McMaster University



Redesigning Medical Device Assurance: Separating Technological and Clinical Assurance Cases

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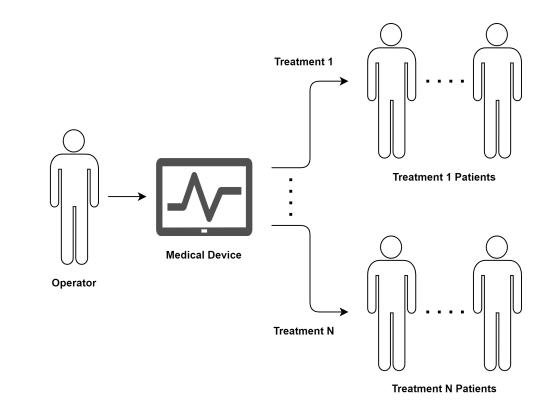
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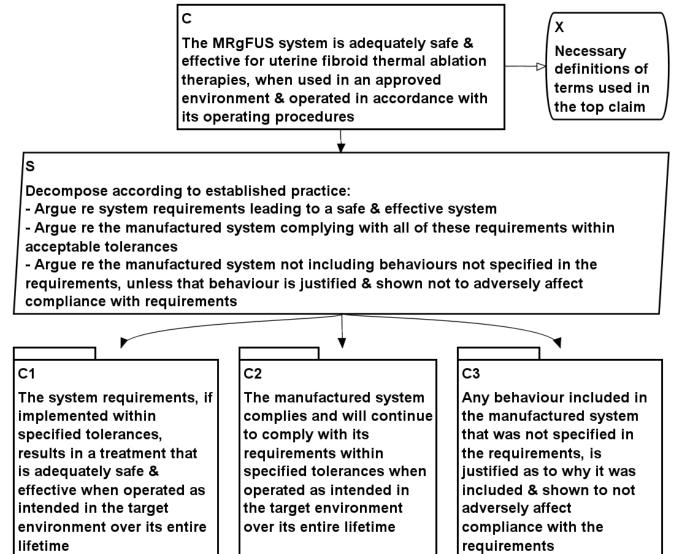
Case Study: MRI Guided Focused Ultrasound

- Can be used for several different treatments
 - Uterine fibroid thermal ablation
 - Enhanced drug delivery
 - Gene delivery
- Different patients undergoing the same treatment for the same pathology can, and often do, react differently





Initial Attempt: Monolithic Assurance Case





What went wrong?

- Monolithic assurance case
 - Becomes unwieldy; Number and complexity of use-cases results in massive assurance cases
 - Difficult to parse and discuss argumentation due to large size and scope, as well as cross-cutting concerns across branches
- Treatment Versatility & Patient Variability
 - Needs to contain argumentation on the system's behaviour over several completely different treatments
 - Needs to cover the varied responses different patients can experience when given the same treatment

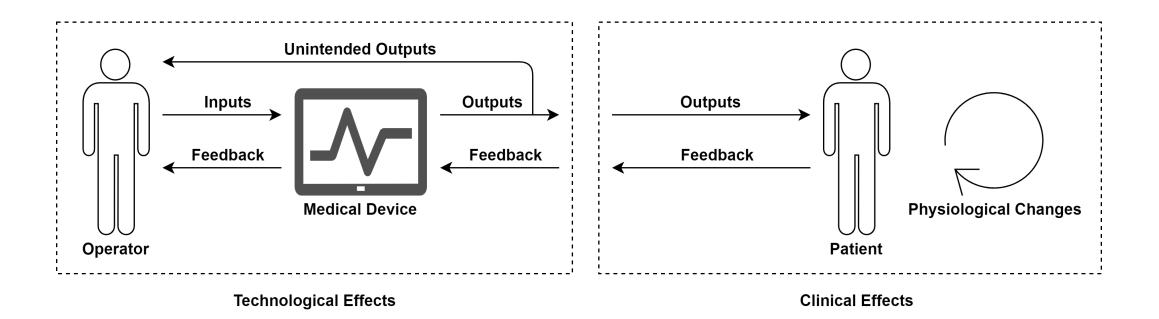


Rethink Assurance Approach

- The difficulty in assuring such a medical device comes from the clinical side
 - Low behavioural overlap across treatments
 - Variability in responses of patients undergoing the same treatment
 - Treatments may be removed, modified or added throughout the lifespan of the medical device
- What if we could separate the assurance argumentation in a way that preserves safety as a systemic property while helping us manage these difficulties?



