Agile for Safety-Critical and Regulatory-Bound Products*

*Agile where you can kill someone

Nancy Van Schooenderwoert, Lean-Agile Partners
Brian Shoemaker, ShoeBar Associates
Session Feedback

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Thank you for providing your feedback 😊
Brian’s Background

- Originally an analytical chemist
- 15 y in clinical diagnostics (immunoassay):
  analytical support → assay development → instrument software validation
- 6 y as SW quality manager (5 in clinical trial related SW)
- 9 y as independent validation consultant to FDA-regulated companies - mostly medical device
- Active in: software validation, Part 11 evaluation, software quality systems, auditing, training
Nancy’s Background

• 15 y safety-critical systems development
• 10+ y agile team coaching
• 5+ y agile enterprise coaching
• Industries: Aerospace, Medical Devices, Sonar Weaponry, Scientific Instruments, Financial Services
• Electrical Engineering and Software Engineering, embedded systems design & devel.
Safety-Critical Agile

- Medical devices with SW provide a bleak picture
  - Impact mapping: “frame” a product for all stakeholders
  - Iterative safety analysis fits well with mapping
  - Story mapping: translate our understanding
  - Agile links the “silos” - and improves products significantly
Many benefits from device S/W

- Augmented reality assists surgeons
- Personal “exoskeleton” helps for walking
- Wearable ultrasound device for pain therapy

But

- Alarming increase in accidents and recalls
Software Related Recalls

Note: Figures are from FDA’s medical device recall database (for US recalls). The Class 1 recalls are multiplied by 10 so they are readable on the same scale as total recalls.
It doesn’t have to be this way

• Agile medical projects
  - Are significantly faster to completion
  - Have significantly fewer defects: \( \frac{1}{4} \) as many!

• ... when compared to traditional projects
  - *Case Study of Extreme Programming used at a Canadian medical systems company*...
Comparison with QSM database of 12,000+ projects

Data courtesy of Michael Mah, Managing Partner at www.qsma.com

"C&T" = Code and Test
Comparison with QSM database of 12,000+ projects

Defects are those found during development in systems integration and QA testing. Post-delivery defects were negligible.

Data courtesy of Michael Mah, Managing Partner at www.qsma.com

Defects are those found during development in systems integration and QA testing. Post-delivery defects were negligible.
No need to “pick any two”

- This breaks the old triangle -
- Can have all 3!

Our goal: Show you key practices that break this old rule
What’s going on?

Traditional team

Feature ideas ➔ Build h/w, s/w ➔ Test and fix ➔ Product

Agile team

Feature ideas ➔ Build h/w, s/w ➔ ? ➔ Product
More work, and done faster?!
‘More Faster’ process step

• What’s inside that mystery process step?

Impact Mapping
Iterative Safety Analysis
Story Mapping
Safety-Critical Agile

- Medical devices with SW provide a bleak picture
- Impact mapping: “frame” a product for all stakeholders
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Impact Mapping - Envision the Product!

Purpose
• Align product rationale with Company’s goals
• Map business value creation
• Accommodate changes
• Comm - Marketing, QA, RA, Development

Who uses it?
• Senior business and technical leaders

Keys of Impact Mapping

- **Why**: Why are we doing this?
- **Who**: Whose behavior do we want to impact?
- **How**: How should our actors’ behavior change?
- **What**: What can we do to support the required impacts?
Case Study: TENS

TENS, or transcutaneous electrical nerve stimulation, is a pain-relief therapy in which weak electrical signals are applied to a patient via standard skin electrodes.

