Response to *Proposed regulatory scheme for personalised medical devices, including 3D-printed devices, February 2019*

Health Technology Management Unit, East Metropolitan Health Service

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Background

In response to the TGA consultation paper *Proposed regulatory changes related to personalised and 3D printed medical devices* of November 2017, Royal Perth Hospital (RPH) made a substantial submission that addressed all of the proposals and asked a number of specific questions about the proposals.

Many of these have been addressed in the present proposal, but there remain a number of areas that require clarification.

The Department of Medical Engineering & Physics at RPH has Australia's oldest Biomedical Engineering service, established in 1969, and operates out of one of the country's largest and busiest hospitals. It provides a service to all patients in Western Australia, supplying custom made medical devices (including surgical planning models) across a wide range of specialities for adult and paediatric patients of all of the major hospitals in Western Australia, public and private. This Department has more experience with custom medical devices than any other group in Australia.

Executive Summary

Recommendations

Given the low risk and potentially large number of devices, all Class I personalised medical devices should have the same regulatory requirements as current Class I custom-made devices, including those made using patient image data.

Tertiary hospitals employing National Engineers Register (NER) registered Biomedical Engineers working with clinicians within the hospital should be exempt from the responsibilities of a Medical Device Manufacturer for both patient-specific and custom-made devices.

Not-for-profit manufacturers should be given either an exemption from or substantially reduced fees, along the lines of the existing Annual Charge Exemption scheme, to reflect the difficulty in funding added compliance costs. Failure to do this will likely stifle innovation in the medical device design and manufacture and result in poorer patient outcomes.

There should be a transition period of at least five years for any substantial changes to the current regulations.

A copy of the manufacturer's statement should also be provided to the medical practitioner requesting the custom device.

General comments

Scope

The proposed changes go far beyond the stated purpose of improving regulation of high risk devices. TGA has included all devices, including Class I devices, under rules designed for much higher risk devices. This approach will place unwarranted and excessive demands on the supplier of low-risk devices.

Many of the proposed changes are justified by reference to 3D printing and increased risk, but the proposed changes are far more wide-ranging than devices made with 3D printing. Nor does the addition of 3D printing to a device production process by itself increase the risk level of that device. The overwhelming majority of currently custom medical devices are Class I.

For example our department produces custom-made orthotic insoles, spinal orthoses, ankle-foot and other lower limb orthoses, prosthetic limbs, maxillo-facial prostheses, plagiocephaly helmets, wheelchair joysticks, cutlery, switch actuators, phone and tablet mounts, surgical drill and cutting guides, stoma plates, CPAP masks and many more. Many of these are made by or using 3D printing; all are Class I devices. Under the current rules for custom-made devices we are not obliged to become a Manufacturer or list these devices on the ARTG, but the proposed changes may require that we do both of those things. These are low risk devices, and do not warrant the added regulatory burden.

Financial impact

These proposed changes will have a substantial effect on our service. We produce many custom-made medical devices under the current regulatory framework. Many will now no longer be considered custom-made devices, if this proposal is adopted.

Even more concerning is the implication (probably unintended) that Class I personalised devices could become Class IIa if they are made using some form of patient imaging. This will impose very substantial costs, as the majority of custom devices that we (and probably most manufacturers) make currently are Class I.

As a public hospital, we supply our devices at no cost to the patient. We do not have either a budget or an income stream to pay for compliance costs, unlike for-profit medical device manufacturers. An increase in compliance costs will not benefit the Australian public, as it will result in poorer health care outcomes, while the money will only be shifted from the State to the Federal government, with no net benefit to Australia.

Our compliance costs are likely to be very large. The number and range of devices we produce would imply about $350,000 in device examination fees and $11,000 per year in listing alone. Added to this would be the cost of QMS inspections and audits. Other on-costs will be at least one additional staff member, training for existing staff, external consultants to assist initial setup and software. We estimate the total start-up cost of at least $450,000 and $160,000 per annum thereafter.

Likely impact

It is not the core business of a hospital to be a medical device manufacturer and seeking a budget allocation from scarce funding to become one is unlikely to be successful.

If these proposals are adopted it is highly likely that services such as ours will simply cease to exist. This will result in significant and ongoing increased costs to the public health system, the loss of knowledge and skills in medical device design and manufacture (reducing Australian competitiveness in a field in which we are currently World-leaders), and inferior outcomes for patients who have come to expect a high level of care.

The TGA should also understand and appreciate the impacts that these proposed regulatory changes may have on other hospital services who currently supply custom made medical devices. These potentially include maxillofacial prosthetics, orthotics and prosthetics, providers of mobility aids and custom wheelchairs, providers of communications technology and more.

For many years, for-profit manufacturers have been generally uninterested in developing solutions for "one-off" cases. In contrast, it is our mandate to treat all patients referred to our service, which has enabled patients to be successfully treated who would otherwise have poor outcomes.