Technological & Clinical





Technological Effects

- Consider the medical device solely as a system that produces deterministic outputs given specific inputs
- Technological Effectiveness: How well does the system produce the outputs when given a corresponding set of inputs?
 - i.e. Ultrasound focus positioning, amplitude, duty cycle, timing, etc.
- Technological Safety: How safe is the system when producing the outputs?
 - i.e. Enforced power limits, safeguards against emergent behaviour, etc.

Clinical Effects



- Assuming the technological effects are sound, consider the medical device in relation to how it can be used to provide safe and effective treatments to a variety of different patients
- Clinical Effectiveness: How well does the system produce the intended physiological changes in the patient and/or resolve pathology?
 - i.e. Adequate energy deposition in targeted tissue, acceptable clinical trial outcomes
- Clinical Safety: How safe is the system when producing the outputs?
 - i.e. Energy not deposited in unintended tissue, adverse events within acceptance



Technological Assurance Case (TAC)

lc

ls

Ха

Technological effects: The outputs of the medical system, independent of clinical effects

Xb

Technological effectiveness: The intended technological effects are achieved, within their performance requirements

Xc

Technological safety: Use of the system must not cause unacceptable harm or loss to any person or the environment. Harm to a patient undergoing therapy caused by outputs of the system is not included. That specific safety concern is the focus of the relevant Clinical Assurance Case The MRgFUS system delivers its technological effects, and is technologically safe & technologically effective when used in the intended environment & in compliance with its standard operating procedures

Decompose according to established practice, with V&V limited to the medical device itself:

- Argue re system requirements leading to a technologically safe & technologically effective system

- Argue re the manufactured system complying with all of these requirements within specified tolerances

 Argue re the manufactured system not including behaviour not specified in the requirements, unless that behaviour is justified & shown not to adversely affect compliance with requirements

C1

The system requirements, if implemented within the specified tolerances, results in a system that delivers the intended outputs & is safe in delivering the desired outputs when operated as intended in the target environment

C2

The manufactured system complies and will continue to comply with its requirements within the specified tolerances when operated as intended in the target environment C3

Any behaviour included in the manufactured system that was not specified in the requirements, is justified as to why it was included, & shown to not adversely affect compliance with the requirements



Clinical Assurance Case (CAC)

Xa

Clinical effects: The biological/physiological response produced through appropriate control of technological effects and operating procedures

Xb

Clinical effectiveness: The clinical effects achieve the intended improvement in the patient's quality of life

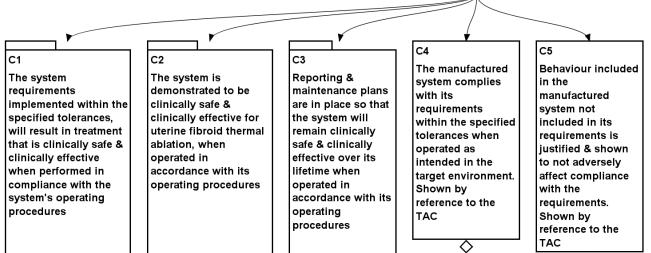
Xc

Clinical safety: The use of the system does not produce clinical effects that result in unacceptable harm to patients The MRgFUS system is clinically safe and clinically effective for uterine fibroid thermal ablation therapies, when used in an approved environment, and operated in accordance with its operating procedures and within its operational assumptions

- Argue re system requirements leading to a safe & effective treatment

Argue re system is demonstrated to be safe & effective in use
 Argue re system will be maintained so that it remains safe & effective

