A Model-Integrated Approach to Implementing Individualized Patient Care Plans Based on Guideline-Driven Clinical Decision Support and Process Management

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Goals

- Create a tool to manage a ubiquitous, complex clinical process

- Deploy the tool in the ICUs and ED

- Evaluate changes in clinical practice

- Iterate, targeting other clinical problems

The ICU Environment

- Information-intense environment

- Humans have limited data-managing capacity

- Mismatch: unnecessary variation, clinical errors, poor compliance with guidelines

- Technology to the rescue

1 Ann Intern Med. 2000;132:373-383.
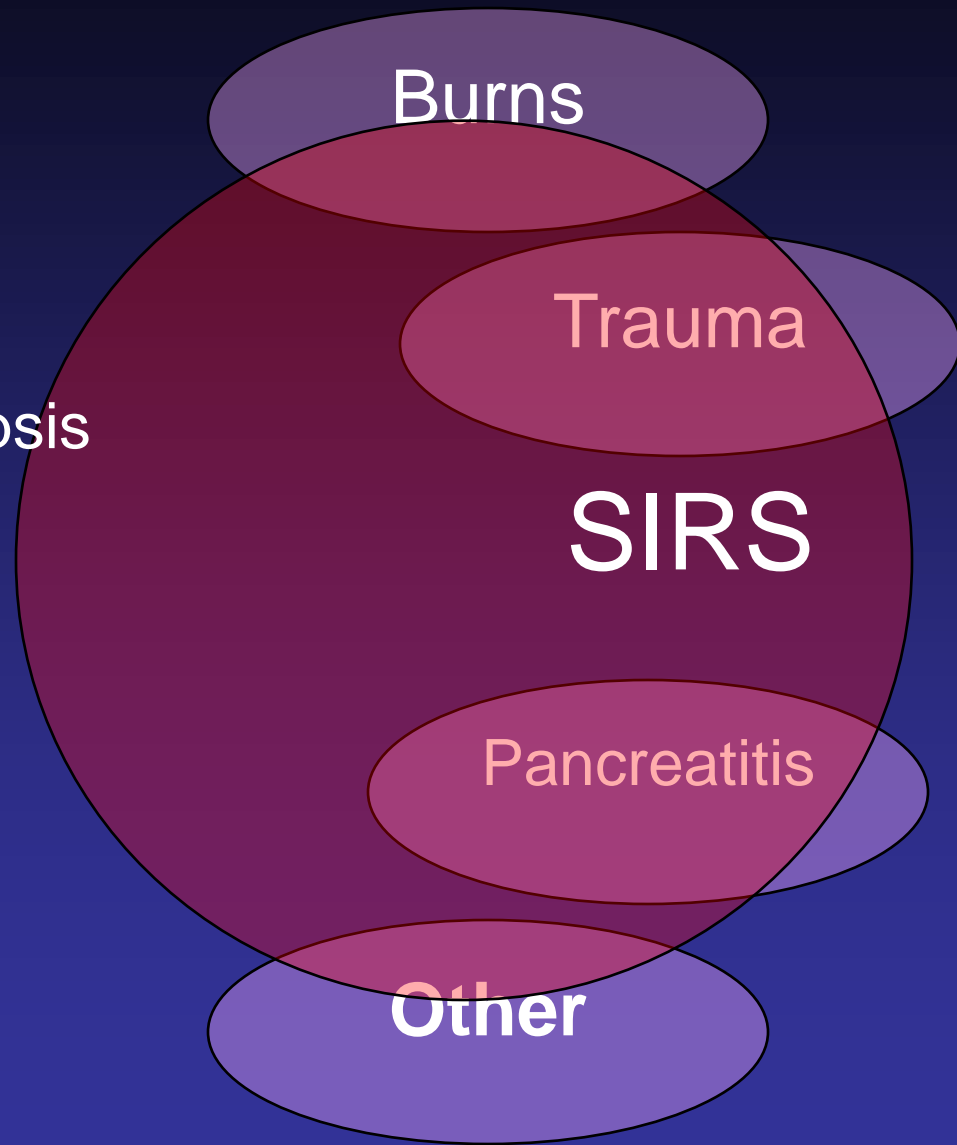
Sepsis is Common

- 1-3 cases per 1000 in the population

- 750,000 cases in the US annually

- Who gets sepsis?
    - Men > women
    - Typically in their 6th or 7th decade
    - Immunocompromised

- Despite these observations, no definitive age, gender, racial, or geographic boundaries

Sepsis is Deadly

- Mortality approaches 30% in patients with severe sepsis

- Mortality roughly correlates with the number of dysfunctional organ systems

- On average, patients have 2-3 organs failing at presentation to the ICU

Sepsis is Expensive

- Average hospital stay is 3-5 weeks for severe disease

- Average patient bill is tens of thousands of dollars

- $17 B annual expenditure to the US healthcare

- 40% of all ICU costs?

