Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Medical devices manufactured at the point-of-care

Analysis of survey responses by sector

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Contents

Overview

Prior to February 2021, most medical devices that were designed and manufactured to suit an individual patient/client were known as “custom-made” medical devices. These kinds of devices were exempt from the requirement to have TGA approval or to be included in the Australian Register of Therapeutic Goods (ARTG) before they could be imported, exported, or supplied (although they were subject to other regulatory obligations). As a condition of exemption, these kinds of devices were required to meet all other regulatory requirements for medical devices including reporting adverse events.

Over the past two decades, rapid advances in computing technology and materials have resulted in significant changes to medical imaging, manufacturing and, as a result, medical device technology. Easier access to this technology and newer methods of manufacture such as 3D-printing allow more complex and, in some cases, higher-risk medical devices to be “personalised” for an individual patient/client.

In 2021, following extensive consultation, the Australian Government introduced a new framework for the regulation of these kinds of devices, to ensure that these kinds of devices continue to be safe and fit for their intended purpose and perform as expected throughout the life of the device, thereby delivering safe outcomes for patients. The new framework changes the legal definition and the rules for “custom-made” devices by:

- Reducing the number and scope of devices that are considered “custom-made”
- Requiring most devices that are designed and manufactured for individuals to have TGA approval and inclusion in the ARTG before they can be imported, exported or supplied.

In response to stakeholder feedback received during the implementation of the new framework, the TGA is focusing on how the new framework applies to manufacturing at the point-of-care and what refinements could be made to ensure regulation is appropriate without introducing unnecessary burden for point-of-care facilities.

Four surveys, which closed on 17 May 2023, were conducted to obtain more information about point of care manufacturing activities in four sectors from the following cohorts:

1. Allied health sector
2. Dental sector
3. Manufacturing hubs at the point-of-care
4. Hospital and healthcare facilities where medical devices are manufactured at the point-of-care

The following paper provides an overview of the survey results from the four surveys. It includes:

- a snapshot of response numbers
- brief insight into the demographic of respondents
- information relating to the adaptation, design, manufacture and supply of medical devices
- identification of emerging themes and issues.

Allied health sector

240 responses were received for the allied health survey; 234 responses from allied health professionals, one from a private individual concerned about the collection of patient data and five from dental prosthetists who had inadvertently filled out the wrong survey. Only the 234 responses relating to the sector were analysed.

Respondents

144 respondents (62%) were individuals, and 90 (38%) were responding on behalf of a clinic/facility/organisation.

The majority of respondents identified themselves as:

- Physiotherapists (36, 13%)
- Occupational Therapists (42, 16%)
- Podiatrists (34, 13%)
- Orthotists (16, 6%)

Some responses included multiple descriptions/professions.

Roughly half of the respondents identified that they were members of their respective peak/professional body. 42% were unsure or did not answer.

Organisational structures

89 (35%) of the respondents identified that they were operating within a government clinic/service. 53 (21%) identified that they were operating from a private clinic/service.

Approximately 31% of respondents worked for an organisation with multiple clinics/facilities, 18% worked for an organisation with one clinic/facility and 13% worked for one clinic/facility of an organisation with multiple clinics/facilities.

66 (28%) of the respondents identified that the organisation/clinic/facility they were operating in had accreditation with Australian Commission on Safety and Quality in Health Care (ACSQHC).

Device-related activities

Modification, assembly and adaptation

A significant proportion of respondents (200, 85%) reported that modification, assembly, or adaptation of medical devices to suit individuals does take place at their organisation/clinic/facility; 25 responded that these do not take place at their organisation/clinic/facility while 9 were unsure.

114 (57%) respondents source their medical devices from Australian suppliers, 73 (37%) source medical devices from both Australian suppliers and overseas suppliers. 12 (6%) indicated that they are unsure where their medical devices are sourced.

Device design

102 (44%) respondents indicated they are involved in the design or modification of an existing design for a device. 112 (48%) respondents said they were not involved in these activities and 20 (8%) said they were unsure whether these kinds of activities were taking place.

Of those who report they are undertaking these activities, 91 were using physical impressions, 26 were creating a design template and inputting patient/client parameters, and 42 were using CAD software to design a device.

Design approval processes varied but did include both Ahpra professionals and practitioners/professionals with other training/accreditation.

Manufacturing medical devices

131 (56%) of the respondents are involved in manufacturing activities within their organisation/clinic/facility. Of these respondents, 99 (76%) indicated the devices manufactured are for use on their own clients, 2 (1%) said the devices were for someone else's patient/client, and 30 (23%) said they manufactured devices for both their own patients/clients as well as someone else's.

Of those respondents who identified that they were manufacturing devices, the majority (78, 60%) indicated that the devices were being made from materials and components sourced from Australian suppliers only, followed by 42 (32%) who identified that their materials and components were sourced from both Australian and overseas sources.

