CS 520
Theory and Practice of Software Engineering
Fall 2022

Process-model-based guidance for medical clinicians

November 29, 2022
Many medical procedures are complex and inherently error prone

- Multiple specialty teams
- Concurrent activities
- Team communication
- Exceptional situations where problems are identified and need to be addressed
Goal: Support Human Performance in the Operating Room

Reduce preventable errors by providing guidance to surgical teams carrying out medical procedures (or processes)

• Model normative situations and non-normative (i.e. unusual or exceptional) situations where problems are identified and must be addressed
• Provide automated guidance based on a validated medical process model both offline and online
Limitations of Previous Approaches

- Process guides (e.g., checklists) often do not model some situations that are highly complex and high risk — e.g., non-normative situations, team communication

- Most guides are static so lack dynamic process context

- Dynamic guides hardcode the process so cannot be easily updated when that process changes

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Our approach

1. **Model** the recommended medical procedure (or process)

2. **Validate** this process model

3. **Provide automated guidance** to the medical clinicians based on the process model
Our approach

1. **Model** the recommended medical procedure (or process)
2. **Validate** this process model
3. **Provide automated guidance** to the medical clinicians based on the process model

After the real-world process changes, modify the process model, revalidate that model, and automatically update the guidance.
Case studies

- Blood transfusion
- Chemotherapy
- Emergency room care
- Infusion therapy
- Memory and aging care
- Cardiac surgery
Case studies

- Blood transfusion
- Chemotherapy
- Emergency room care
- Infusion therapy
- Memory and aging care
- **Cardiac surgery**
  - Aortic valve replacement (AVR)
  - Coronary artery bypass grafting (CABG)
Collaborators

• Medical clinicians
  – e.g., Anesthesiologists, Doctors, Nurses
• Human factors and UI experts
  – e.g., Brigham & Women’s Hospital STRATUS lab
• Biomedical engineers
  – e.g., Mass General Hospital OpenICE lab
• Computer scientists
1. Model the medical process

1.1) Elicit the medical process
• From published documents and medical clinicians

1.2) Define the medical process model
• Use the Little-JIL process modeling language which is expressive and has rigorous execution semantics
Elicit the medical process
Little-JIL Process Modeling Language

- Hierarchically decomposes the process model into steps
- Has rigorous execution semantics
Little-JIL Process Modeling Language

• Hierarchically decomposes the process model into steps

• Has rigorous execution semantics

[Cass2000]
Little-JIL Process Modeling Language

• Hierarchically decomposes the process model into steps
  - Pre-Requisite
  - Post-Requisite
  - Substep(s) and their order
  - Exception Handler(s)
  - Resources, Other Data, Exceptions Thrown

• Has rigorous execution semantics

[Cass2000]
Little-JIL Process Modeling Language

• Hierarchically decomposes the process model into steps

• Has rigorous execution semantics


Concurrent program

Pre-Requisite

Post-Requisite

Substep(s) and their order

Exception Handler(s)

Resources, Other Data, Exceptions Thrown
Heparinization Modeled in Little-JIL

- HDR Recommended Heparin Dose > 400
- Decision to Use Pump Sucker == YES
- Report suspicion of heparin resistance
- Administer HDR recommended heparin then verify ACT
- Turn on pump sucker
- Follow heparin resistance protocol
- Perform heparinization
- Gather anesthesiology, perfusion, and surgery team leaders
- Treat heparin resistance
- Report low ACT

Carried out by: Perfusion
Carried out by: Perfusion
Carried out by: Perfusion
Carried out by: Surgeon
Heparinization Modeled in Little-JIL

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- Gather anesthesiology, perfusion, and surgery team leaders
- Treat heparin resistance
- Report low ACT
- Try to address problem Low ACT
Heparinization Modeled in Little-JIL

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- Decision to Use Pump Sucker == YES
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- Administer HDR recommended heparin then verify ACT
- Turn on pump sucker
- Follow heparin resistance protocol
- Perform heparinization
- Gather anesthesia, perfusion, and surgery team leaders
- Treat heparin resistance
- Address problem No More Alternatives
- Report low ACT