Treatment

- Surviving Sepsis Campaign

- "To improve the management, diagnosis, and treatment of sepsis."

- Reviewed evidence, graded literature, formulated consensus guidelines

- Suggested the use of protocols and bundles

Current Conclusions
Re: Sepsis Bundles

- Associated with positive changes in practice

- More rapid resolution of organ failures

- Reduction in total hospital, ED or ICU LOS

- Decrease hospital costs

- Mortality effect

The Clinical Protocol

Identification of a Septic Patient

Hypoperfusion

Empiric abx

EGDT

Steroid consideration

Xigris consideration

Glucose control

DVT prophylaxis

Stress ulcer prophylaxis

No hypoperfusion

Empiric abx
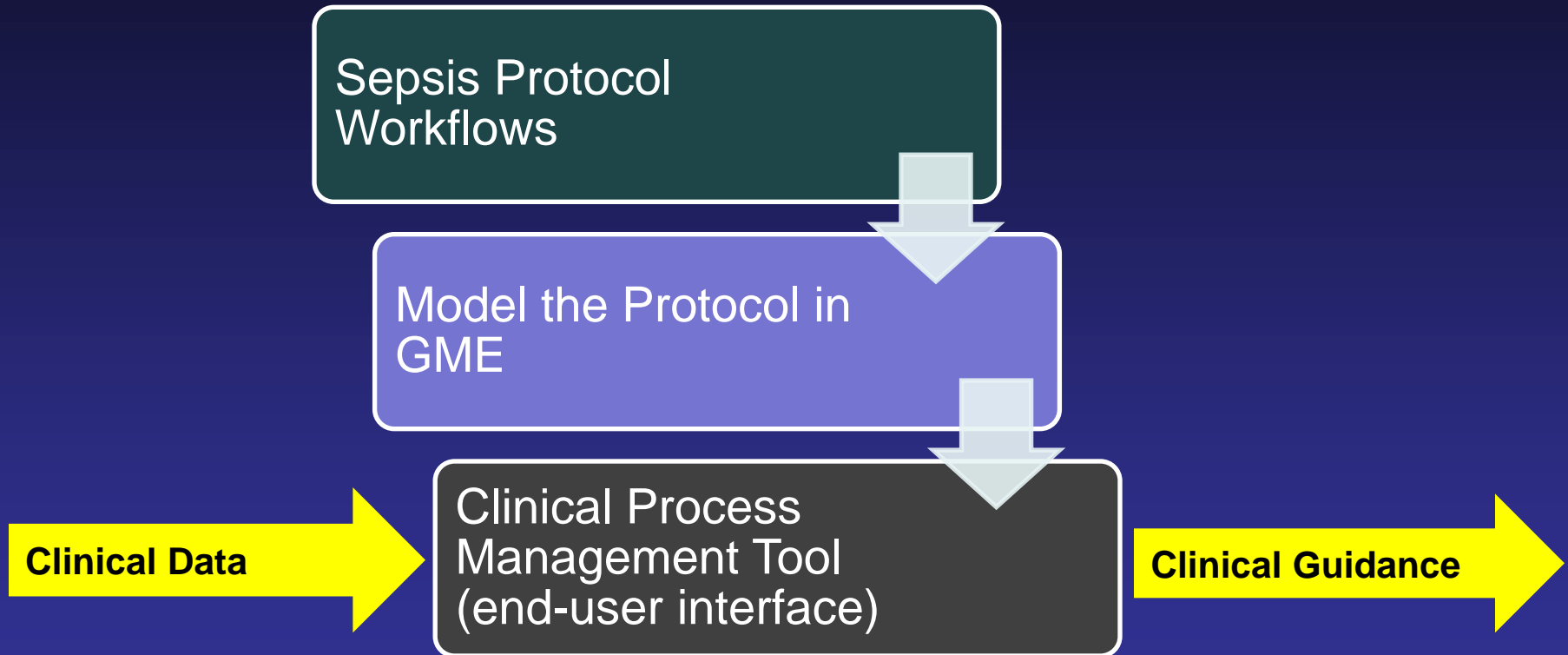
Xigris consideration

Glucose control
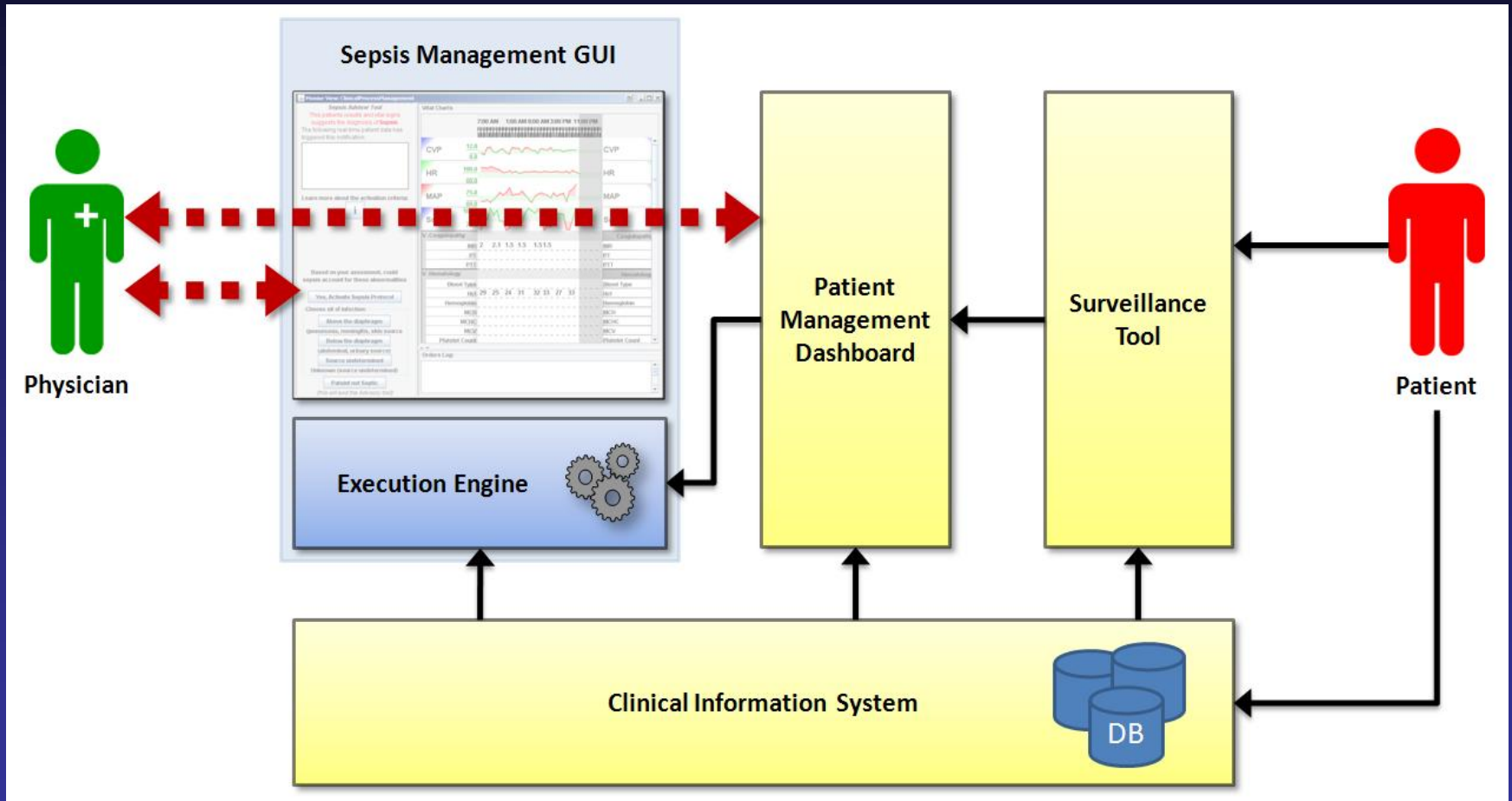
DVT prophylaxis

Stress ulcer prophylaxis

The STEEP Application

- Identify patients based on modified SIRS criteria

- Prompt clinical teams

- Provide real-time process management recommendations based on live patient data

