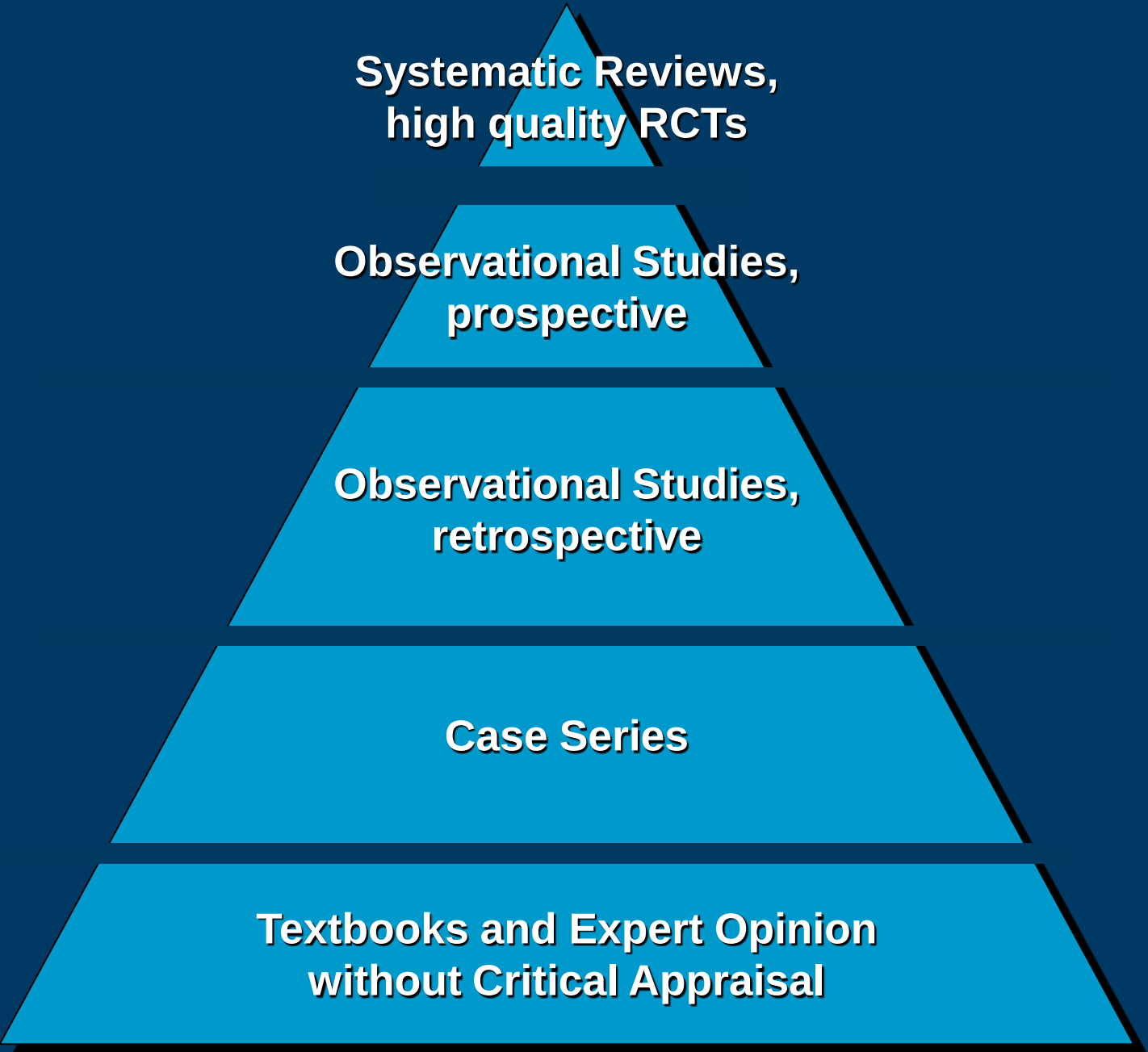
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A “Movement” Emerged (EBM): *(Eddy’s categorization)*

- “Evidence-Based Individual Decision-making” (EBID)
 - Brings current knowledge to the bedside in real-time.
 - **DIRECT** use of evidence to impact the care of an **INDIVIDUAL** patient.
- “Evidence-Based Guidelines” (EBGs)
 - Policies/standards that help guide clinical decision-making based upon state-of-the-art knowledge.
 - **INDIRECT** use of evidence to change policy, practice, regulations, insurance coverage, etc.

BOTH are based upon a hierarchy of evidence quality



**Systematic Reviews,
high quality RCTs**

**Observational Studies,
prospective**

**Observational Studies,
retrospective**

Case Series

**Textbooks and Expert Opinion
without Critical Appraisal**

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WHERE WE STAND IN THE DEVELOPMENT OF EMS EBGs:

- An overview of the road that's ahead of us
- Necessary steps for TRULY “evidence-based” guidelines
- Update on the development of a national model for EMS EBGs

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Step # 1: Critical evaluation of the literature

Comprehensive, systematic literature review.

- 121 different approaches for rating individual study quality.
(Lohr: Intl J Qual Health Care 2004;16:9-18)

Evaluation of relevant authoritative guidelines if they exist (AHA: CPR/ACLS)

Evaluation of extant guidelines/protocols from EMS systems.

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Step # 2: *Critical evaluation of the CUMULATIVE evidence*

Must evaluate the quality of the BODY of evidence

This is more difficult than rating a single investigation.

- Assess consistency/heterogeneity of study designs
- Assess comparability of Risk Adjustment among studies
- Weight each study (study size, methodology, quality)

40 methods for rating the strength of a body of evidence.
(Lohr)

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 **Step # 3: *Critical evaluation of the CHAINS of evidence***

Rare to find a body of knowledge that “*writes the guideline for you.*”

Requires explicit cognitive steps that translate DIRECT evidence into guidelines through INFERENCES.