For example, in 1984 our department designed and manufactured the world's first custom-made device designed from CT data for a patient who would have otherwise had his arm amputated. Instead, he has enjoyed 35 years of functional use of his arm and economic engagement. If we cease to produce custom-made medical devices, this benefit to the community will be lost.

Potential benefits

None of the purported benefits of these changes are relevant to the Public Health sector. Increased market opportunities are not relevant for a non-commercial operation. Nor does the Public Health sector compete with commercial providers. Furthermore, Australian Public Hospitals Accredited under the NSQHS Standards for safety and quality are already subject to third party quality oversight of their operations, albeit not from TGA.

Alternative or additional strategies

All Class I personalised medical devices should have the same regulatory requirements as current Class I custom-made devices.

Exempt non-profit and charitable institutions (including all public hospitals) from any and all fees payable to achieve and maintain regulatory clearance as a medical device manufacturer.

Responses to proposals

1. Introduce new definitions for personalised medical devices

Do you support the proposal?

In general we agree with adopting the IMDRF definitions, which are an improvement on the original proposal. Several important points remain unclear.

The TGA definitions, while drawn from the IMDRF document, do not include the important emphasis on responsibility in that document. The proposal should be re-written to emphasise that custom-made devices are the responsibility of the authorised professional requesting them, while patient-matched devices are the responsibility of the manufacturer.

This is a much more important distinction than between of a device "matched to the patients' anatomy" and one that "address … specific anatomo-physiological features", or even whether a batch process is used for all or part of the production.

What do you consider to be the benefits and disadvantages this proposal?

The definition of "patient-matched device" is vague and open to interpretation, which will lead to confusion. The change in classification of currently custom-made devices will impose a substantial regulatory burden (see below).

While there may be benefits to commercial manufacturers in having harmonised definitions, this is of no benefit to a non-commercial operator. This is particularly so in the case of Class I patient-matched devices (see below) where the proposed changes will incorrectly elevate the risk class of many devices.

Will be any unintended consequences arising from this proposal?

The proposal states that patient-matched devices require oversight according to their risk classification (page 7):

> The patient-matched category of devices, which currently falls under the custom-made definition in Australia, will no longer be eligible for this exemption, and instead will require third party regulatory oversight according to the device risk classification.

The rest of the document, however, appears to extend the rules for Class IIa devices to all patient-matched devices, regardless of risk. This is not reasonable & should be changed to explicitly indicate that Class I patient-matched devices are treated differently due to their lower risk (i.e. the same as Class I custom-made devices).

For adaptable medical devices the proposal states (page 14):

> This means, that for devices that are classified above Class I, they already hold appropriate conformity assessment evidence.

The implication here is that manufacturers of Class I adaptable devices will need a higher standard of conformity assessment than currently. To say that manufacturers of higher-risk devices already have the appropriate evidence implies that manufacturers of Class I devices do not. This is not appropriate for the lowest risk class devices, which by number are the vast majority of currently

custom-made devices. The justification for this proposal was to better regulate high-risk devices, not to place greater burden on low-risk devices.

What changes would you need to make (if any) to meet the new arrangements?

We will need to make extensive changes to our compliance processes to comply with this proposal. At a minimum we will have to become a Manufacturer under TGA regulations.

What financial impact (both costs and savings) would this proposal have for you?

We produce a wide range of custom medical devices, from Class I to Class III, and under these proposals will need to have many of them listed on the ARTG. This represents a significant burden on our service (see details below).

What period would be needed for you to implement this proposal?

A minimum of five years would be needed, given the time required to restructure and recruit staff to perform the extra compliance duties.

2. Change the requirements for supplying custom-made medical devices in Australia, so that additional information must be provided to the TGA and to patients and, to allow the TGA to inspect manufacturing sites

Do you support the proposal?

We generally agree with this proposed change.

What do you consider to be the benefits and disadvantages this proposal?

There could be substantial cost implications in extending document retention from 5 years to 15 years. Paper records incur substantial costs due to their volume, and electronic records need to be periodically migrated and checked to ensure they are not kept on orphaned technology and/or suffer from media degeneration.

This should not be an issue for Public Hospitals. For example, WA Health policy already requires keeping records for 15 years post last visit or 10 years post death of a patient.

Will be any unintended consequences arising from this proposal?

Patients often misunderstand documents supplied to them, and often worry about information they are given. A statement about their custom device could also lead some patients to be unduly concerned about their device, and this could lead to poor health outcomes.

As an example, one patient was concerned about their custom-made titanium cranioplasty plate and was reassured that it was quite strong. This patient later hit their *in situ* plate with a hammer to demonstrate the strength to friends and subsequently required further medical care.