- Serve as a data repository

Sepsis Tool Architecture

Sepsis Protocol Workflows

Model the Protocol in GME

Clinical Data

Clinical Process Management Tool (end-user interface)

**Clinical Guidance**

Proposed Architecture

Motivation behind creating treatment protocols

- Assuming that evidence based medicine is best practice (research is always correct, and publicly available)
- All we have to do is keep up with relevant research
- Number of new publications is overwhelming*
- But let us assume we do manage to figure out what is best practice
- How do we make sure that physicians (including interns, residents, fellows, etc.) will know about it and treat according to it?
- Our proposed solution: build protocols in a formal manner and use them to achieve clinical process management

*Daniel Masys, M.D., "The Informatics of 21st Century Healthcare", MOTHIS 2007 (keynote)

Decision Support vs. Process Management

- Decision Support
  - decisions/answers to specific questions at independent points during treatment

- Process Management
  - guides you trough a complete treatment, it's like a GPS, it also recalculates if not followed
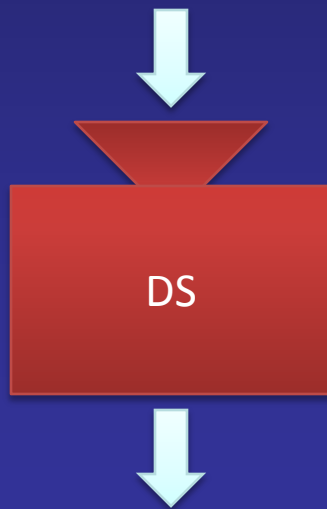
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Creating a modeling language for representing treatment protocols

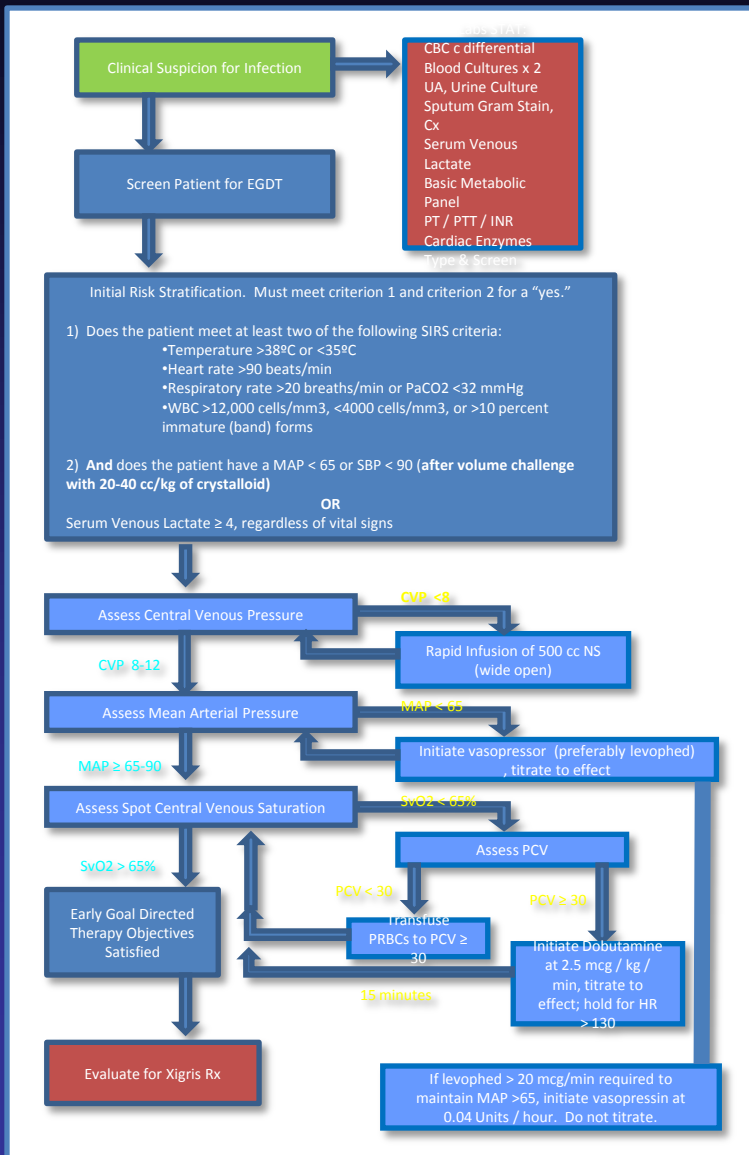- We started out with the flow diagrams available in current literature (for treating sepsis)