- Example: Animal studies → Human studies → Guideline applied across a broad population in dramatically different settings.

Inevitably requires judgment, extrapolation, experience, inference, and opinion

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 **Step # 4:** *Critical evaluation of the PREHOSPITAL implications of the body of evidence*

Strong evidence for EFFICACY of an intervention does not mean that it will be EFFECTIVE in the field.

- Lack of prehospital studies must be taken into account even with strong positive evidence in other settings.
- The LAB vs. the STREET →
 - EFFICACY vs. EFFECTIVENESS

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Step # 5: Critical evaluation of other pertinent issues

--Systems-related factors:

- Rural vs. urban settings
- Demography: e.g., is a specific peds guideline needed?
- Operations: e.g., response/transport intervals
- Patient populations: e.g., cost-effectiveness varies with prevalence

--Socioeconomics: Impact on effectiveness and outcomes

--Impact of delaying an intervention: Does it have to be done?

- Extremes are easy: Cardiac arrest; Tinea pedis
- Urgent...but not emergent interventions

--Cost

--Feasibility and practicality

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Step # 6: *Evaluation of whether a guideline is appropriate at all*

When should a stand be taken that clearly states that insufficient evidence exists...and that a guideline is inappropriate?

- What if there are already LOTS of guidelines out there?

Are there interventions that should be “trashed” despite their widespread use?

If **CONSENSUS** is the basis for a guideline, how is this distinguishable from **EVIDENCE**-based guidelines?

- What are the implications of having these guidelines **LOOK** equally authoritative when they make it to the street?

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Step # 7: An intentional, sustainable plan for recurrent revisions of the guidelines

--If there's a lack of commitment to future changes based upon new evidence...is it best not to start in the first place?

- Guidelines are NOT harmless!!!
- Guidelines hang around a LONG time!!!

Examples:

- Diethylstilbestrol (DES)
 - 1938 – 1971: Recommended by expert consensus to prevent miscarriage
 - 4.8 million pregnant women received it
 - 1971 FDA halted its use: No statistical benefit but significant harm (vaginal cancer, breast cancer, etc.)
- “Once a C-section...ALWAYS a C-section” (over 90 years ago)

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The Potential Advantages of Guidelines

- Reduced variation in care
- Provides specific guidance to providers
- Improved patient outcomes
- Improved system efficiency
- Provides potential for specific benchmarks
- Reduced cost

Great Methodologies Emerging

- **AGREE: “Appraisal of Guidelines for Research and Evaluation.”**
 - Powerful tool for evaluating the quality of evidence
 - Developed by international collaborative group including 16 partners from 12 countries
- **GRADE: “Grading of Recommendations Assessment, Development and Evaluation”**
 - Allows grading of the strength of a recommendation for specific clinical guidelines

Valid

Reliable
Clear

Implementable

Recommendations

Credible

Transparent

Unbiased

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**Developing the
National Model for EMS EBGs**

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- NHTSA EMS Office/FICEMS/NEMSAC
- 2007: National EMS EBG Steering Committee
 - Charged with development of background documents and recommendations for a...
- National consensus conference: Sept 2008
 - Stakeholders from EMS, government & academia

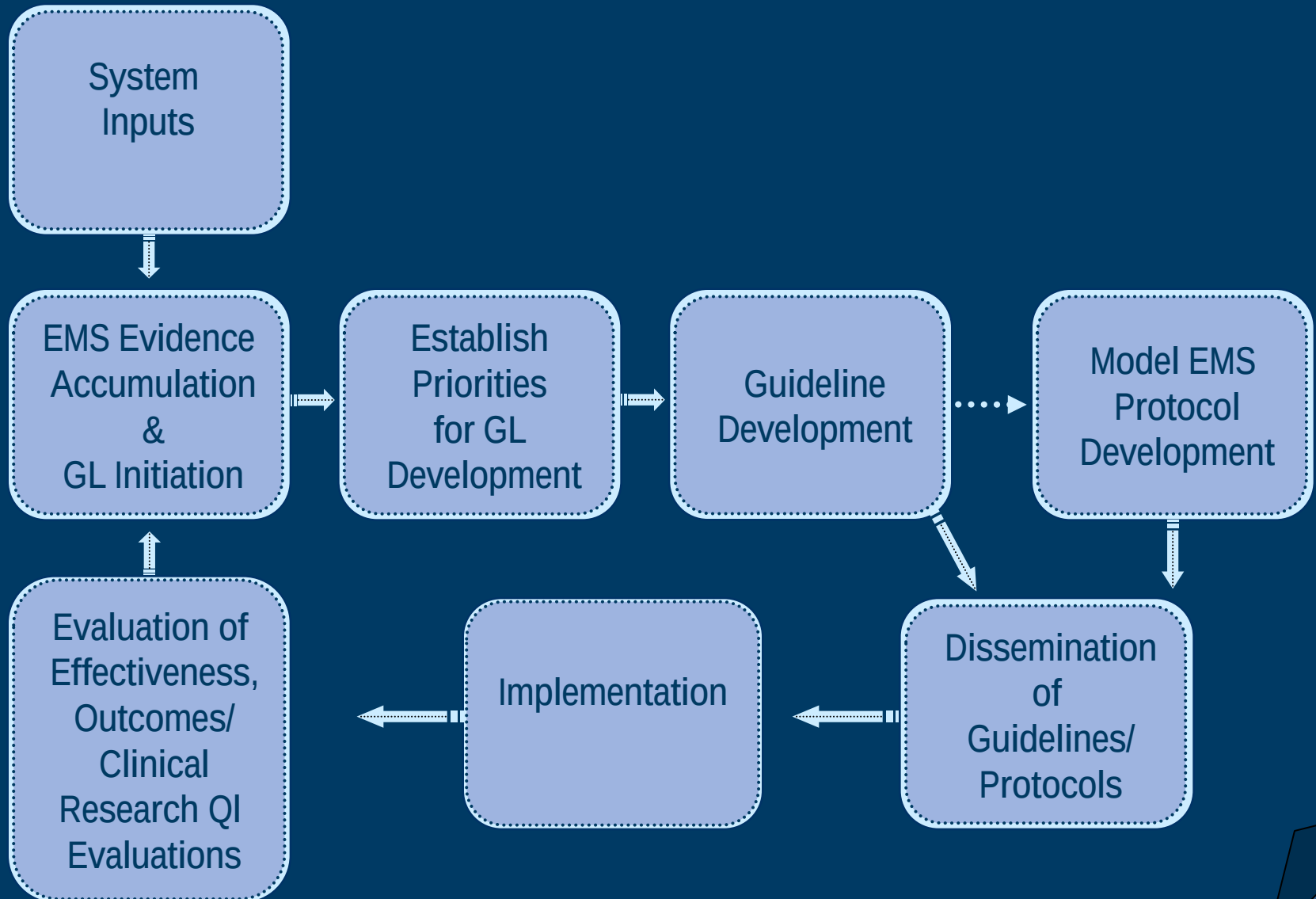
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Purpose of Conference