The goal is for treatment to be fully automated: working parameters are to be set dynamically, with no manual adjustment required other than regulating stimulus intensity, which is manually set at the perception threshold.
Example TENS Devices
TENS Goals

Our design goals map directly to the two requirements for a medical device:

a) System must be effective
   (relieves pain)

b) System must be safe
   (not likely to harm patient)
Impact Map for TENS

What is our goal?
*Sell 2000 units in the first 3 years on the U.S. market*

Who can help or prevent us reaching our goal?
*Physicians, Patients, FDA, Support*

Behavioral change helping/obstructing our goal
*Physician* Can adopt this TENS system with confidence
*Patient* Cannot be shocked or burned; experience lasting pain relief; willing to provide testimonial about relief
*FDA* Grant clearance to sell device

Features supporting/preventing impact:
- Prompted setup sequence; limits on intensity, duration
- Therapy stop if electrical malfunction detected
- Proprietary pulse algorithm (from extensive research)
- Convincing safety profile
Impact Map for TENS

Goal

Actors

Physicians
- Can adopt TENS with confidence

Patients
- No concern about injury

FDA / regulatory body
- Pain is eliminated or reduced

Support
- Grant clearance

Deliverables

Prompted setup sequence
Settings Limits
Fault Detection during therapy
Proprietary Pulse Algorithm
Convincing safety profile

(other)
Impact Mapping - There’s More

- We have covered only a portion of impact mapping - enough to get you started
- We have found the method extremely useful for linking marketing and customer requests to development
- We highly recommend reading the Gojko Adzic book to understand the questions to ask.
No need to “pick any two”

- Impact Mapping helps by:
  - Aligning stakeholders
  - Keeping our aim on moving target
  - Focus on behavior
Safety-Critical Agile

- Medical devices with SW provide a bleak picture
- Impact mapping: “frame” a product for all stakeholders
- Iterative safety analysis fits well with mapping
- Story mapping: translate our understanding
- Agile links the “silos” - and improves products significantly
Risk Management MUST Iterate

ISO 14971 §3.1: Mfr "shall establish, document and maintain throughout the life-cycle an ongoing process“ for analyzing, evaluating, and controlling risks.

Early in project
- Preliminary
- High-level
- Approximate

Late in project
- Refined
- Detailed
- Specific
Who Should Take Part?

- Electronic / Mechanical engineers?
- Physicians / Nurses?
- Patients who have used other TENS devices?
- Researchers who work on pain relief?
- Regulatory experts (review of other devices on market)?
Fault Tree Analysis

**Shock**
- Electrode or wire shorted
- Excessive current

**Burn**
- Too much energy delivered
  - Initially set too long
  - Duration increased during therapy

**Spasm**
- Electrodes placed on head or neck
  - Use Error

**Other Device Failure**
- Pt has susceptible device
- Therapy given too nearby

**spam**
- Excessive Impedance
- Set too high

1. Electrode or wire shorted
2. Excessive current
3. Initially set too long
4. Duration increased during therapy

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Risk Stories

As a caregiver, I want to ensure that therapy will stop if short, open circuit, or high impedance is detected, to avoid harming the patient.

As a caregiver, I want the unit to limit the therapy duration, to avoid harming the patient.

As a caregiver, I want the unit to prevent setting duration longer once therapy has begun, to avoid harming the patient.

As a caregiver, I want the unit to prevent setting output too high, to avoid harming the patient.
Is this a Once-Up-Front Activity?

• Standards and regulatory bodies EXPECT risk management to be iterative!

• Partway into development, key customers ask for ability to control the device via a remote.
  - How might your company answer?
  - What safety issues might this raise?
  - Would we revisit our hazard analysis?
Is this process ever “complete”?

- Do we know enough about hazards when a project begins?
- Will we learn as potential users try out our design?
- What other analyses can we do when we have a detailed design?
- Might we bring in other stakeholders later in development?
Risk Management is Cyclic

Plan

Do

Act

Check
No need to “pick any two”

- Iterative Safety analysis helps by:
  - Sharper focus
  - Incorporate new info “in flight”
  - Avoid recalls and accidents better than before
Safety-Critical Agile

- Medical devices with SW provide a bleak picture
- Impact mapping: “frame” a product for all stakeholders
- Iterative safety analysis fits well with mapping
- **Story mapping**: translate our understanding
- Agile links the “silos” - and improves products significantly
Story Mapping - The Next Step

**Purpose**

- Ensure product will fit user needs
- Envision minimum viable product
- Plan releases
- Communication - Marketing, QA, RA, Development