First iteration
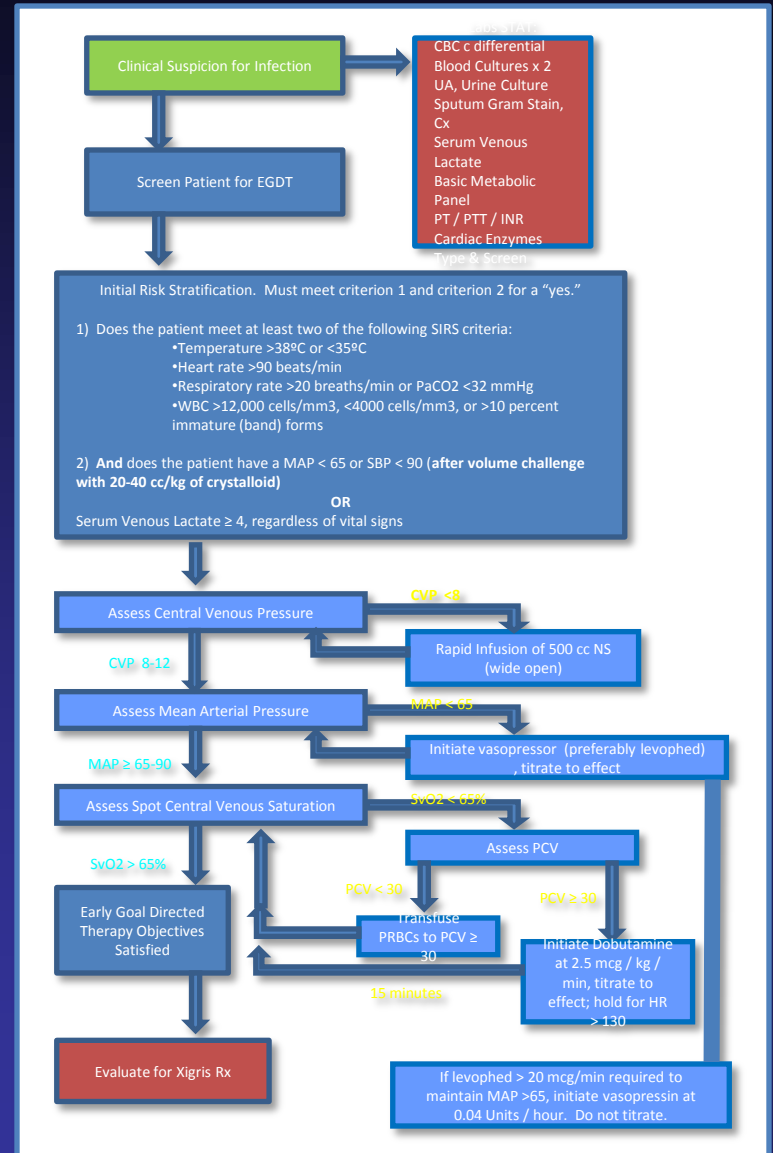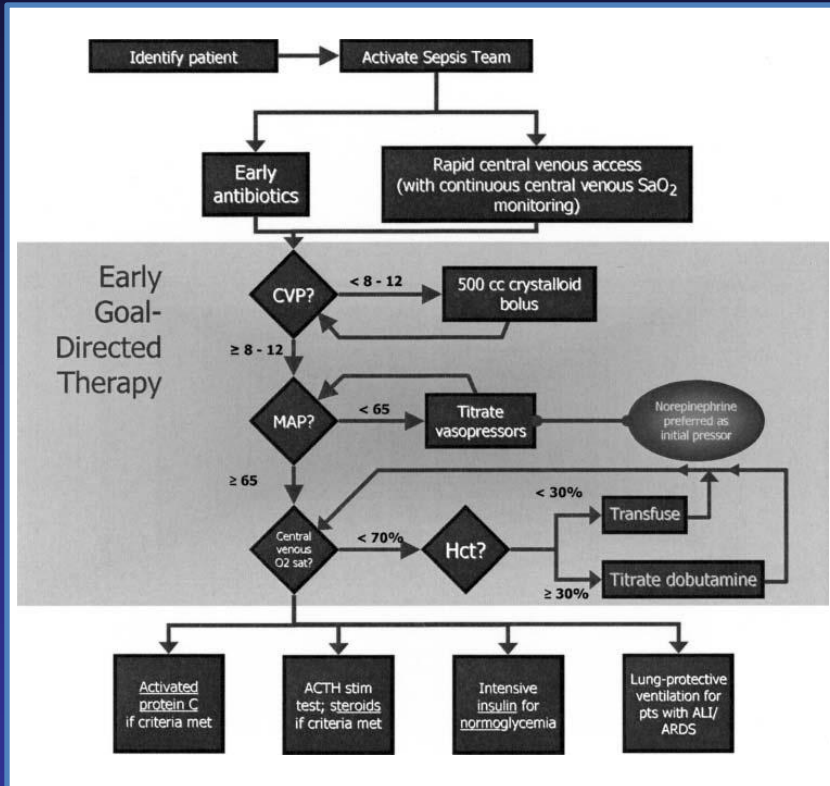
*A Blueprint for a Sepsis Protocol, Shapiro et. al., ACAD EMERG MED d April 2005, Vol. 12, No. 4