Carried out by: Perfusion
Carried out by: Anesthesiology and Perfusion
May report problem Low ACT
Carried out by: Surgeon
Carried out by: Anesthesiology, Perfusion, Surgeon
Try different alternatives to address problem Low ACT
May report problem No More Alternatives
Heparinization Modeled in Little-JIL

perform heparinization

HDR Recommended Heparin Dose > 400

Decision To Use Pump Sucker == YES

report suspicion of heparin resistance

administer HDR recommended heparin then verify ACT

turn on pump sucker

follow heparin resistance protocol

gather anesthesiology, perfusion, and surgery team leaders

treat heparin resistance

report low ACT

Carried out by: Perfusion

- Carried out by: Anesthesiology and Perfusion
- May report problem Low ACT

Address problem NoMoreAlternatives

Carried out by: Surgeon

- Carried out by: Anesthesiology, Perfusion, Surgeon
- Try different alternatives to address problem LowACT
- May report problem NoMoreAlternatives
Heparinization Modeled in Little-JIL

1. HDRRecommendedHeparinDose > 400
2. HDR Recommended Heparin
3. DecisionToUsePumpSucker == YES
4. Decision To Use Pump Sucker
5. Decision To Use Pump Sucker
6. Turn on pump sucker
7. Follow heparin resistance protocol
8. Report suspicion of heparin resistance
9. Administer HDR recommended heparin
10. Then verify ACT
11. Perform heparinization
12. Gather anesthesiology, perfusion, and surgery team leaders
13. Treat heparin resistance
14. Report low ACT
15. Address problem NoMoreAlternatives
16. May report problem LowACT
17. Carry out by: Perfusion
18. Carry out by: Anesthesiology and Perfusion
19. May report problem LowACT
20. Carry out by: Surgeon
21. Carry out by: Anesthesiology, Perfusion, Surgeon
22. Try different alternatives to address problem LowACT
23. May report problem NoMoreAlternatives
2. Validate the medical process model

- Manual reviews by medical clinicians
- Automated analyses (e.g., model checking)
Automatically generated process review document

### Perform Heparinization

**Requires:**
The following team members should be scheduled and available: anesthesiologist, perfusionist, surgeon. Additionally, the following people and equipment should be scheduled and available: CPB pump, patient.

The following should be provided: target ACT (in s), HDR recommended heparin dose (in u/kg), decision to use pump sucker

**What to do:**
To perform this step, the following should be done in the listed order:

- If HDR recommended heparin dose (in u/kg) is greater than 400 u/kg, report suspicion of heparin resistance
- administer HDR recommended heparin, then verify ACT
- If the problem Low ACT is identified, follow heparin resistance protocol should be done. If follow heparin resistance protocol is completed without problems, this step should continue on to the next step. If the problem Low ACT is identified, then this step should be considered completed with a problem and the identified problem should be reported.

- If decision to use pump sucker is YES, turn on pump sucker

**Outcomes:**
If the problem Low ACT is identified, then this step should be considered completed with a problem and the identified problem should be reported.

### Report Suspicion Of Heparin Resistance

**Requires:**
The perfusionist is needed to perform this step.

The HDR recommended heparin dose (in u/kg) should be provided.

**What to do:**
Perform Heparinization

Requires:
The following team members should be scheduled and available: anesthesiologist, perfusionist, surgeon. Additionally, the following people and equipment should be scheduled and available: CPB pump, patient.

The following should be provided: target ACT (in s), HDR recommended heparin dose (in u/kg), decision to use pump sucker.

What to do:
To perform this step, the following should be done in the listed order:

- If **HDR recommended heparin dose (in u/kg)** is greater than 400 u/kg, report suspicion of heparin resistance
- administer HDR recommended heparin then verify ACT

  - If the problem **Low ACT** is identified, follow **heparin resistance protocol** should be done. If follow **heparin resistance protocol** is completed without problems, this step should continue on to the next step. If the problem **Low ACT** is identified, then this step should be considered completed with a problem and the identified problem should be reported.