- To provide input on the process for national EMS evidence-based guidelines:
 - Methodology and organization
 - Sustainability of the process
 - Provide the basis for implementing EBGs into EMS care
 - Ensure an ongoing method for revising guidelines
 - Integrate with other national EMS system development strategies (National EMS Scope of Practice Model, National EMS Education Standards, etc.)

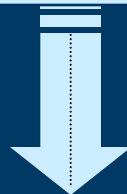
Draft National Model : Awaiting FICEMS Endorsement

EMS Evidence-based Guideline Development Process



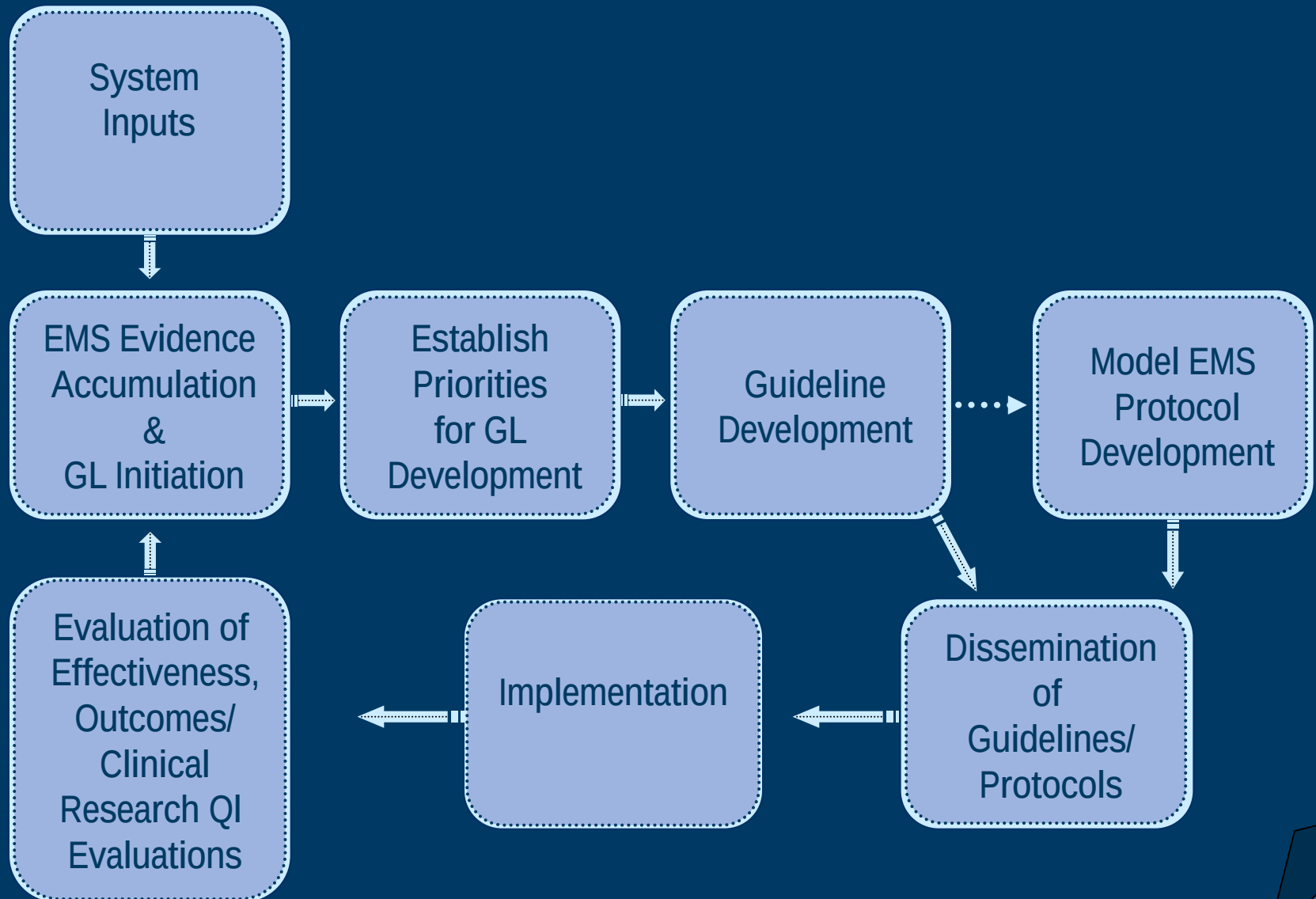
System Inputs

1. External evidence synthesis processes, e.g.,
Cochrane systematic reviews, EPCs
2. Externally developed protocols from existing systems with
EBG processes in place (Nova Scotia EMS System)
3. Prehospital components of externally developed
guidelines, e.g., AHA, NAEMSP, BTF
4. Scope of practice & national EMS education standards
5. Individual researchers, medical directors & EMS personnel
6. Academic institutions