Creating a modeling language for representing treatment protocols

- We started out with the flow diagrams available in current literature (for treating sepsis)

- Rigid structure, simple operational semantics, but cumbersome (jumping around in the tree causes a messy representation)
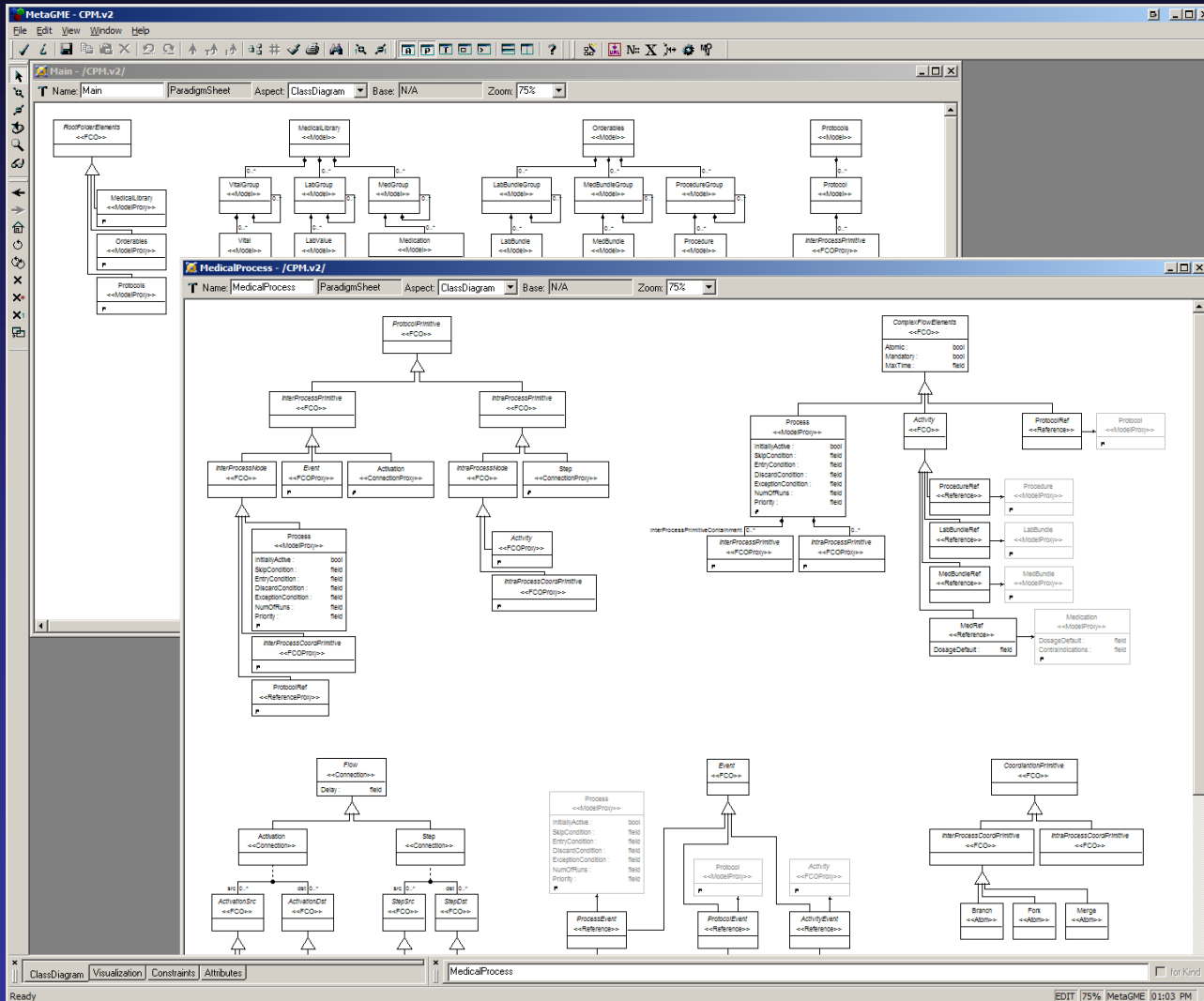
Further iterations