- If **decision to use pump sucker** is YES, turn on pump sucker

Outcomes:
If the problem **Low ACT** is identified, then this step should be considered completed with a problem and the identified problem should be reported.

Report Suspicion Of Heparin Resistance

Requires:
The perfusionist is needed to perform this step.

The HDR recommended heparin dose (in u/kg) should be provided.

What to do:
Automated analyses

• **Model checking**: Assumes that the modeled steps are performed correctly, but determines whether key steps are always done in the required sequence

• **Fault tree analysis**: What steps would need to be misperformed for a particular hazard to become likely to occur?

• **Discrete-event simulation**: Assess how different what if scenarios impact the potential outcomes
Little-JIL
integrated development environment

Diagram semantics:
- D: Data component
- T: Tool component
Little-JIL
integrated development environment
3. Provide process-model-based guidance to medical clinicians

• **Narration View** for supporting walking through selected training situations (i.e. offline)

• **“Smart” Checklist User Interface** dynamically providing context-aware support during real-world situations (i.e. online)
3. Provide process-model-based guidance to medical clinicians

- **Narration View** for supporting walking through selected training situations (i.e. offline)

- **“Smart” Checklist User Interface** dynamically providing context-aware support during real-world situations (i.e. online)

Similar to regression testing

After the real-world process changes, modify the process model, revalidate that model, and automatically update the guidance
3. Provide process-model-based guidance to medical clinicians

- **Narration View** for supporting walking through selected training situations (i.e. offline)

- **“Smart” Checklist User Interface** dynamically providing context-aware support during real-world situations (i.e. online)

After the real-world process changes, modify the process model, revalidate that model, and automatically update the guidance.
Offline guidance for training

- Automatically generate a narration view providing ahypertext description to selectively explore the alternative paths through a given process model.
Online guidance:
Smart Checklist User Interface

• Automatically create a “smart” checklist user interface to help each specialty team understand:
  – its own dynamic process context
  – the contexts of the other teams

• Dynamically update the user interface by matching the process model against monitored process execution events
  – Store the process history to create post-procedure documentation
Online guidance:
Smart Checklist User Interface (cont.)
Online guidance:
Smart Checklist User Interface (cont.)
Online guidance:
Smart Checklist User Interface (cont.)

Similar to a debugger
Online guidance: Post-procedure documentation

• Automatically create a **process history view** summarizing the actual path through the **process model** completed and can edit to further customize it.
Process-model-based

Process Model

Open Integrated Clinical Environment (OpenICE)

Patient Device Data

Process Execution Monitor

Smart Checklist System

Smart Checklist User Interface

Process History

Narration Generator

Narration View
Process-model-based
Usability

• UI expert design review
• Focus groups held to collect:
  – Questions, comments, and suggestions
  – Usability Survey

<table>
<thead>
<tr>
<th>The System Usability Scale</th>
<th>Strongly disagree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Version</td>
<td>1    2    3    4    5</td>
<td></td>
</tr>
<tr>
<td>1 I think that I would like to use this system.</td>
<td>0 0 0 0 0</td>
<td></td>
</tr>
<tr>
<td>2 I found the system unnecessarily complex.</td>
<td>0 0 0 0 0</td>
<td></td>
</tr>
<tr>
<td>3 I thought the system was easy to use.</td>
<td>0 0 0 0 0</td>
<td></td>
</tr>
<tr>
<td>4 I think that I would need the support of a technical person to be able to use this system.</td>
<td>0 0 0 0 0</td>
<td></td>
</tr>
<tr>
<td>5 I found the various functions in the system were well integrated.</td>
<td>0 0 0 0 0</td>
<td></td>
</tr>
<tr>
<td>6 I thought there was too much inconsistency in this system.</td>
<td>0 0 0 0 0</td>
<td></td>
</tr>
<tr>
<td>7 I would imagine that most people would learn to use this system very quickly.</td>
<td>0 0 0 0 0</td>
<td></td>
</tr>
<tr>
<td>8 I found the system very cumbersome to use.</td>
<td>0 0 0 0 0</td>
<td></td>
</tr>
<tr>
<td>9 I felt very confident using the system.</td>
<td>0 0 0 0 0</td>
<td></td>
</tr>
<tr>
<td>10 I needed to learn a lot of things before I could get going with this system.</td>
<td>0 0 0 0 0</td>
<td></td>
</tr>
</tbody>
</table>
Results