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EMS Evidence-based Guideline Development Process





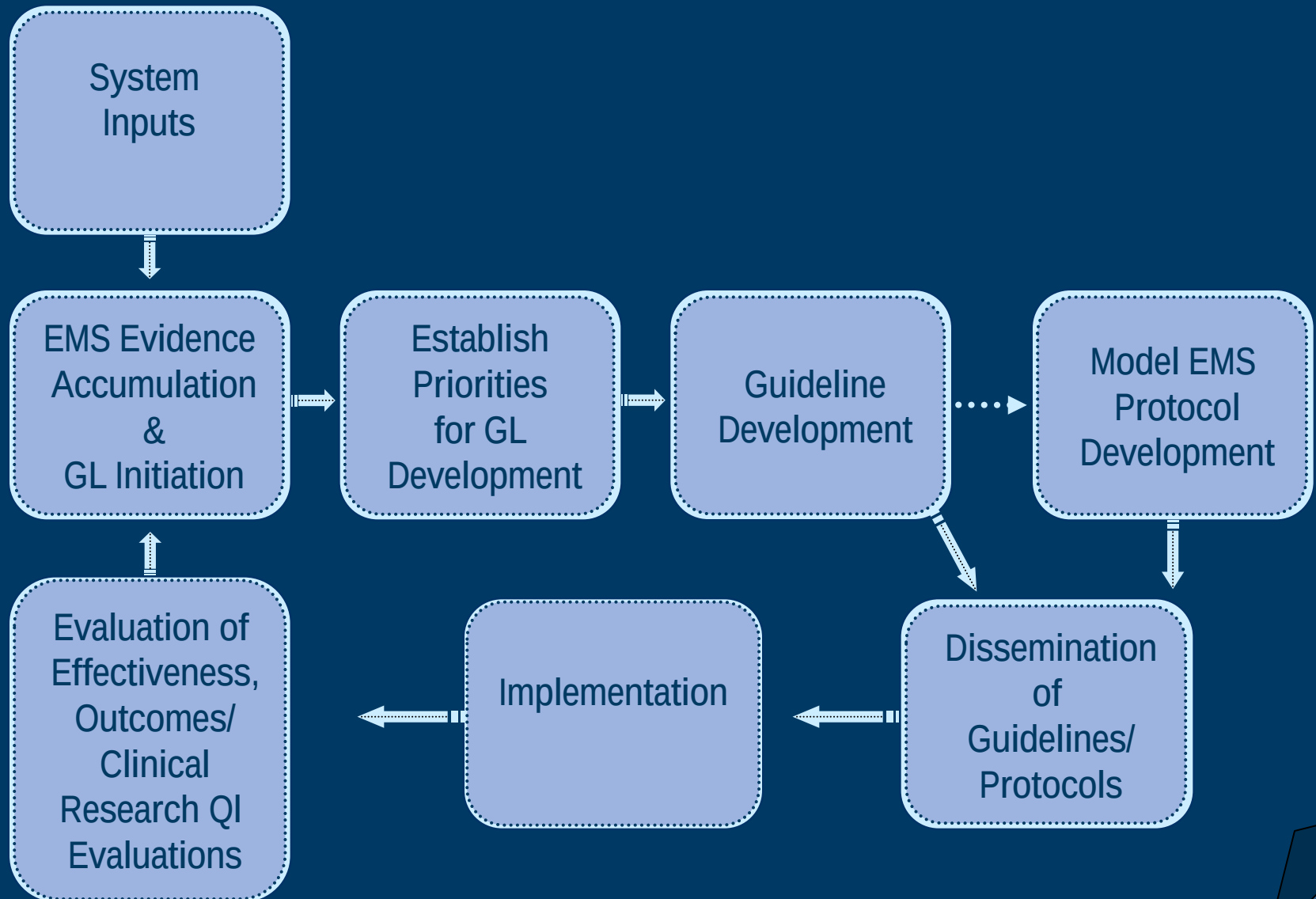
EMS Evidence Accumulation, Evaluation & GL Initiation

1. Accept proposals for GL topics
 2. Identify existing systematic reviews
 3. Recommend need for (or conduct) systematic review
- 