**Who uses it?**

- Product managers/ marketers and hands-on technical teams

Keys of Story Mapping

- Start with your customer’s activities using your envisioned product (horizontal axis)
- Vertical axis: increasing levels of completeness in implementation
  - First level is a releasable “walking skeleton”
  - Next levels flesh out more features
- Benefit: Avoids releases that are unusable due to dependence on less urgent stories not yet implemented
Example TENS Devices
## TENS Device Story Map

### User Actions
- **Attach electrodes, connect leads**
- **Power up device**
- **Enter treatment settings**
- **Begin therapy**
- **Allow therapy to proceed**
- **Disconnect when complete**

### Laboratory Tests
- **Leads keyed for correct polarity**
- **Confirm which leads connected**
- **Duration must be < 30 minutes**
- **Ensure pulse pattern is changing**
- **Manual stop if anything wrong**

### Feasibility Study
- **Ensure outputs initially = 0**
- **Duration can NOT be changed**
- **Monitor pulse pattern for 'hot spots'**
- **Auto stop if pulses not changing**
- **Stop therapy if electrical malfunction**

### Pivotal Study
- **Integrity must be < safe limit**
- **Monitor pulse pattern for 'hot spots'**
- **Auto stop if pulses not changing**
- **Stop therapy if electrical malfunction**

### Risk Mitigation Story
- **Give warning if electrode shorted**
- **Prompt for Duration & display throughout**
- **'Intensity' knob sets Voltage amt.**
- **Display "Duration" countdown**
- **Therapy ends when time limit reached**

### Feature Story
- **Begin therapy**
- **Enter treatment settings**
- **Power up device**
- **Attach electrodes, connect leads**

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**Release 1**
- **Leads keyed for correct polarity**
- **Confirm which leads connected**
- **Duration must be < 30 minutes**
- **Ensure pulse pattern is changing**
- **Manual stop if anything wrong**

**Release 2**
- **Ensure outputs initially = 0**
- **Duration can NOT be changed**
- **Monitor pulse pattern for 'hot spots'**
- **Auto stop if pulses not changing**
- **Stop therapy if electrical malfunction**

**Release 3**
- **Integrity must be < safe limit**
- **Monitor pulse pattern for 'hot spots'**
- **Auto stop if pulses not changing**
- **Stop therapy if electrical malfunction**

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**ShoeBar Associates**
TENS Device Story Map

User Actions:
- Attach electrodes, connect leads
- Power up device
- Enter treatment settings
- Begin therapy
- Allow therapy to proceed
- Disconnect when complete

Laboratory Tests:
- Leads keyed for correct polarity
- Confirm which leads connected

Feasibility Study:
- Ensure outputs initially = 0
- Do complete power-on self test

Pivotal Study:
- Intensity must be < safe limit
- Monitor pulse pattern for 'hot spots'
- Auto stop if pulses not changing
- Stop therapy if electrical malfunction

Risk Mitigation Story:
- Duration can NOT be changed

Feature Story:
- Prompt for duration display throughout
- Duration must be < 30 minutes
- 'Intensity' knob sets voltage amount

Verticals show how system will support the user activity (at top)
A mechanical engineering story supports “Attach electrodes” activity.
Risk mitigation story

This story came from the Risk Analysis, not from users

In prior iteration, mitigation was via lab procedures
New need for safety analysis

Remote control to enter or change settings

← New feature requested for Release 4

Next iteration of safety analysis gives new Risk Mitigation stories

Warning if weak signal

Encrypt wireless signal
Main actor here is the system, not user; a common pattern in embedded systems.
“Proprietary pulses” were developed in a prior research project. This pattern is also very common for embedded systems.
Seed Projects

(PhD thesis) → Proprietary Pulses research Project → TENS Project

(Other sub-systems)
TENS Device Story Map

User Actions
- Attach electrodes, connect leads
- Power up device
- Enter treatment settings
- Begin therapy
- Allow therapy to proceed
- Disconnect when complete

Laboratory Tests
- Give warning if electrode shorted
- Prompt for Duration & display throughout
- 'Intensity' knob sets Voltage amt.
- Deliver proprietary pulses
- Display "Duration" countdown
- Therapy ends when time limit reached

Feasibility Study
- Leads keyed for correct polarity
- Confirm which leads connected
- Duration must be < 30 minutes
- Ensure pulse pattern is changing
- Manual stop if anything wrong