What changes would you need to make (if any) to meet the new arrangements?

New forms would have to be written and approved by the Health system. These forms will need to become part of the document control systems at both the Departmental and Health level, as they will be publications of the Health Department, which will take some time to achieve and incur increased costs.

What financial impact (both costs and savings) would this proposal have for you?

There would be no savings, and a small increase in costs.

What period would be needed for you to implement this proposal?

This change could be implemented within a year.

3. Introduce a framework for regulating medical device production systems which will allow healthcare providers to produce lower risk personalised devices for treating their patients, without the need for manufacturing certification

Do you support the proposal?

Despite clarification from the previous proposal, the definition of a Medical Device Production Systems (MDPS) remains ambiguous. There are no approved systems currently in existence, making it difficult to determine where TGA sees the bounds of this definition.

This proposal requires considerably more thought and clarification.

As in our previous submission we note that many processes in such a system are highly operator dependent. The proposed definition makes no allowance for this, but instead assumes that a conforming system will always produce conforming devices. It is hard to see how this could be controlled without unduly restricting the ability of the facility to provide quality devices.

For example, differences between metal artefact reduction software on different imaging systems can produce quite different outcomes. To control this a MDPS would have to mandate a particular imaging system with specified software.

While automated metal artefact reduction software can help when modelling from CT scans with large metallic implants, it is often necessary to manually edit the model to obtain quality results. If the MDPS allowed manual editing then the output quality is contingent on the operator. If it does not, then in many cases a usable output could not be produced.

What do you consider to be the benefits and disadvantages this proposal?

This proposal could benefit Healthcare providers who do not have the expertise to produce custom medical devices, as they would be able to buy a Conforming MDPS.

We do not see any benefit to our service from this proposal, and note that it would likely stifle innovation (see below).

Will be any unintended consequences arising from this proposal?

This requirement would discourage innovation & increase costs. Consider the widespread use of Open Source software in medical image manipulation and 3D modelling. This software is often of the highest quality and has superior features to commercial software, but doesn't fit the TGA regulatory model of commercial products with national sponsors.

What changes would you need to make (if any) to meet the new arrangements?

We would need to procure and commission one or more suitable MDPS, train staff in their use and incorporate them into our existing clinical and quality systems.

What financial impact (both costs and savings) would this proposal have for you?

If the proposal required the replacement of many of our existing systems the cost would be substantial. We have in the order of $1,000,000 invested in our current software and hardware.

What period would be needed for you to implement this proposal?

Depending on the cost of a MDPS, procurement and commissioning of replacement systems could easily take three or more years in a Public Health setting.

4. Update the classification rule for medical devices that record diagnostic images so that it includes any device for this purpose and not just X-rays, for example 3D-printed models of patient anatomy

Do you support the proposal?

Our previous objections to the proposed rule remain and are restated below.

> **5.4 Medical devices intended to record diagnostic images**
>
> A medical device that is intended by the manufacturer to be used to record diagnostic images is classified as Class IIa. This includes software and anatomical models intended for diagnosis or investigation of the anatomy.

The term "diagnostic images" is not appropriate for this clause, as imaging data used to make an anatomical model is not always diagnostic, but often taken for treatment planning or recording purposes. This definition needs to be reworded to make this clear, if the intention is that models made from non-diagnostic imaging should be covered by this clause.

Is the phrase "software and anatomical models" intended to refer to digital and physical anatomical models respectively? A digital model is in fact data, which can be viewed and manipulated by any suitable software. Or is this phrase intended to refer to software used to view and analyse medical imaging data?

These ambiguities should be resolved.

Most anatomical models are not used for diagnosis or investigation, but rather for planning procedures, as a step in producing a device or for explaining a procedure or condition to a patient. The preamble text discusses models used for planning surgery, but the proposed rule 5.4 says:

> This includes software and anatomical models intended for diagnosis or investigation of the anatomy.

which does not include surgical planning. Subsequent text (under the heading "What would this mean?") again uses the phrase "diagnosis and investigation".

If non-diagnostic uses of models are intended to be covered by this clause that should be clarified.

What do you consider to be the benefits and disadvantages this proposal?

We believe that this proposal has substantial disadvantages, particularly as it may unintentionally cause current Class I devices to be treated as Class IIa (see below).

Will be any unintended consequences arising from this proposal?

While this proposal discusses anatomical models, it is written too broadly and could be read to cover any device manufactured using imaging data. The chief problem is the definition of "diagnostic images". Many 3D printed anatomical models are not made for diagnosis. In our records only 34% of all of the "anatomical models" that we produce were for surgical planning and none were for diagnosis, although several were used to help understand an already diagnosed pathology or to explain it to a patient.

We do not intend that these models record diagnostic images, so they should not fall under the amended rule for X-Ray film.