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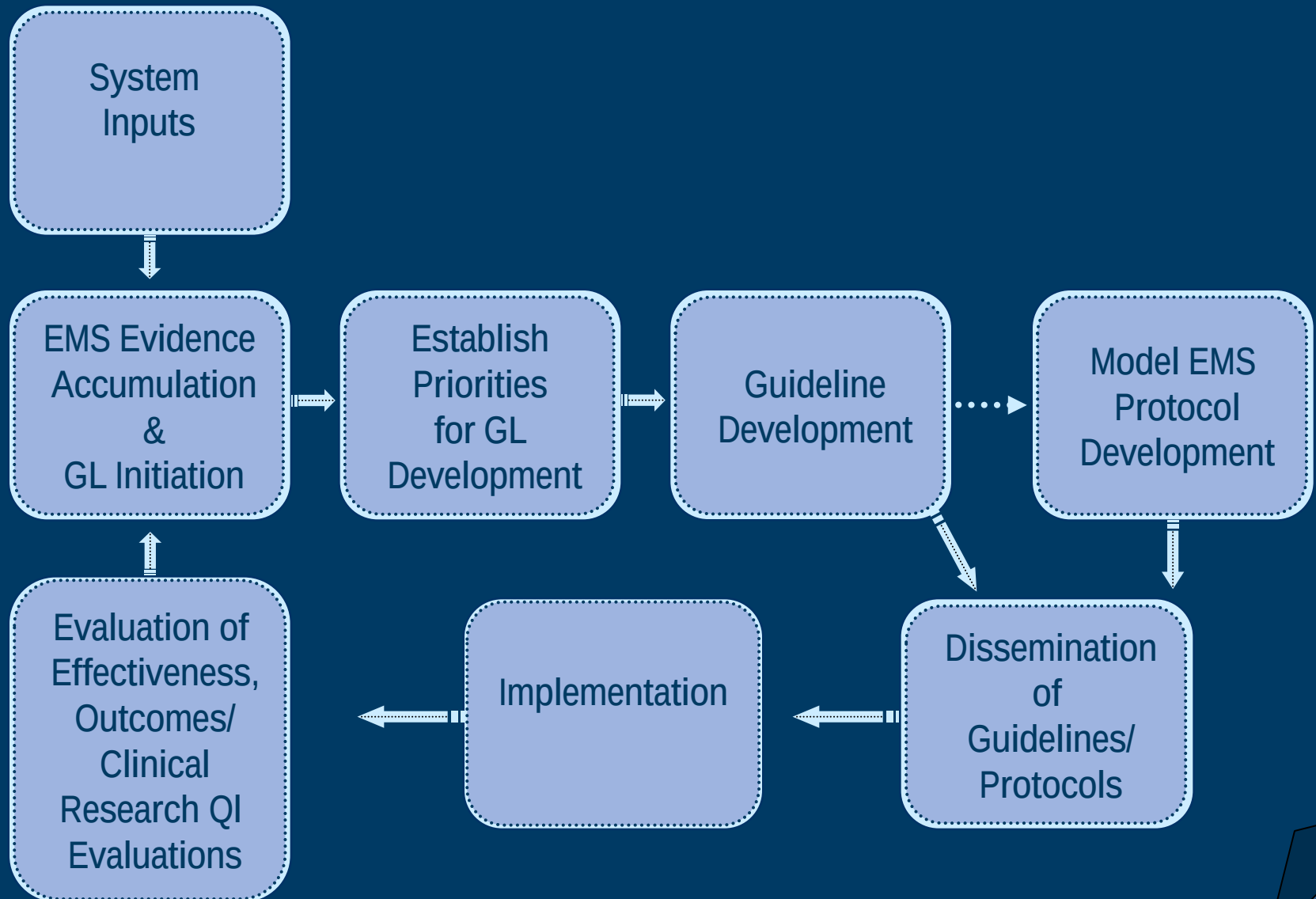


Establish Priorities for GL Development

- Evaluate quality of evidence supporting extant GLs (e.g., AGREE methodology)
 - Evaluate evidence for potential guidelines
 - Recommend topics for further GL development
 - Archive material not selected for reference and future development
- 

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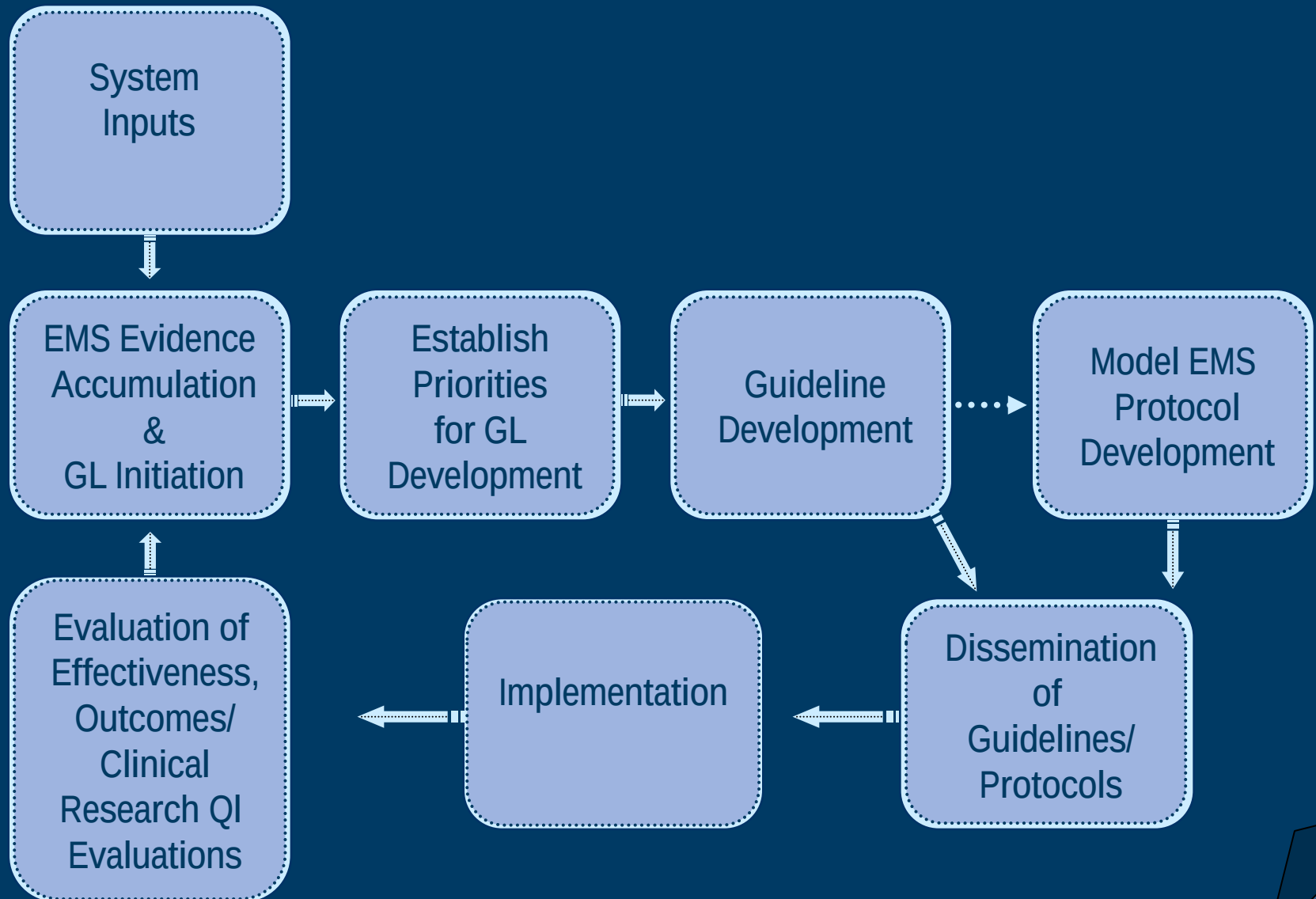