Pivotal Study
- Ensure outputs initially = 0
- Do complete power-on self test
- Intensity must be < safe limit
- Monitor pulse pattern for 'hot spots'
- Auto stop if pulses not changing
- Duration can NOT be changed
- Stop therapy if electrical malfunction

Risk Mitigation Story
- Feature Story

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## Export Shows Traceability

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<td>Pt will not be harmed</td>
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<td>UA19</td>
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</tbody>
</table>

# Impedance response

**Given** therapy is occurring, **When** ckts detect hi Z, **Then** therapy shall be stopped.

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*Output exported from SpecLog impact/story mapping tool and rearranged manually.*
Benefits of Story Mapping

- All stories trace to user activities
- Specific stories can be identified as risk mitigations
- See where H/W, S/W features interleave
- Column-wise view helps see evolving support for each user activity
No need to “pick any two”

- Story mapping helps by:
- Showing timeline view...
- Show user activities plus tech features
- Support cross-functional dialogue
Safety-Critical Agile

- Medical devices with SW provide a bleak picture
- Impact mapping: “frame” a product for all stakeholders
- Iterative safety analysis fits well with mapping
- Story mapping: translate our understanding
- Agile links the “silos” - and improves products significantly
‘More Faster’ process step

• Not a mystery process step anymore!
More work, and done faster - YES

Traditional team

Time

 Agile team
More work, and done faster - YES

Traditional team

Agile team

Time

Feature ideas ➔ Build h/w, s/w ➔ Test and fix ➔ Product

Feature ideas ➔ Build h/w, s/w ➔ Product

✔✔
These are a foundation

- You still need TDD, CI, Retrospectives, etc.
- ← This foundation complements them!

TDD = Test Driven Development;  CI = Continuous Improvement
Mapping - We Have to Bridge Silos

R&D / Engrg  Clinical / Support  Marketing
No need to “pick any two”

- This breaks the old triangle -
- Can have all 3!
Consider

- No regulatory body requires waterfall methods
- No regulatory body prohibits Agile methods
- TIR-45 (from AAMI): info on being Agile and compliant in medical products
- FDA: You must demonstrate conformance to pre-determined requirements, but you can pre-determine them at any time

**NOTE:** We’ve explored all these topics in a white paper available on our web sites, [http://www.shoebarassoc.com](http://www.shoebarassoc.com) and [http://leanagilepartners.com/](http://leanagilepartners.com/)

AAMI = Association for the Advancement of Medical Instrumentation
Future: Internet of (Medical) Things

- 10 Billion Internet-of-Things devices today,
- 30 Billion expected by 2020
- Among fastest growing IoT devices:
  - Mobile, in-home medical devices
  - Intelligent sensors: transportation and buildings
- Radically better quality needed to support this explosive growth!

Source: https://www.abiresearch.com/press/more-than-30-billion-devices-will-wirelessly-conne
## Contact Us!

<table>
<thead>
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<td><a href="mailto:nancyv@leanagilepartners.com">nancyv@leanagilepartners.com</a></td>
<td><a href="mailto:bshoemaker@shoebarassoc.com">bshoemaker@shoebarassoc.com</a></td>
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</table>

- @vanschoo
- @brian_shoe

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![Lean-Agile Partners logo](image1)

![ShoeBar Associates logo](image2)

Medical device recalls obtained by searching the FDA recalls database at [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm)

Van Schooenderwoert, Nancy, 100-to-1 Ratio for Agile Defect Prevention Over Traditional Methods, available on [http://leanagilepartners.com/publications.html](http://leanagilepartners.com/publications.html)


ISO 14971:2007 (2nd ed) Medical devices - Application of risk management to medical devices

Resources

- For assistance in regulatory submission documentation: Shoebar Associates (http://www.shoebarassoc.com/)

- For Agile coaching for safety-critical product development: Lean-Agile Partners (http://leanagilepartners.com/)

- For more info on QSM data comparisons, contact Michael Mah: michael.mah@qsma.com

- Tool mentioned that supports both Impact Mapping and Story Mapping: see TechTalk’s SpecLog at http://www.speclog.net/