Refer to TAC to argue re the manufactured system complies with all of its requirements within specified tolerances
Refer to TAC to argue re the manufactured system does not include behaviour not specified in the requirements, unless that behaviour is justified and shown to not adversely affect compliance with the requirements



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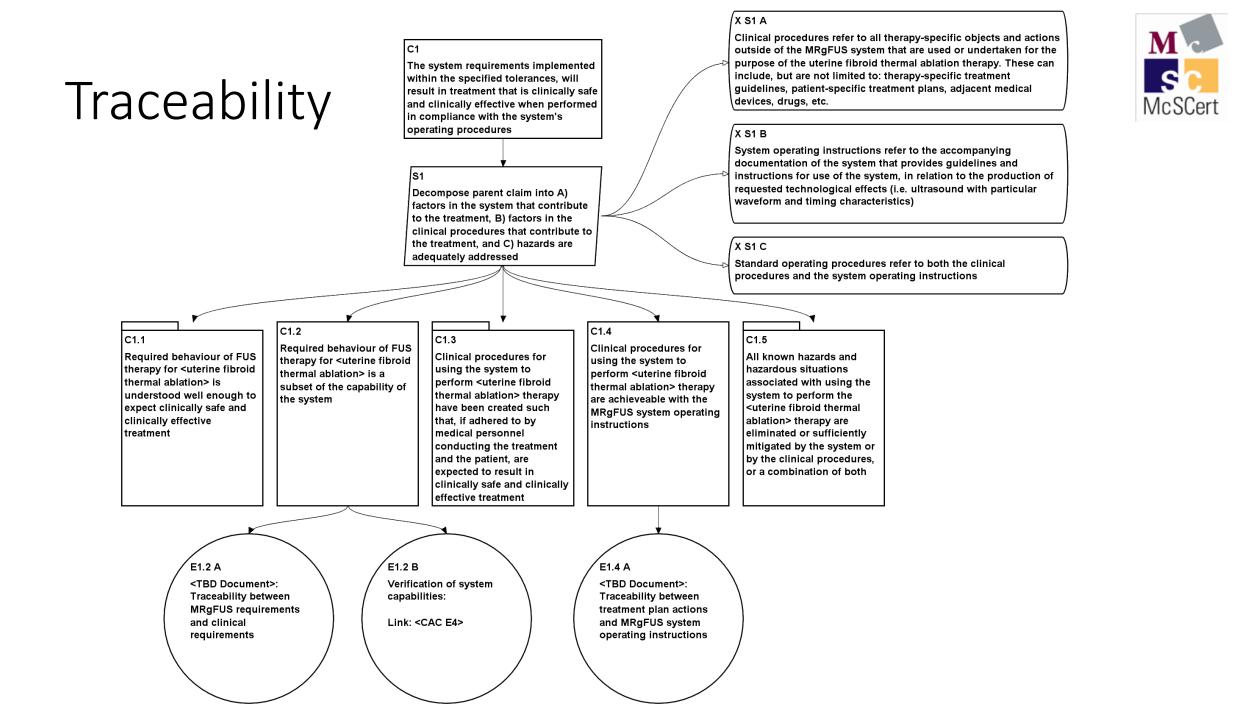
How does this separation work?

- There is only one TAC that focuses on the capabilities of the medical device as a machine that produces a set of outputs when given a corresponding set of inputs
- There are several CACs; one for each treatment type the system will be performing
 - The system isn't just the medical device. The operating procedures, clinical staff, and patients are all part of the system in a clinical context
- Ideally, we only need to have one TAC for the medical device, and can update, add or remove CACs as treatment options for the system as it changes over its lifespan



