TGA Consultation: Regulation of software, including Software as a Medical Device (SaMD)

Response to Questions provided by TGA

1. **Do you support the proposal to change the way medical device software is regulated? Why or why not? If you do not support the proposal, do you have any suggestions for an alternative that would be acceptable to you?**

Unlike most software companies, SmartWard supports the proposal to increase regulation of medical software and believes the principles you espouse in the paper are appropriate for regulating the use of software for medical and therapeutic purposes.

Greater regulation of medical software is justified because of the crucial role that clinical data plays in patient outcomes.[1] It is well recognized that errors in clinical treatments are a major cause of adverse patient outcomes and that poor quality data is one of the significant causes of such harm. [2]

Many industry representatives and organisations are resisting the move[3]. This is not because it is technically infeasible nor because of the net cost to the health sector – reducing errors will save far more than the cost of software compliance. But, as we have seen in the recent banking Royal Commission, the incentives for short term company profits or staff bonuses can run counter to the long-term good of both the industry, the wider economy and the public good.

Studies show that the lack of safety focus and regulation has led to products being used that are unsafe on many levels[4], including things as fundamental as usability[5]. A seminal report in the US, "To err is human", brought to light the high rates of system failures, resultant harm and waste in the healthcare system. It challenged a profession that is trained to heal, to look inwards and heal its own systems[6].

The lead author stated in 2010, "we're either stagnating or moving in reverse … when it comes to patient safety. We have little or no cause for celebration"[7]. In the absence of validated and universally adopted analytical measures of clinical error and harm, the extent and cost of error is huge: The Study reported that up to 98,000 Americans die each year as a result of preventable medical errors.

This may be an underestimate: in 2013, a study published in the Journal of Patient Safety put the number of premature deaths associated with preventable harm at more than 400,000 per year[8]. This is the equivalent of two jumbo jets falling out of the sky every 24-hours. Whichever figure is used, the numbers are alarming – even an order of magnitude reduction at the lower end would still be unacceptably high.

The situation in Australia is generally regarded as similar. The Australian Institute of Health and Welfare reports that adverse events in hospitals in 2015-16 in Australia were 5.4%[9]. A 2008 Victorian Auditor General's report estimated that medical errors cost that State over $500 million, which extrapolated across the nation would mean more than $2 billion dollars of unnecessary costs in the healthcare sector and perhaps the same again in broader costs to the community at large. [10]

No other sector would accept such an error rate. By way of contrast, in the same year as this Study, there were 36.4 million commercial flights worldwide carrying more than 3 billion passengers. 210 people died with an error rate of one accident per 2.4 million fights.

The health medical sector, whose raison d'etre is to care for the sick and injured, should have the least tolerance of errors of any sector, not the highest, and with all elements of care delivery proven to deliver benefits to patients. This is already accepted in the regulation of drugs and medical devices and should be extended to other areas such as the systems that manage patient data and underpin clinical decision-making. **Safety critical performance should be recognized as mandatory. Compliance with an agreed data security standard should also be mandatory. Vendors should also be required to submit to testing and independent validations of their claims, given that few have any evidence base of contribution to patient safety or cost effectiveness**[11]**.**

The problems of the sector run deep. A recent review of electronic records in the US found that at least $36b has been utterly wasted in recent years in the naive hope that Health IT would simply innovate toward better safety.[12]

Clinicians of all types find their that their existing systems are cumbersome and often impede patient care. A recent study found that over 80% of Doctors believe they would be better off with paper than with the current generation of electronic medical records, as the overheads of using the current dominant systems is so high.[13] The damage presently being done to patients also takes a massive toll on healthcare workers, among whom the suicide rate is much higher than the general population. [14]

SmartWard supports TGA nominating appropriate standards for documentation and security. This could be an equivalent of ISO13485 but with all the physical manufacturing and product testing removed and suitable software testing standards incorporated. The analogy of the classes of medical device to classes of software based on risk to patient safety is valid and should be incorporated into the standard.

