Safety first! How a risk based, life-cycle approach to medical device design improves patient safety

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TERMIS + ABMC7 2019

16 October 2019
Outline

• Changes in healthcare and technology
• The regulatory requirements
• What risk management should consider

Note - information presented in this presentation is based on general, personal observations and is not binding on the TGA. You should seek independent advice to ensure all of the legislative requirements are met for your matter.
# Healthcare is changing

### ‘I am my own healthcare professional’
- Variable levels of consumer health literacy
- Ready access to both useful and misleading news, info and data
- *Dr Google and friend on Facebook as experts*

### ‘I expect the best technologies’
- Expect technologies are safe and cause no harm
- May have unrealistic expectations
- May prefer options that best caters for their needs

### ‘I prefer control over decisions that affect me’
- Sourcing devices online
- Vulnerable to targeted advertising via social media
- Different role and interactions with doctors
- May use or customise device off label
- More likely to provide feedback/complaints including on social media
Technology is changing

Flexible manufacturing paradigms
- Novel materials and processes
- Contract manufacturing
- Additive manufacturing
- Shorter product lifecycles

Smarter/ more complex devices
- Wearable tech
- Smart device/apps
- Machine learning & AI
- Preventative health
- Combination devices with medicines and biologicals

New challenges
- Data and cybersecurity challenges
- Definition of manufacturer is more fluid
- Products have more inherent risk but also more promises of benefits
TGA updates regulation to keep up

Action Plan for Medical Devices
• Improve how new devices get on the market
• Strengthen monitoring and follow-up
• Provide more information to patients about devices they use

Global Harmonisation
• Aligning regulatory requirements with European Union
• Contributes to medical device single auditor program (MDSAP)
• Forums with International regulators

Public Consultations
• Software as medical device (SaMD)
• Personalised medical devices
• IVD self tests
• Essential Principles
• https://www.tga.gov.au/open-consultations-reviews
… but the principles remain the same

All medical devices must have evidence to demonstrate they meet the **Essential Principles** (about safety of the devices) and **conformity assessment procedures** (about the QMS requirements).

Researchers have a unique role to play in the device development process

1. Be the champion for your technology. Take a life-cycle approach—your planning and risk assessment should cover all stages of **device lifetime**, and spanning the **development cycle**.

   How are the material and technologies impacted through each stage?

   - **Device lifetime**
Complexity adds risk

2. Can we design out risks where possible?

‘Everything should be made as simple as possible, but no simpler’

Caveat that safety mechanisms can introduce necessary complexity and this requires a balance of risk/benefit
Risk can be managed

3. Complexity and risk aren’t inherently bad, they are necessary and can be managed
   – Defined in ISO 14971: systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk
   – What evidence can you provide to demonstrate risks have been mitigated and that the device performs as intended?

   • Top management commitment- demonstrating culture of safety- your culture is defined by your choices
   • The risk management process and system is an integral part of the medical device lifecycle
   • Good risk management practices demonstrates to the regulators the manufacturer has in place measures to address risks and ensure ongoing safety and performance of their devices
   • Good risk management practices protects the company, the product and consumers
Essential Principle 2

Design and construction of medical devices to conform with safety principles

(1) The solutions adopted by the manufacturer for the design and construction of a medical device must conform with safety principles, having regard to the generally acknowledged state of the art.

(2) Without limiting subclause (1), in selecting appropriate solutions for the design and construction of a medical device so as to \textit{minimise} any risks associated with the use of the device, the manufacturer must:

(a) first, identify hazards and associated risks arising from the use of the device for its intended purpose, and \textit{foreseeable misuse}\* of the device; and

(b) second, \textit{eliminate, or reduce, these risks as far as possible} by adopting a policy of inherently safe design and construction; and

(c) third, if appropriate, ensure that \textit{adequate protection measures are taken}, including alarms if necessary, in relation to any risks that cannot be eliminated; and

(d) fourth, inform users of any residual risks that may arise due to any shortcomings of the protection measures adopted.

*Note: \textit{misuse} includes incorrect or improper use of the device

This Essential Principle is reproduced from TGA requirements, but similar statements are found in EU MDR ‘Essential Requirements’, in ISO 16142-1:2016 and IMDRF documents
Risk assessment

ISO 14971 only provides an example. It is up to the manufacturer to design their severity and probability levels and some include additional considerations (e.g. detectability). Categories should be clearly defined to minimise confusion or ambiguity. Probabilities should be quantified. Thresholds should be appropriate and reasonable. Standards set the minimum requirements.
Manufacturers are responsible for **actively** monitoring risks of their devices on the market, not just when things go wrong, or wait for things to go wrong

- Notify the TGA and/or responsible regulators
- Identify new hazards and update risk management documentation (use other manufacturer’s issues and cases as inputs too)
- Update risk probability/ severities
- Perform investigation, root cause analyses and Corrective and Preventative action (CAPA)
- Consider new or additional mitigation measures
  - E.g. new product version design
  - Add new features e.g. alarms
  - Closer monitoring or alter acceptability criteria
    - This changes product specifications and should be re-validated
  - Undertake appropriate recall action
Symptom of issues

- Observable issues from our premarket assessments and post-market investigations:
  - Hazard/risk not identified or updated/acknowledged
  - Risk matrix not appropriate
  - Risk not properly mitigated
  - Inconsistency between risk document and other documents
  - Tests and validations not carried out per risk management documents
  - Risk not informed by post-market experience
  - No regular review or update

- Issue with Risk management process and documents points to non-compliance with Essential Principle 2
  - Grounds for TGA to reject new device application or to cancel the ARTG entry of existing device
Take home message

• Healthcare technologies, complexities and consumer use are changing over time, but the principles of managing risk and demonstrating safety and performance remains the same
• Complexity isn’t bad, just requires more careful planning and risk management
• The risk assessment documentation must be reviewed regularly and periodically and kept up to date
• Good risk management practices earns trust from the regulator and protects your product and consumers

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