The majority of the medical devices being manufactured were for external use only indicating they are likely to be lower risk devices (Class I). Two respondents indicated they were manufacturing medical devices for use in a body orifice for a short period of time (less than 30 days continuously), one respondent indicated they make surgically invasive devices that are not permanently implanted and one makes permanently implantable devices.

Approval for device design and manufacture varied, as did quality assurance processes. Respondents indicated:

- We have a Quality Management System that has been certified against ISO 13485 (2, 1%)
- We have a Quality Management System that has been certified against ISO 9001 (5, 2%)
- We have a documented internal QMS (including established design parameters, supply chains, operation procedures etc) (49, 21%)
- We have Australian Health Service Safety and Quality Accreditation (27, 11%)
- We have National General Practice Accreditation (1, 0%)
- Unsure (50, 21%)
- There are minimum competency requirements for staff involved in design and/or manufacture of the device (75, 31%)
- We are subject to review from external bodies who have reviewed and/or certified our internal QMS (26, 11%)
- Other (5, 2%)

Adverse events and reporting

Respondents reported a range of mechanisms for recording adverse events (AE) including the following:

- Internal review within the manufacturing/clinical team (203, 46%)

- Reporting to the TGA (33, 8%)
- Reporting to Australian Commission on Safety and Quality in Health Care (19, 4%)
- Reporting to NDIS Quality and Safeguards Commission (43, 10%)
- Reporting to AHPRA (36, 8%)
- Reporting to State/territory government (30, 7%)

Respondents made a number of comments relating to adverse events including:

AEs documented via internal incident management systems

Registered to hospital incident reporting system

Aged Care Q&S Commission

AOPA

NSW Health incident reporting system

External reporting to supplier/manufacturer of devices

Patients can complain via internal and external mechanisms. There is a process where complaints can be referred to the HCCC or AHPRA for external review.

Hospital complaints officer

Incidents and accidents are reported via hospital IMS+ systems. These incidents are reviewed by department managers and monitored by hospital / District Clinical Governance Units. Actions and education are undertaken, depending on recommendations from the reviews.

Internal reporting to state government body, safety learning system, information management reporting

RiskMan

Communication and education

The sector broadly sought more information to support them with meeting regulatory obligations, primarily asking for:

- Standardised QC checklists when assessing PoC manufacturing
- Governing oversight to provide clear representation and communication channels between regulation and AH professionals.
- Clarity regarding legislative onus for manufacturers vs healthcare professionals (morphology vs non-morphology etc).

Themes

There are multiple professions that fall under allied health, with no one governing/regulatory body providing guidelines or communication regarding obligations and legislation. This theme is evident across health care organisations as well, with organisations and providers incorporating statutory government bodies, private entities, NGOs etc.

There is significant divergence with regard to raw material sourcing, manufacturing, modification, quality assurance, patient information/training and adverse event reporting throughout not just the

sector as a whole but within each profession (i.e., significant discrepancies between occupational therapists).

There is no consensus with regard to legislative obligations for the modification and manufacture of medical devices, with some responders outlining their belief that healthcare professionals who prescribe the device are liable for regulation, as opposed to the person manufacturing the device.

There is significant concern regarding the financial and administrative burden associated with absorbing legislative responsibility.

Protocols surrounding modification/manufacturing processes seem largely driven by either internal processes, or education (including ongoing education received through employment training). These protocols and processes are patient-centric and modelled on healthcare practice frameworks rather than medical devices manufacturing protocols.

Concerns were raised regarding the distinction between manufacturing resulting from instructions received from a healthcare professional, as opposed to allied health driven manufacturing, and whether this transfer of decision making resulted in a difference in legislative burden. The key take-away point was there exists a lack of clarity about who is responsible for adherence to TGA regulations.

Dental health sector

400 responses were received for the dental sector survey. 396 responses were received from dental health professionals, one from a private individual concerned about the collection of patient data and three from members of the allied health sector who had inadvertently filled out the wrong survey. Only the 396 responses relating to the dental sector were analysed.

Respondents

275 respondents (69%) were individuals, and 121 (31%) were responding on behalf of a clinic/facility/organisation.

Noting that some responses included multiple descriptions/professions. The majority of respondents identified themselves as:

- dentists (incl. specialists) (211; 53%)
- dental prosthetists (79; 20%)
- dental technicians (33; 8%).

The following identified membership with a representative peak:

- Australian Dental Association (ADA) – 55%
- Australian Dental Prosthetists Association (ADPA) – 21%
- Australian Dental Technicians Australia (ADTA) – 5%

Organisational structures

298 (76%) of the respondents were operating from a private clinic/service, 47 (12%) were from a government clinic/service, and 36 (9%) identified as operating from a private laboratory/workshop.