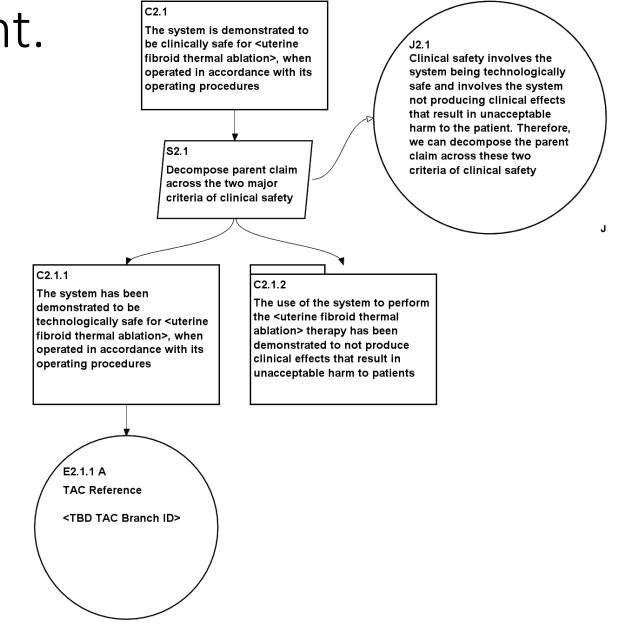
What Evidence Belongs in Each?

- Evidence in the TAC
 - System hazards mitigated (i.e. standard operating procedures)
 - Energy levels, targeting, and timing of ultrasound waveforms within tolerance
- Evidence in the CAC
 - Thermal ablation of uterine tissue demonstrated
 - Resolution of uterine fibroids; size of fibroids decrease and pain improvement
 - No unacceptable harm; all harm to patients is deemed acceptable according to the risk-benefit analysis of the treatment





Traceability Cont.



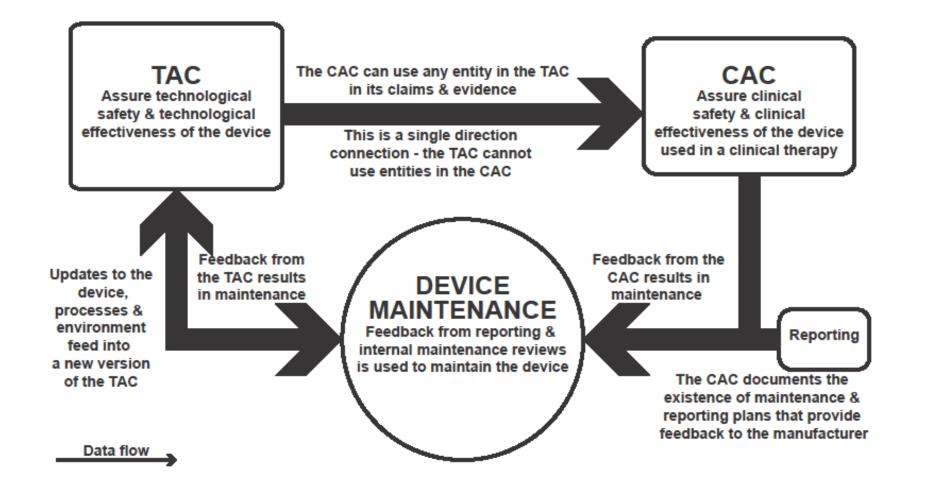


Preservation of Safety as System Property

- Safety is a global system property, so how do we preserve this?
- The CACs argue safety as a global system property, in a similar manner to the argumentation in the monolithic assurance case
 - Contains all of the argumentation for safety and effectiveness, including the material in the TAC, but instead of duplicating its entirety, we only need to reference branches as needed



TAC & CAC over the System Lifecycle



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Next Steps

- Develop assurance case templates that can be reused for specific types of medical devices
- Investigate the viability of CAC templates that can be reused across different types of treatments
- Determine applicability of the approach to medical devices with more restricted scope
- Determine if the approach may have use in other industries

Conclusion



- We have introduced a new assurance method for medical devices that preserves safety as a systemic property, while aiding in management of complex multimodal systems
- The separation of concerns with regards to the technological and clinical aspects of a medical device have been useful in constructing strong argumentation in an MRI guided focused ultrasound case study