• Automatically provide online and offline guidance to medical teams to reduce preventable errors

• Leverage a process model capturing best practices

• During focus group evaluations, clinicians could see many benefits of such guidance
Some future directions

• Continuing to develop the process-model-driven guidance system based on clinician feedback, e.g.,
  - Semi-automate the scribing
  - Automatically adjust the process guidance based on the clinicians’ real-time cognitive load

• Further evaluating this system by conducting clinical human simulation studies
  - Collaborating with STRATUS Simulation Laboratory at Brigham and Women’s Hospital
APPLICATION OF SOFTWARE ENGINEERING TOOLS AND TECHNIQUES
Smart Checklist framework architecture

Little-JIL process model
[JUL file]

Little-JIL interpreter

2. User command (decoded)

Smart Checklist Server

1. User command (encoded)

Smart Checklist Client (i.e. UI)

3. View updates (decoded)

4. View updates (encoded)
Smart Checklist framework architecture

Little-JIL process model
[JUL file]

Little-JIL interpreter

2. User command
   (decoded)

Smart Checklist Server

1. User command
   (encoded)

Smart Checklist Client (i.e. UI)

3. View updates
   (decoded)

4. View updates
   (encoded)

Similar to
Java virtual machine
Smart Checklist framework architecture

Little-JIL process model [JUL file]

1. User command (encoded)

2. User command (decoded)

3. View updates (decoded)

4. View updates (encoded)

Mediator design pattern
Mediator design pattern

The **Mediator** is responsible for all of the communications among a set of **Colleagues**. (The Colleagues never communicate directly with each other.)

Example:

- Smart Checklist server is the Mediator and Colleagues are Little-JIL interpreter and Smart Checklist UI.

https://en.wikipedia.org/wiki/Mediator_pattern
Process history trace
Process history trace

Similar to Java stack trace
Testability
References

- [http://laser.cs.umass.edu/bugzilla/](http://laser.cs.umass.edu/bugzilla/)

Process Driven Guidance for Complex Surgical Procedures

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Abstract

Surgical team processes are known to be complex and error prone. This paper describes an approach that uses a detailed, validated model of a medical process to provide the clinicians who carry out that complex process with offline and online guidance to help reduce errors. Offline guidance is in the form of a hypertext document describing
Basic Stats app (Version 3)

- src/
  - BasicStatsApp.java
  - gui/ // Views and Controllers
    - BasicStats.java
    - BasicStatsGUI.java // Is the Composite
    - view/
      - *View.java // Are the Components
  - model/
    - BasicStatsModel.java
- test/
  - BasicStatsTests.java (3 old + 9 new = 12)

Goals:
- Architecture: MVC
- OO design principles and patterns: Composite
- Satisfies more best programming practices:
  - Understandability with documentation
  - Modularity with architecture and design patterns
  - Extensibility
  - Testability

git clone https://github.com/LASER-UMASS/basic-stats -b v3.0.0
Basic Stats app (Version 4)

Goals:

- Architecture: MVC
- UI design principles: Undo functionality
- OO design principles and patterns:
  - Applied Composite
  - Optionally apply Strategy or Template method
- Satisfies more best programming practices:
  - Understandability/Maintainability with documentation
  - Extensibility with design patterns
  - Testability (2 new test cases)
  - Debuggability (5 IDE screenshots)

git clone https://github.com/LASER-UMASS/basic-stats -b v4.0.0