Approximately half of respondents were working in an organisation that only had one clinic/facility. 75 (19%) identified themselves as sole traders, 9 (2%) identified as independent contractors, and 101 (25%) indicated their organisation operated multiple clinics/facilities.

301 (75%) respondents indicated that their clinic/facility/organisation had one or more employees registered with Australian Health Practitioner Regulation Agency (Ahpra).

151 (38%) indicated their clinic/facility/organisation was accredited by the Australian Commission on Safety and Quality in Health Care (ACSQHC). 108 (27%) said they were not accredited and 137 (35%) said they were unsure.

Device-related activities

Modification, assembly and adaptation

A significant proportion of respondents (329, 83.8%) reported that modification, assembly, or adaptation of medical devices to suit individuals does take place at their organisation/clinic/facility; 36 responded that these do not take place at their organisation/clinic/facility while 31 were unsure.

277 (84%) respondents source their medical devices from Australian suppliers, 41 (12%) source medical devices from both Australian suppliers and overseas suppliers, and 15 indicated that they are unsure where their medical devices are sourced.

Device design

300 (76%) respondents indicated they are involved in the design or modification of an existing design for a device. 74 (19%) of respondents said they were not involved in these activities and 22 (5%) said they were unsure whether these kinds of activities were taking place.

Of those who report they are undertaking these activities, 263 (66%) were using physical impressions (with 236 [60%] of respondents identifying that they were designing the device based on these impressions), 103 (26%) were creating a design template and inputting patient/client parameters and 160 (40%) were using CAD software to design a device. 96 (24%) respondents did not answer this question.

191 (48%) respondents indicated an Ahpra-registered practitioner had to review and approve the design of the device before it was made. 113 (29%) identified that there was no approval process for the design of the device before it was manufactured.

Manufacturing medical devices

283 (72%) respondents indicated that manufacturing activities are taking place within their organisation/clinic/facility. Of these respondents, 196 (50%) indicated that the devices manufactured are for use on their own clients, 26 (7%) said the devices were for someone else's patient/client and 61 (15%) respondents said they manufactured devices for both their own patients/clients as well as someone else's.

People identified as conducting the manufacture of the devices:

- Ahpra-registered health practitioner as a component of their practice (259, 65%)
- A relevant, trained health professional as a component of their practice (66, 17%)
- Someone other than an Ahpra-registered or trained person (33, 8%)

Of those respondents who identified that they were manufacturing devices, the majority (256, 91%) indicated that the devices were being made from materials and components sourced from Australian suppliers only, followed by 26 (9%) who identified that their materials and components were sourced from both Australian and overseas sources. Only one respondent said they were exclusively using imported materials in the devices they were manufacturing.

Respondents indicated a wide range of devices were being manufactured, from removeable devices used continuously for short periods (such as splints, aligners, dentures) through to surgically invasive devices that were either permanently implanted or intended to be removed after an extended period. These devices range from Class I (low risk) through the Class IIb (medium/high risk).

Approval protocols for device design and manufacture varied, as did quality assurance processes. Respondents indicated:

- We have a Quality Management System that has been certified against ISO 13485 (28, 7%)
- We have a Quality Management System that has been certified against ISO 9001 (17, 4%)
- We have a documented internal QMS (including established design parameters, supply chains, operation procedures etc) (140, 35%)
- We have minimum competency requirements for staff involved in manufacture of the device (86, 22%) noting these varied and alluded to nonspecific training and competency. Others included:
    - AHPRA registration,
    - dentists, BDSc
    - qualified prosthetists,

    - dental technology qualifications,
    - dental assistants,
    - registering with appropriate regulating body, training,
    - CEREC training,
    - in-house training,
    - written protocols for manufacturing process,
    - high level of experience and competency among other less specific responses.
    - Diploma of Dental Technology, Advanced Diploma Dental prosthetics
    - DDS
- We are subject to review from external bodies who have reviewed and/or certified their internal Quality Management System. Examples included NSQHS accredited, quality control of the manufacturers, annual audit by ACT Health, mandatory and regular assessment against the National Safety and Quality Health Service (NSQHS) Standards (23, 5.8%)
- Other (28, 7%)

Adverse events and reporting

Respondents reported the following measures for managing adverse events:

- 86% internal review within the manufacturing/clinical team
- 20% report to Ahpra
- 11% report to their state/territory government
- 11% report to the TGA
- 9% do not report events
- Other – professional indemnity insurer, IMS (incident management system), etc.

Respondents made a number of comments relating to adverse events including:

- These events are not rare or serious enough to merit reporting.
- Catastrophic events would be reported to “associated authorities”.
- Adverse events don’t occur with oral appliances, only the need for minor adjustments.
- It’s difficult to identify adverse events as the mouth is a “dynamic environment” with many factors that may contribute to something going wrong.