We believe that the onus should be on software developers to demonstrate the efficiency and efficacy of their software – effectively an evidence base that shows benefits to the sector in terms of patient outcomes and net economic impact. The amounts spent on medical software in Australia, including software to maintain clinical records is huge, running into hundreds of millions of dollars in single hospitals. It is not only legitimate but imperative that this expenditure be evaluated in relation to the improvements in patient outcomes it delivers vis-a-vis other potential expenditures of the health budget.

As a general comment, we suggest that you stop using the terminology 'software as a medical device' because it implies the issue is an extension of medical device regulation and hence only applies to software on the periphery of medical devices rather than a valid and timely extension to the use of software for any medical or therapeutic purpose. We suggest you adopt Safety Critical Software Standard.

2. **What do you consider to be the benefits and disadvantages of the particular proposals for change?**

Robust, well designed, safety critical software can pay for itself. We have collaborated with University researchers to evaluate our technology to demonstrate that it can simultaneously improve compliance while freeing up the time of clinicians so that they can spend more time with patients. When clinicians spend more time with patients, there is ample research to show that patient outcomes improve, readmissions fall and costs are saved through shorter lengths of stay.[15]

On this basis, Deloitte Access Economics estimated the impact of our safety critical hybrid eMR-clincal workflow engine to be of the order of $50,000 in real savings per bed per annum.[16]

The performance of our system also shows that preparing suitable documentation and using other safety critical development measures is best practice for software development and confers

significant benefits in software maintenance over the long term. Provided the documentation is collected at the outset of software development, it is neither onerous nor costly and the discipline involved reduces the risk of defects and improves overall risk management. Over time this delivers significant business benefits.

Software producers who have not collected such documentation in the past will, however, struggle to retrospectively create the appropriate documentation and are likely to oppose regulation of their products as proposed by the TGA. Our view is that the cost to them is a necessary price for improving patient well-being by following safety critical standards.

The harsh reality that the software sector has to face is that software that lacks the capability to minimize errors cannot be accepted where patients lives and well-being are at risk. Moreover, all software used in healthcare delivery needs the capability to adapt to changes in clinical practice and knowledge. Undocumented and expensive-to-change code bases that can't reflect best practice care inevitably creates further patient risks over its lifetime.

Proper documentation during development can also help overcome an endemic problem that has bedeviled the health sector for over three decades – the difficulty of integrating different components of software deployed for different functions in the hospital. Documentation helps to specify and support open APIs that facilitate integration with other software products.

While you have not raised the prospect of requiring a sound evidence base of clinical benefit before software can be deployed, we believe that such a measure will force the sector to address chronic problems of data integrity. Many IT clinical systems cannot effectively capture the care record near the point-of-care. Instead, clinicians and/or ward staff create important electronic Medical Records (eMRs) at different times to the actual patient care delivery, and away from the point-of-care. This inevitably leads to errors from faulty memory and/or transcription from paper jottings and records. Peer-reviewed studies have regularly pointed to poor data integrity as a major cause of incorrect clinical decisions and a key contributor to the stubbornly high rates of patient harm in healthcare.

Incorrect data not only causes incorrect decisions by clinicians who subsequently use the data. It also means that any mega data analysis will also be misleading, corrupting the evidence-base for improved care and treatments. There is a huge emerging opportunity for pattern analysis of electronic clinical data captured over large patient populations to identify clinically significant correlates and to evaluate the efficiency and effectiveness of clinical treatments and practices within different patient populations. This could eventually herald the era of personalized medicine, whereby treatment is tailored to each individual's unique genetic, metabolic and other biological traits. But the source data must be accurate. By requiring clinical data sets to have appropriate and proven quality assurance would unlock the power of data.

3. **Do you believe there will be any unintended consequences arising from the proposed changes?**

There will be an economic cost associated with transition as discussed above for those who have not maintained adequate documentation of their product. This cost is far less than the cost of non-safety critical software used in clinical decision-making.

The positive impacts of safety regulation are evident in the aviation sector.[17] Research has already shown the applicability of the approaches taken to safety validation in systems design in aviation transfer to health IT.[18]

4. **What changes would you need to make (if any) to meet the new arrangements? If not, what are the impediments?**

In the absence of detail on the processes to be used to implement and monitor regulations, our expectation based on the use of suitable standards such as ISO13485 adapted to software development is that we would require minimal change to our practices and trajectory into the market for our software.