Guideline Development

1. Document risks & benefits of intervention.
First do no harm.
2. Develop strength of recommendation, e.g., GRADE
3. Document rationale for “no recommendation”;
disseminate.
4. EMS “contextualization”
5. Write or endorse guideline
6. Provide feedback to originating institution or
organization

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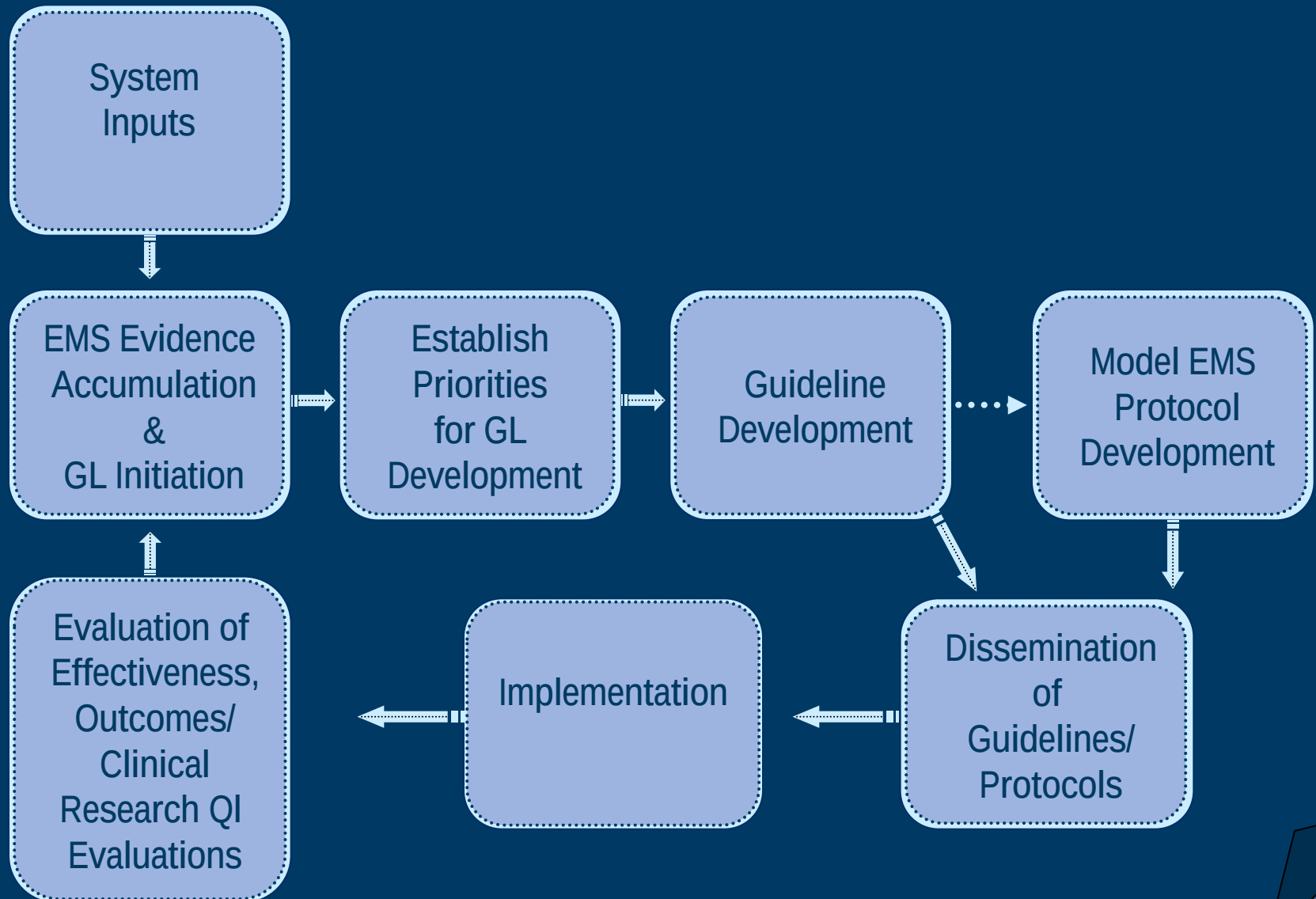


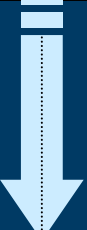
Model EMS Protocol Development

1. EMS “contextualization”
2. Clinical implications of strength of recommendation
 - Protocols must carry with them information related to the strength of evidence, risks, and caveats.
 - This allows EMS leaders and medical directors to understand the potential implications of implementation