Communication and education

173 (44%) of respondents are unsure of their regulatory obligations to the TGA and 77 (19%) advise they don’t have any.

When asked what would help them to meet their regulatory obligations, the most common responses were:

- Greater clarity from the TGA about whether I have regulatory responsibilities - 72%
- Factsheets with specific information relevant to the dental sector - 72%
- More information from peak/professional bodies about my specific regulatory responsibilities - 62 %
- Dedicated online training about regulatory responsibilities that can be undertaken at any time - 47%
- Regular, direct engagement through presentations/webinars with the TGA - 41%
- I would like to know whether the materials and equipment I’m using are approved by the TGA - 37%

Themes

Manufacture of devices is prevalent in this sector, including the manufacture of permanently implantable medical devices.

Regulatory responsibilities

259 of 283 respondents (92%) considered PoC manufacturing to be a component of clinical practice by an Ahpra-registered health practitioner, with the regulation of these medical devices falling under the remit of Ahpra. Both Ahpra-registered and other respondents were almost universal in their agreement that regulatory responsibility for devices supplied to patients/clients rests with Ahpra-registered practitioners. Comments made by respondents include:

> *All AHPRA registered oral health practitioners are "accountable" for the delivery of dental care to patients throughout our clinic network. They may delegate "responsibility" of various activities to clinic staff though they cannot delegate accountability.*

In a vast percentage, the following tasks rest on a Ahpra-registered health practitioner (dentists and dental prosthetists):

- Modification, assembly or adaptation of medical devices
- Completion of the design or modification of the design
- Approval of the device design before it is forwarded for manufacture (where it is a separate process) 190/300
- determination of whether an on-site manufactured device is appropriate

However, 3-5% of the responses suggested that the above tasks were being performed by dental technicians alone who are not in the remit of Ahpra.

Some comments implied that the TGA regulates materials and that Ahpra is the more appropriate regulator for the medical device design/manufacturing aspects of dentistry:

> *All materials used are supplied by Australian suppliers and are TGA approved and regulated. All manufacturing and design is done by registered dental professionals within the scope of practice outlined by AHPRA.*
>
> *…add use of non TGA approved materials to AHPRA reporting.*
>
> *most issues are either patient related or iatrogenic (in which case the regulator is AHPRA).*
>
> *The only thing the TGA can regulate and they already do is to make sure materials provided by suppliers are TGA approved.*

Understanding TGA regulation

Almost half the respondents were unsure if they or their organisation/clinic/facility had regulatory obligations to the TGA. More than two thirds expressed a desire for greater clarity from the TGA about whether they have regulatory responsibilities. These responses suggest many respondents are potentially unaware that they have regulatory responsibilities to the TGA.

A commonly expressed misunderstanding is that as long as raw materials or components are sourced from an Australian supplier, the medical devices thus produced are exempt from ARTG inclusion. To this end, nearly 40% of respondents indicated they would like the ability to know whether the materials and equipment they are using are approved by the TGA.

Further, there appears to be little awareness that even for medical devices that are exempt from inclusion in the ARTG, regulatory requirements still apply, including reporting adverse events to the TGA.

Only ten percent of respondents reported that they report adverse events to the TGA. Responses also indicate a difference in understanding of what an adverse event is, and whether it should be reported to the TGA:

> *The only adverse event is an appliance not fitting and this is determined prior to issue.*
>
> *Adverse event is considered when the device has to be remade.*
>
> *If there was a catastrophic event then this would be reported to the associated authorities.*
>
> *I've never experienced an adverse event in relation to what we make. The devices are extremely low risk. I just done [sic] see it.*
>
> *Have not had an adverse event serious enough that it required external reporting*
>
> *I have never seen any adverse reaction to any oral appliance in my 21 years of practice except minor adjustments which are done in house as and when needed.*
>
> *I would report first and foremost to my Professional Body (the ADA) and my professional indemnity insurer and then take all steps advised. I have never had to report any adverse events beyond these two bodies.*
>
> *If a device doesn't fit or fails in an unacceptable time then it is simply remade or the design altered after my professional assessment of the reason for failure. I would not normally consider this an "adverse event".*
>
> *I don't think we do anything that can 'go wrong' and it is not clear what this means. Any adverse outcomes for us would be restoration failure which is then failure of material (not mixed properly) or clinician fault. Design etc needs to be fixed but we have never had a significant failure is 20 years that would warrant reporting outside our rooms.*

Low incidence of QMS

The survey results demonstrate evidence of low levels of awareness and low rates of accreditation to ACSQHC standards. Survey responses also demonstrated a poor understanding of what comprises quality assurance or a quality management system, with several comments suggesting clinical competence and training are adequate measures to ensure quality assurance. Only a small percentage of clinics/facilities/organisations have implemented a robust quality management system conforming to ISO 13485 or ISO 9001. There is no QMS in place in more than half the survey represented clinics/facilities/organisations.