5. **What financial impact (both costs and savings) would implementing the proposed amendments have for you? If possible please provide a breakdown of the impacts. This information will be used to quantify the financial impact to all affected stakeholders.**

While we expect that the financial impact on us would be minimal, we note that we have already spent approximately $1 million on independent evaluation of our software to develop an evidence base of efficiency and effectiveness.

In addition to the University studies, our system was evaluated from the perspectives of security, reliability, scalability and usability in an under-the-hood technical review by CIO Group technical experts from the Department of Defence. It achieved the first ever perfect score in such an evaluation. Our system has been rated as among the very best patient safety initiates in the world as demonstrated by being a finalist in the World Patient Safety Innovation Awards.

Regulation inevitably comes at a cost to vendors and raises the bar for new entrants and innovation in the sector. But given the wider economic and social benefits from improving the safety performance of the sector, the need for improved safety is unarguable.

A challenge for the TGA is to find ways to find mechanisms that ensure that the regulation of the sector does not deter new entrants from the sector or make the bar prohibitive for existing players to raise their performance. Mechanisms for sharing some of the economic benefits of better safety performance should be explored, as the health sector currently does not reward safety critical performance in software.

6. **What period would be needed for your organisation to implement the proposed changes? This information will be used to inform any transitional arrangements.**

The answer to this question depends on the final choice of the documentation standard but as noted, we do not expect it to be unwieldy in our case – probably not more than a few months.

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[1] Preventable deaths: https://www.aihw.gov.au/reports/australias-health/australias-health-

[2] ECRI Institute is a US –based independent nonprofit that researches the best approaches to improving patient care. Ref: https://www.ecri.org/press/Pages/ECRI-Institute-Announces-Top-10-Health-Technology-Hazards-for-2015.aspx

[3] MSIA Newsletter 27 March 2019

[4] Health IT inefficient and dangerous: https://www.motherjones.com/politics/2015/10/epic-systems-judith-faulkner-hitech-ehr-interoperability/

[5] Development of the Evidence-based Adult General Observation and Response Charts (Australian Commission on Safety and Quality in Health Care; see also Human factors engineering and patient safety. J Gosbee, T Anderson Qual Saf Health Care 2006; 40:195–201

[6] **To Err is Human: Building a Safer Health System.** Institute of Medicine (US) Committee on Quality of Health Care in America; Kohn LT, Corrigan JM, Donaldson MS, editors. Washington (DC): National Academies Press (US); 2000.

[7] Transcript of Arthur Levin's address to the Consumer's Union 2009

[8] A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care, James, John T. PhD, Journal of Patient Safety: September 2013 - Volume 9 - Issue 3 - p 122–128

[9] *Source:* National Hospital Morbidity Database; Table S1.4.30

[10] Victorian Auditors Generals Report – Patient Safety in Public Hospitals. May-2008. ISBN 1 921060 68 9

[11] A Framework for Selecting Digital Health Technology Ostrovsky A, Deen N, Simon A, Mate K. A. IHI Innovation Report. Cambridge, MA: Institute for Healthcare Improvement; June 2014. (Available at www.ihi.org).
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: [13] Why Doctors hate their computers https://www.newyorker.com/magazine/2018/11/12/why-doctors-hate-their-computers
[14] Suicides among health care professionals: https://www.mja.com.au/journal/2016/205/6/suicide-health-professionals-retrospective-mortality-study-australia-2001-2012
[15] Needleman et al, Nurse-Staffing Levels and the Quality of Care in Hospitals, The New England Journal of Medicine, 2002; 346:1715-1722 May 30, 2002 DOI: 10.1056/NEJMsa012247
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[18] Setting the Human Factor Standards for Health Care: Do Lessons from Aviation Apply? A Report on the human factors in health care workshop held as part of the Sixth International Australian Aviation Psychology Symposium, Sydney 6 December 2003