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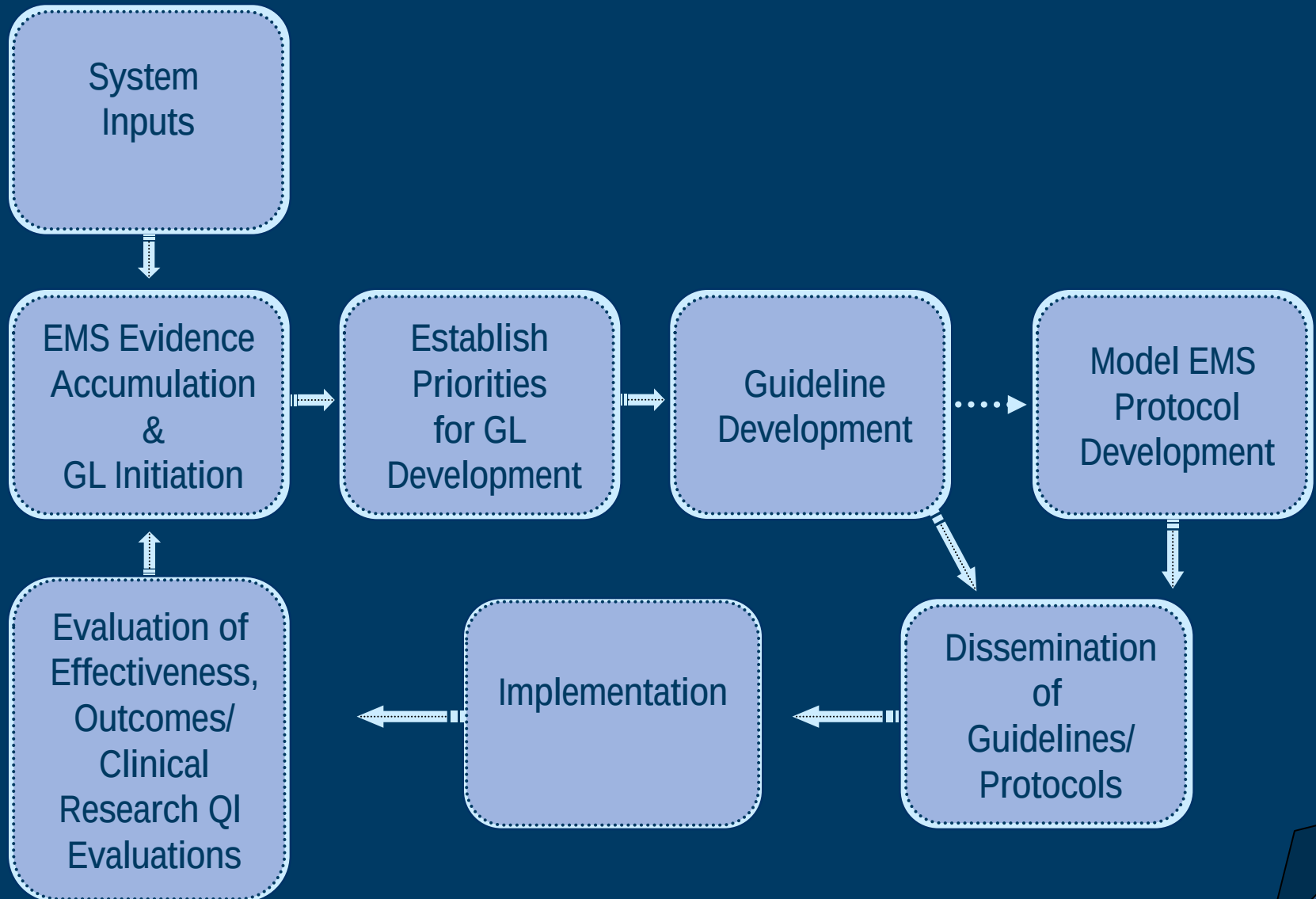