Changes to regulation

Several respondents pushed back against increased regulation on the grounds of a "long and safe track-record" within the sector and expressed concerns that increased regulation may:

- disproportionately increase regulatory burden in a small market such as Australia,
- result in increased costs for patients,
- reduce the availability of products, materials and services, and
- hurt smaller labs.

On the other hand, some respondents supported further regulation, expressing the following concerns about the existence of unregulated labs and technicians:

> *…public needs products approved for clinical use by a regulator such as the TGA.*
>
> *Bring back registration for laboratory technicians*
>
> *Bring back regulation of labs*

Others cautioned against duplication of regulation:

> *…organisation level quality control/assurance (for manufacturing specifically, but care provided in general) should be part of the practice accreditation process done through the Australian Dental Association…*
>
> *simplification of the TGA regulatory obligations for medical devices, especially if they are sourced/ manufactured by TGA approved materials and equipment and to avoid duplication with existing regulatory and governance obligations which also covers Safety and Quality like the NSQHS, ahpra [sic] and the state health department.*

There were also suggestions to limit increased regulatory control to a subset of dental devices.

> *I completely agree with a custom made bone implant needing extra approval and requirements but there should be very little restrictions and rules and compliance around providing crowns, bridges, splints etc and other custom made devices to patients so long as the material used is approved.*
>
> *…The ONLY thing that the TGA should focus on with regards to regulatory responsibilities is the installation or use of devices, in line with the Spaulding Classification, which are devices which are inserted into and come into contact with sterile tissues. This should be regulated at a practice level.*

Manufacturing hubs

29 responses were received for the POC manufacturing hubs survey. 28 responses were received from respondents who work in manufacturing hubs and one response was from a private individual concerned about the collection of patient data. Only the 28 responses relating to manufacturing hubs were analysed.

Respondents

Respondents included privately (13, 46%) and publicly (10, 36%) funded organisations as well as education/research institutions. Three respondents received both private and public funding while two respondents did not select a funding source. Seven (25%) of the responses were from education/research institutions. One of the education/research institutions advised that they are manufacturing devices for experimentation purposes only and do not currently supply devices for use commercially.

24 respondents described the kind of facility they work in, answering as follows:

- hospital-based dedicated manufacturing hubs (9, 38%)
- clinical practices with manufacturing capability (9, 38%)
- private manufacturing facilities (9, 38%)

The remaining manufacturing facilities were described as a university, research organisation or off-site manufacturing hub connected to a hospital, or as an educational institution not connected to a hospital.

Organisational structures

The most common types of professionals working in POC manufacturing hubs were:

- Administrators (13, 48%)
- Engineers (any type) (12, 44%)
- Technical officers (10, 37%)
- Orthotists/Prosthetists (9, 33%).

Within the engineering profession, the most common types of engineers reported were biomedical engineers (11, 37%) and production engineers (7, 23%).

The majority of manufacturing hubs (23, 82%) have employees who are members of peak industry/professional bodies. Four (14%) respondents said none of their staff members were a member of a peak industry/professional body. One facility (4%) was unsure whether any employees are members of a peak/professional body.

The most common peak industry/professional bodies (with at least 5 manufacturing hubs) are:

- RACS - Royal Australian College of Surgeons (7)
- AOPA - Australian Orthotic Prosthetic Association (7)
- APA - Australian Physiotherapy Association (5)

- AOA- Australian Orthopaedic Association (5)
- APodA - Australian Podiatry Association (5)
- Engineers Australia (5)
- OTA - Occupational Therapy Australia (5)
- SPA - Speech Pathology Australia (5)

The majority of the manufacturing hubs have Ahpra-registered health practitioners involved with manufacturing activities (18, 64%) – nine (32%) had no Ahpra-registered staff and one facility was unsure.

Device-related activities

Risk classification and types of medical devices

Respondents were asked about the classification of medical devices they manufacture and responded as follows:

- Class I (21, 75%)
- Class IIa (12, 43%)
- Class IIb (6, 21%)
- Class III (1, 4%)

No manufacturing hubs reported the manufacture of Class I (sterile) or Class I (measuring) medical devices.

Five (18%) manufacturing hubs were unsure of the classification of devices they manufacture.