Likewise, we do not believe that a device produced using diagnostic images should be considered as recording diagnostic images. For example a surgical guide made to fit a bone surface derived from diagnostic images should not be covered by this rule.

An example of this is the Voxelcare system (ARTG ID 278937), which we currently use. In this system the patient's foot is scanned, the scan is used by a clinician to define the appropriate insole and the insole is CNC carved from a blank. Clearly the final device is Class I, and the system is appropriately listed as Class I. But the scan of the patient's sole is used by a clinician to design their intervention (in the form of an orthotic insert). Under the proposed definition the system could be Class IIa as it records "diagnostic images".

Furthermore, the blanket Class IIa designation for anatomical models is not appropriate. Even when used in diagnosis, is it understood that the information embedded in an anatomical model is not of the same order as that in a diagnostic image. No diagnosis would be made completely or even substantially on the basis of an anatomical model. These models are rather used to confirm an existing diagnosis or to better understand the pathology, not as a primary diagnostic tool.

Finally, we believe that if these changes increase costs, as they are likely to, there will be an incentive for people to have models printed overseas and posted to Australia. Medical imaging data is easily shared across the Internet and the models are cheap to post. Would these be treated like the importation of any other medical device for personal use? If not, how would this trade be policed?

What changes would you need to make (if any) to meet the new arrangements?

The changes required would depend on the final wording adopted. If it resulted in a reclassification of currently Class I devices then substantial changes will be required.

What financial impact (both costs and savings) would this proposal have for you?

The financial impact depends on the final wording adopted. If it results in a reclassification of currently Class I devices then the extra compliance costs will be substantial. We produce a large number of Class I custom-made devices, both types of device and individual devices, and many of them could be caught in this change.

What period would be needed for you to implement this proposal?

If there was a change to our Class I devices, implementing this change would require at least five years.

5. Regulate medical devices with a human origin component, for example a 3D-printed implant incorporating cells from the patient, as medical devices with a biological component rather than as pure biologicals

Do you support the proposal?

In our response to this issue in the previous consultation we asked for clarification about devices that are made entirely from biological materials, and gave the example of allograft bone fixation devices. These are clearly devices and should be regulated as such.

This issue has not been addressed by TGA.

Apart from that point, we believe that the regulation requirements of a product should be determined by a risk analysis of both the biological and non-biological components.

What do you consider to be the benefits and disadvantages this proposal?

There may be substantial benefits to regulating devices with a biological component as devices. The risk assessment framework for devices can be easily extended to cover a biological component, but it would be difficult to regulate a device using the biologicals framework.

That said, we do not feel that high-risk biologicals would be adequately covered by the device framework. Consider including a risk assessment for the biological component into the device framework, and if high-risk (Class 4) regulating as both a device and a biological.

Will be any unintended consequences arising from this proposal?

The proposed wording does not cover devices that, while clearly devices, are made completely from a biological tissue.

It is possible that the device regulatory framework will miss some high-risk biological components, increasing risk. This may be a greater problem in jurisdictions with different regulators for devices and biologicals.

What changes would you need to make (if any) to meet the new arrangements?

We do not believe that we would have to make any changes to meet this arrangement.

What financial impact (both costs and savings) would this proposal have for you?

We do not believe that this change would have a significant financial impact on us.

What period would be needed for you to implement this proposal?

We do not believe that this change would apply to our service.

6. Make it clear that any modifications or adaptations to personalise a medical device that has already been supplied must have been intended by the original manufacturer of the device

Do you support the proposal?

The minimalist changes suggested in the section “What would change?” seem reasonable if they only emphasise the existing regulations, but without an example of the proposed text it is hard to comment.

However, if this is all that is contemplated then the change does not seem necessary. The current regulations already require the assembler or modifier to work within the limits set by the manufacturer.

The justification for this proposal seems confused. There is nothing special about 3D printing compared to other manufacturing processes. The finished device produced depends on more than just the material and instructions, but so do many Class I devices, including external prostheses and custom orthoses.

What do you consider to be the benefits and disadvantages this proposal?

There do not seem to be any real benefits from this proposal.

Will be any unintended consequences arising from this proposal?

The change in philosophy to no longer consider raw materials as medical devices affects more than 3D printing. Custom orthoses and external prostheses are manufactured from materials deemed to be therapeutic goods, and it is considered sufficient to regulate the raw material in these cases.

There are hundreds of orthoses and external prostheses produced in Australia every week. A change to the way these are regulated would have wide-ranging consequences.

What changes would you need to make (if any) to meet the new arrangements?

Without the proposed wording we do not know what changes we would need to make.

What financial impact (both costs and savings) would this proposal have for you?

Without the proposed wording we cannot estimate the financial impact.

What period would be needed for you to implement this proposal?

Without the proposed wording we cannot estimate the time to implement this proposal.