Dissemination of Guidelines/Protocols

1. Linked to EMS Education Agenda for the Future →
Core Content → Scope of Practice Model →
National EMS Education Standards
 2. Linked to National EMS Education Program Accreditation
 3. Publications: peer-reviewed journals, trade press,
textbooks, govt. reports.
 4. New products: educational materials, QI improvement
materials
 5. Target stakeholder organizations
 6. Multimedia approach: ems.gov, podcasts, etc.
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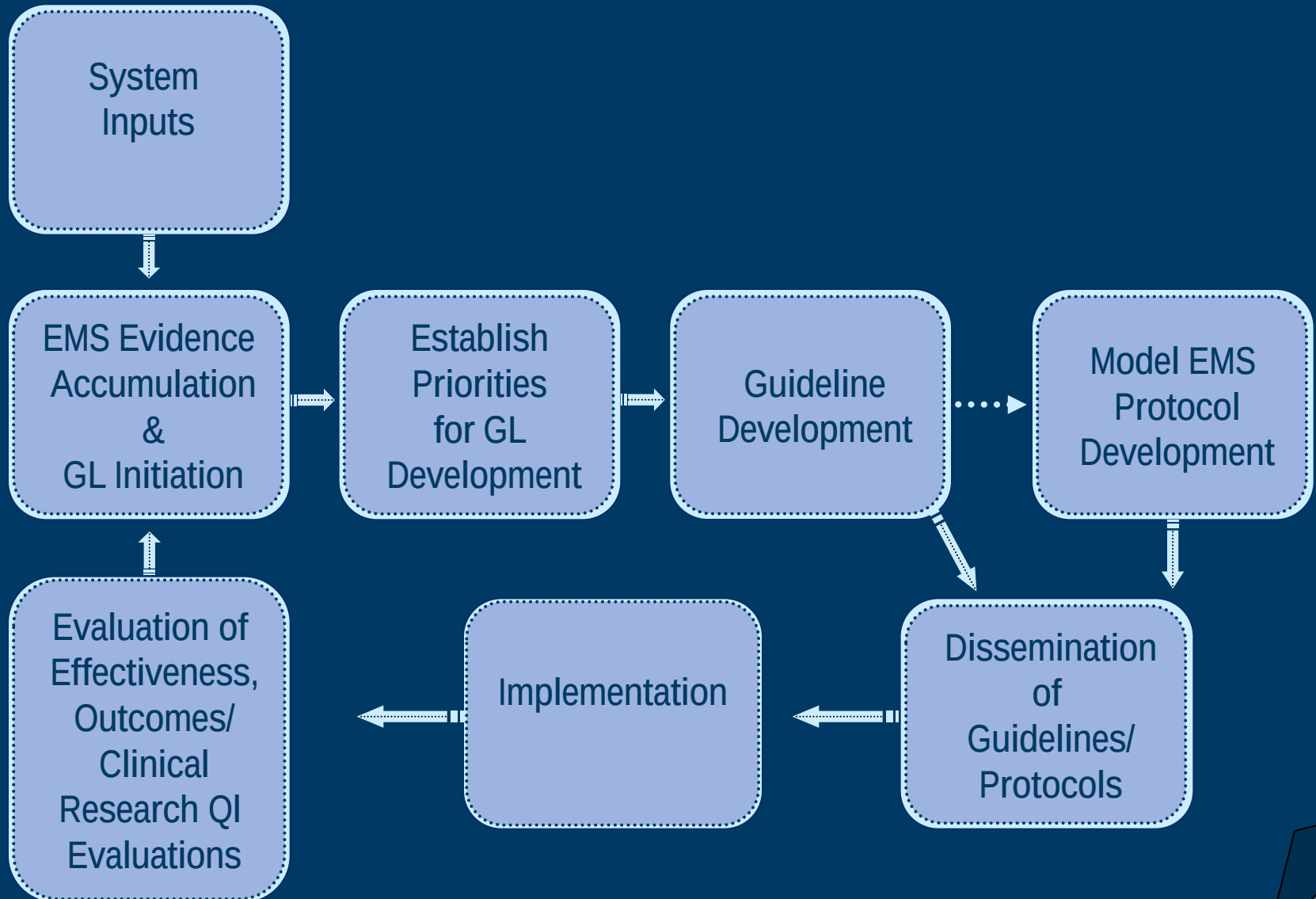


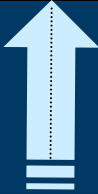
Implementation

1. Linked to National EMS Provider Certification/Recertification
2. Linked to National EMS Agency accreditation
3. Development of GL implementation “tool kits,” webinars, manuals, integration in local protocols
4. Partnerships with national organizations to facilitate interpretation, application & medical direction.
5. Potentially linked to funding and reimbursement, e.g., CMS, 3rd party
6. Development of health informatics & clinical decision support software.
7. Develop QI measures & tools – local, regional, state & tribal

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EMS Evidence-based Guideline Development Process





Evaluation of Effectiveness, Outcomes/Clinical Research, QI Evaluations

- GL/protocol pilot testing/feasibility studies (may occur during development process)
 - Monitor local QI benchmarks & indicators, QI processes at all levels
 - Apply NEMSIS data in evaluation process
 - Outcomes research: EMSOP – local, regional statewide, national
 - Clinical research of specific questions
 - Systems research (EMSOP II & IV)
 - Cost effectiveness, cost-utility, cost-benefit analyses (EMSCAP papers)
 - Implementation research – analysis of barriers & facilitators to implementation
- 

Building the National Model

Where do we go from here?

Overall goal

- Well-defined, consistent national system for the development and dissemination of prehospital EMS evidence-based guidelines
 - Integrated with National EMS Scope of Practice Model, National EMS Education Standards
 - Integrated into practice

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Where do we go from here?

Implementation

- Define ongoing, sustainable and consistent system
 - Coordinated Federal and national effort
- Integrate into practice of new EMS personnel
 - Modification of national EMS scope of practice model
 - Modification of national EMS education standards
- Integration into practice of existing EMS personnel
 - Coordination with continuing education requirements of national EMS certification

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Where do we go from here?

Implementation

- Financial sustainability
 - Federal funding?
 - Grants
 - EMS Evidence-based Practice Center (AHRQ)
 - Private funding?
 - Other alternatives?

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Where do we go from here?

Research

- Evaluate:
 - New guideline/protocol development
 - Components of the model
 - Effectiveness of implementation strategies
 - Impact of guidelines on patient outcomes

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HUGE QUESTIONS

- Where will funding come from for a sustainable model?
- Is wide-spread implementation feasible since EMS is intensely “local.”
 - E.g. In Arizona, there are nearly 200 EMS medical directors and each of them has the regulatory authority to determine clinical protocols for their system.
- Can the barriers to knowledge transfer be overcome:
 - E.g. National TBI guidelines are in 3rd edition from BTF and 2nd edition from NAEMSP...and yet...in many systems...the prehospital management for TBI is still hyperventilation.
- Are we **SURE** we mean **EVIDENCE**-based guidelines...OR...do we **REALLY** mean **CONSENSUS**-based guidelines?
 - Long tradition: “GOBSAT Method”
- Is EMS really ready for **EVIDENCE** as the basis for what we do???

QUESTIONS

???



Draft National Model EMS Evidence-based Guidelines Development Process

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- * COI/Disclosure required for all participants, including submitters

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