The types of devices made in the greatest number of manufacturing facilities are:

- Medical devices for external use only that are used continuously for 30 days or less (these devices may be used for longer periods but not continuously. Examples include orthotics and weight-bearing prosthetic limbs) – these are manufactured in 17 (68%) of the survey-included manufacturing hubs
- Medical devices for external use only that are used continuously for 30 days or more (these kinds of devices are not removed throughout the duration of use. Examples include knee immobilisers, splints, etc) – these are manufactured in 10 (40%) of the survey-included manufacturing hubs
- Surgical planning models – these are manufactured in 9 (36%) of the survey-included manufacturing hubs

These results generally correlate with the answers given regarding classification of medical devices made by manufacturing hubs, indicating respondents are generally able to accurately identify the class of devices they are making.

Of note, only two manufacturing hubs (8%) make medical devices that are permanently implanted (Examples include prosthetic implants, cranio-facial implants, orthopaedic devices, etc).

Commentary provided by respondents in relation to the devices they are manufacturing includes:

We mostly develop for experimentation but do not manufacture for sale.

We expect to be producing a number of higher risk devices from 2024, pending 3rd party QMS accreditation (we are working towards ISO13485).

We have listings for surgical guides and medical devices for use in a body orifice in preparation

Virtual 3D model mainly. Very few 3D printed models

Starting materials used to manufacture medical devices

The majority of respondents source their starting materials from both Australian suppliers and directly from overseas (15, 54%). Nine respondents (32%) source their starting materials from an Australian supplier only. Two (7%) advised that they only source materials directly from overseas. The remaining two facilities (7%) were unsure where their facility sources starting materials from.

Only six (21%) respondents advised that they are using starting materials specifically intended for use in the manufacture of a medical device.

Quality Management Systems and other risk management protocols/strategies

26 of the 28 facilities (93%) responded to the question seeking information about the use of Quality Management Systems and/or other risk management protocols/strategies for medical devices they manufacture.

- Only eight of the 26 POC manufacturing hubs (31%) have a QMS certified to either ISO 9001 or ISO 13485:
  - Two facilities have both ISO 9001 and ISO 13485 certification for their QMS.
  - Two facilities have only ISO 3485 certification.
  - Four of the facilities have only ISO 9001 certification.
- 18 (64%) respondents said their devices were made within a documented QMS that would ensure their devices meet the Essential Principles. 17 (61%) respondents claimed their devices meet the Essential Principles.
- 22 (79%) respondents noted staff are required to meet minimum competency requirements.
- Three respondents have Australia Health Service and Quality Accreditation.

Information about manufactured medical devices

26 of the 28 facilities provided the following details about information supplied with or about the devices they manufacture:

- Instructions For Use (25, 96%)
- Labels (21, 81%)
- Meeting TGA advertising code requirements (12, 46%)

Adverse events and reporting

Only 26 of the 28 facilities responded to the question about adverse event reporting:

- 20 (77%) advised that they report adverse events to the TGA
- Eight report to the NDIS Commission
- Five report events to Ahpra
- Two report to (ACSQHC)

Communication and education

Respondents provided a range of responses to the question of who regulates activities at their facility:

- TGA (22, 79%)
- NDIS Quality and Safeguards Commission (9, 32%)
- State/territory government (9, 32%)
- Ahpra (7, 25%)
- ACSQHC (4, 14%)
- NASRHP (2, 7%)

Two facilities (7%) advised that they were not regulated by any of the options available.

The most requested/popular options for measures that would help respondents with meeting their regulatory requirements are:

- Regular, direct engagement through presentations/webinars with the TGA (23, 88%)
- Dedicated online training about regulatory responsibilities that can be undertaken at any time (21, 81%)
- Greater clarity from the TGA about whether we have regulatory responsibilities (20, 77%)
- Knowing whether materials and equipment we're using are approved by the TGA (16, 62%)

Sixteen (59%) of respondents expected to receive information about their regulatory obligations from their peak industry/professional body and nine expected to receive information from their state/territory government health department.

Themes

Survey results indicate that there is a wide range of different organisational types currently managing and operating medical device manufacturing hubs. This includes organisations with different funding and operational models (hospital-based, clinical practices with manufacturing capability, educational institutions, and private manufacturing facilities).

Responses also indicate a diverse range of professionals are working in these medical device manufacturing hubs including Ahpra-registered practitioners, relevantly trained health professionals

who aren't registered with Ahpra, engineers, trained technicians and administrators. Most manufacturing hubs (64%) advised that they do have Ahpra-registered health practitioners working within their facilities.

With respect to device classification, 75% of medical device manufacturing hubs advised they manufacture Class I medical devices. The next most common classes of devices made by manufacturing hubs are Class IIa (43%) and Class IIb (21%) medical devices. Only one manufacturing hub advised that they produce Class III medical devices. No manufacturing hubs reported that they are making Class I (sterile) or Class I (measuring) medical devices.

Of concern, five of the manufacturing hubs (18%) were unsure of the classification of devices that they manufacture. 21% of facilities responding to the survey advised that they only use starting materials that are specifically intended for use in the manufacture of medical devices, indicating the specification instrument enabling exemption of devices has had a limited impact on this sector.