Clinical Suspicion for Infection

CBC c differential
Blood Cultures x 2
UA, Urine Culture
Sputum Gram Stain, Cx
Serum Venous Lactate
Basic Metabolic Panel
PT / PTT / INR
Cardiac Enzymes
Type & Screen

Screen Patient for EGDT

Initial Risk Stratification. Must meet criterion 1 and criterion 2 for a "yes."

1) Does the patient meet at least two of the following SIRS criteria:
- Temperature >38ºC or <35ºC
- Heart rate >90 beats/min
- Respiratory rate >20 breaths/min or PaCO2 <32 mmHg
- WBC >12,000 cells/mm3, <4000 cells/mm3, or >10 percent immature (band) forms

2) **And** does the patient have a MAP < 65 or SBP < 90 (**after volume challenge with 20-40 cc/kg of crystalloid)**
                          OR
Serum Venous Lactate ≥ 4, regardless of vital signs

Assess Central Venous Pressure

CVP <8

Rapid Infusion of 500 cc NS (wide open)

CVP 8-12

Assess Mean Arterial Pressure

MAP < 65

Initiate vasopressor (preferably levophed), titrate to effect

MAP ≥ 65-90

Assess Spot Central Venous Saturation

SvO2 < 65%

Assess PCV

SvO2 > 65%

PCV < 30

PCV ≥ 30

Early Goal Directed Therapy Objectives Satisfied

Transfuse PRBCs to PCV ≥ 30

Initiate Dobutamine at 2.5 mcg / kg / min, titrate to effect; hold for HR > 130

15 minutes

Evaluate for Xigris Rx

If levophed > 20 mcg/min required to maintain MAP >65, initiate vasopressin at 0.04 Units / hour. Do not titrate.

Clinical Process Modeling Language (CPML)

- CPML supports the design, specification, analysis, verification, execution and validation of complex clinical treatment processes.
- CPML is built upon the Generic Modeling Environment (GME) from the Institute for Software Integrated Systems (ISIS) at Vanderbilt University.
- There are three main components in CPML
  - Medical Library
    - a placeholder for hierarchically categorizing general medical knowledge
  - Orderables
    - a library for orderable medications, procedures, etc. and
    - executable (medical) actions that are specific to a healthcare organization built from the elements defined in the Medical Library)
  - Protocols
    - concept, in which treatment protocols can be described

GME approach

1. Development of abstractions in Domain-Specific Modeling Languages (DSMLs)
2. Construction of the models: capturing the key elements of operation
3. Translation (interpretation) of models
4. Execution and simulation of models