Only 31% of POC manufacturing hubs reported having a QMS certified to either ISO 9001 or ISO 13485. Only four had ISO 13485 certification. Of further concern, only 65% of POC manufacturing hubs (17) said that their devices meet the Essential Principles. Most manufacturing hubs (96%) indicated they do supply their devices with Instructions For Use.

The survey results highlighted a need for increased awareness and understanding of regulatory obligations for organisations managing and operating medical device manufacturing hubs. POC manufacturing facilities about their adverse reporting for medical devices they manufacture. Of concern, 23% of manufacturing hubs advised that they do not report adverse events to the TGA. Only 46% of facilities advised that they were meeting TGA advertsing code requirements.

Survey respondents were asked to indicate who was responsible for regulating activities at their facilities. Most manufacturing hubs (79%) advised that TGA regulates activities at their facility. Concerningly, two facilities (7%) advised that they were not regulated by any of the provided options. When POC manufacturing hubs were asked directly if they had regulatory obligations to TGA, 19 facilities (68%) agreed, three facilities disagreed (11%) and 6 facilities (21%) were unsure if they had regulatory obligations to TGA.

Overall, the survey results suggest there is a need for increased communication and education of TGA regulatory requirements for medical device manufacturing hubs.

Commentary

Respondents provided suggestions for helping them understand and meet regulatory obligations for medical devices. Responses included:

> *[We need] Different regulations for POC manufacturing compared to commercial manufacturing.*
>
> *Regulatory obligations need direct engagement and communication from the TGA to state public health officials. Health Service Executive teams and hospital management. We currently are receiving no guidance, advice or support from centralised safety, compliance, and quality departments.*
>
> *Clear and precise understanding from both Federal and state authorities, as both are going down different pathways of understanding through funding bodies.*
>
> *As a point of care manufacturing facility, we manufacture devices for all sub-specialties. Engineer accreditation is virtually non-existent, because peak professional bodies out there*

are set up for civil engineering, not biomedical, and have very steep barriers to membership, such as refusing to recognise some degrees obtained overseas.

Our organisation is regulated by ACSQHC, but currently our manufacturing department is not included in the membership/audit process. We could add our department to the [ACSQHC] assessment process if this was an appropriate regulatory pathway.

Hospitals and health care facilities – For policy/governance teams

29 responses were received for the hospitals and health care facilities survey. 28 responses were received from respondents who work in hospitals or healthcare facilities and one response was from a private individual concerned about the collection of patient data. Only the 28 responses from hospitals and healthcare facilities were analysed.

Respondents

We received survey responses from a range of hospitals and healthcare facilities across Australia. This included facilities located in NSW, ACT, QLD, WA, TAS and VIC.

Facility size varied:

- Over 100 staff (19, 68%)
- 21 to 100 staff members (four, 14%)
- 2 to 20 staff members (five, 18%)

Only six of the 16 facilities (38%) indicated that they were accredited under the Australian Health Service Safety and Quality Accreditation (AHSSQA) Scheme.

Device-related activities

Modification, assembly and adaptation

Most hospitals and healthcare facilities (21, 75%) advised that modification, assembly or adaptation of medical devices to suit individuals takes place in their facility. Six (21%) of respondents advised that these activities did not occur in their facilities and one respondent was unsure if these activities occurred within their facility.

Of the 21 respondents who said they were participating in these kinds of activities:

- Most said an Ahpra-registered health practitioner was responsible for carrying out these activities (18, 86%)
- Two (10%) advised that trained health professionals in orthotics and prosthetics were responsible for carrying out these activities
- One respondent advised that the piece of equipment being adapted in their facility was a dental chair that could be adjusted for left and right-handed dentists

Device design

The following responses were received in response to the question asking whether the design or modification of an existing design of medical devices for manufacture by someone else takes place in their facility:

- Yes (10, 36%)
- No (11, 39%)

- Unsure (7, 25%)

Of the ten respondents who said yes;

- Eight (80%) were taking an impression of a patient/client's anatomy, either physical or virtual, and providing the impression, or a model made from the impression, with written instructions to the manufacturer.
- Five (50%) were using Computer Aided Design (CAD) software to design a device that could be manufactured.
- Three (30%) were using a CAD software design template provided by someone else to input patient/client parameters to establish a device design.
- Two (20%) were providing written instructions only to the manufacturer of the device.
- Three (30%) were unsure of the technologies and methods used to design or modify device designs.
- One hospital advised that grinding of an orthotic was used to modify the design of a device when it was causing problems for a patient.