1. Metamodel

2. Sepsis models

Experimental Architecture
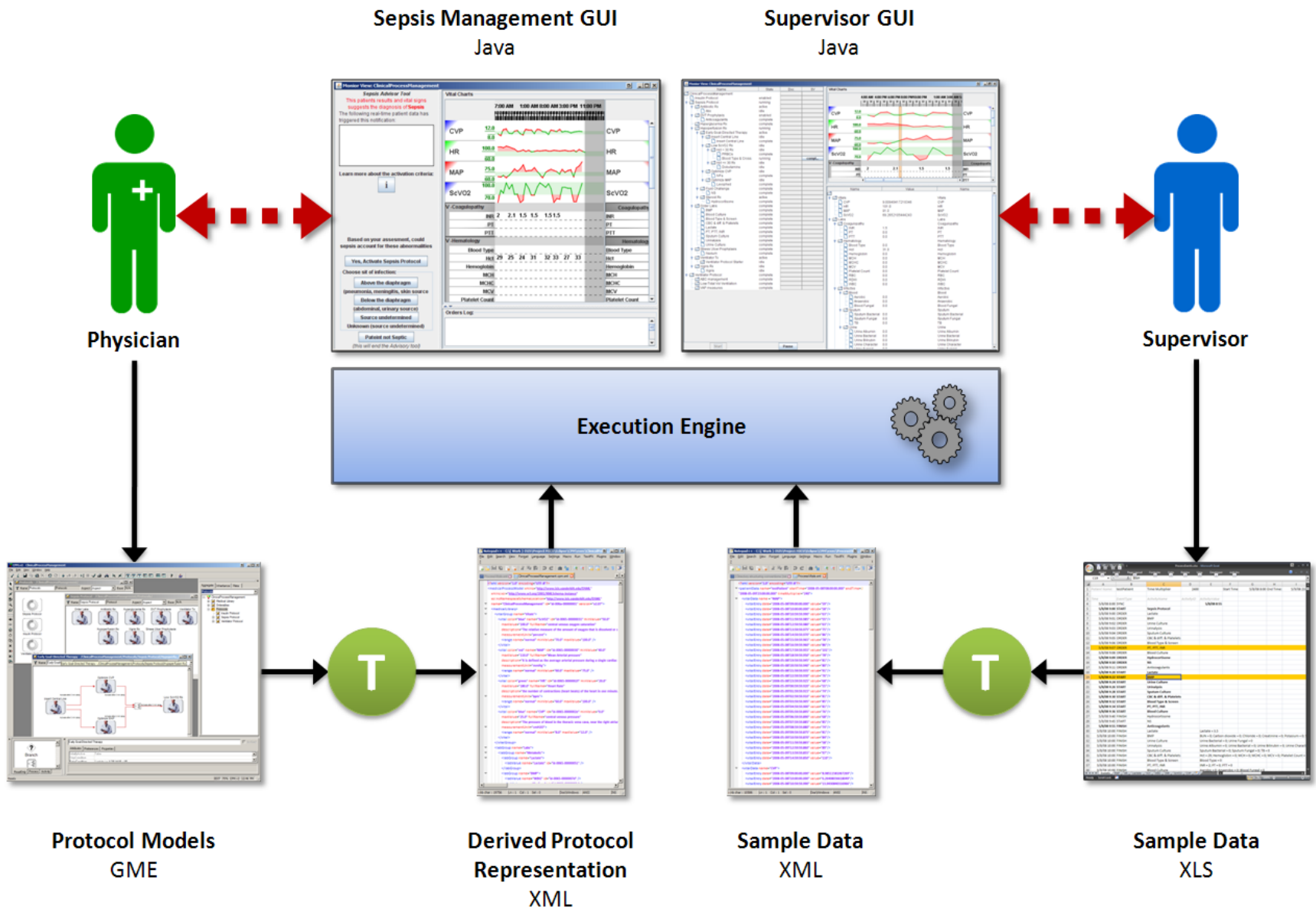
Results

- Developed a modeling environment for formally representing clinical guidelines and treatment protocols
- Captured a treatment protocol for sepsis using the modeling environment working together with healthcare professionals
- Developed a execution and simulation environment for the validation of the protocol and for the testing of the effectiveness of the tool
- Created execution plan for clinical testing

These techniques are being applied to the management of sepsis in acute care settings at Vanderbilt Medical Center

Future Work

- Integrate with team-based clinical practice
- Interface with existing clinical systems to be able to monitor of all relevant clinical conditions
- Evaluate the effectiveness of the tool using historical outcome metrics
- Experiment with supportive technologies
  - such as large touch-screens
- Verify continuity in existing implementation
- Target other acute and chronic diseases