Device design in these facilities is completed by:

- An Ahpra-registered health practitioner (6, 60%)
- A relevant trained health professional such as an orthotist or a prosthetist (3, 30%)
- People with training relevant to design of medical devices who are not health professionals or registered with Ahpra including rehabilitation engineers, biomedical engineers, industrial engineers, clinical design engineers, speech pathologists and trained technicians (5, 50%)

Further statistics of note include:

- Of the six facilities that advised that an Ahpra-registered health-practitioner was designing devices, only two also advised that engineers were also involved in completing designs for medical devices.
- In two of the three facilities where design is completed by a relevant trained health professional (not Ahpra-registered), engineers were not indicated as being involved in the design process.
- Two respondents (20%) advised that they were unsure who completes the design or modification of the design. One of these two 'unsure' facilities also indicated that an Ahpra-registered health practitioner completes the designs. This response may indicate that the respondent was not always sure who completes the design when it is not completed by an Ahpra-registered practitioner.

We asked these same ten hospitals and healthcare facilities to describe who approves the design before it is forwarded for manufacture.

Most survey respondents indicated that either an Ahpra-registered health practitioner or other relevant, trained health professional approves the device design before manufacture. One of the respondents advised that there was no separate approval for the device design and one facility advised that they were unsure if there was a separate approval process for the design.

Only one of the healthcare facilities confirmed that both the engineering and clinical perspectives are considered when approving device design before forwarding it for manufacture:

There are two approvals before devices are provided for clinical use:

(1) Biomedical Engineer (technical review)

(2) Clinical Review (almost always an AHPRA-registered health practitioner, but may be a non-registered health professional such as medical physicist in some cases)

Manufacturing of medical devices

In response to whether the manufacture of medical devices takes place within their facility:

- Yes (16, 57%)
- No (8, 29%)
- Unsure (4, 14%)

These devices are intended for:

- Patients/clients of the facility only (13, 81%)
- Patients/clients of other practitioners/facilities in addition to their own patients/clients (3, 19%)

No facility reported manufacturing devices solely for supply to other practitioners/facilities.

Of the 16 facilities manufacturing devices solely for their own patients/clients:

- Either an Ahpra-registered health practitioner or a relevant, trained health professional (including occupational therapists, podiatrists, orthotists, prosthetists, allied health assistants, prosthetic technicians, etc) or both were responsible for manufacturing devices.
- One facility advised that both Ahpra-registered and relevant trained health professionals manufacture devices and that *"Rehabilitation engineers, biomedical engineers and trained technicians manufacture devices in response to clinical referrals"*.
- Fourteen advised that devices are approved or signed off by an Ahpra-registered health practitioner or relevant trained health professional. The other two facilities advised that approval occurs through an internal policy approval/process only.
- Two facilities advised that approval was received by sign off from someone with specific credentials relevant to manufacturing devices. In these two cases, the approval measures were:

  Sign-off for each device type is specified in our quality management system

  Biomedical Engineer (first sign-off), and then sign-off from a health practitioner

These results suggest that approval measures vary for different types of devices being manufactured, and it is unclear in most cases whether this was a decision made by the organisation, or if the approval processes occurred organically due to necessity.

Starting materials used to manufacture medical devices

Respondents indicated starting materials used in the manufacture of their devices were sourced from:

- An Australian supplier (9, 56%)

- Both Australian-based and overseas suppliers (5, 31%)
- Unsure of the origin (2, 13%)

Of the 21 respondents who indicated they are engaged in the modification, assembly or adaptation of medical devices:

- Fourteen (48%) advised they source their medical devices from an Australian supplier
- Five (7%) said they sourced their medical devices from both Australian and overseas suppliers
- Six (21%) said they were unsure where the devices were sourced
- Four declined to answer.

Quality Management Systems and other risk management protocols/strategies

The 16 facilities manufacturing medical devices reported the following risk management protocols and strategies:

- Two (13%) have independently certified QMS systems.
  - One of these facilities has QMS certification against both ISO 9001 and ISO 13485.
  - One has QMS certification against ISO 9001 and is working towards obtaining ISO 13485 certification.
- Seven (44%) had a documented internal QMS system (including the two facilities with certified QMS systems).
- Six (38%) indicated they were accredited under the AHSSQA scheme
- Seven (44%) indicated they were unsure what risk management protocols and strategies are in place.

Three facilities advised that there are minimum competency requirements for staff involved in design and/or manufacture of the device. These facilities advised that their minimum competency requirements for staff are:

> *Design and manufacturing qualifications (staff must be employed as a Biomedical Engineer with appropriate bachelor's degree qualifications). Staff must complete mandatory training in risk, safety, use of health data, internal QA system training.*
>
> *Different manufacturing activities have different competency requirements. This is determined based on the risk analysis for the manufacturing process and the final device class.*
>
> *Yes, must meet minimum competencies for manufacture and TGA regulations.*

One respondent, who identified themselves as responsible for auditing healthcare facilities, provided a comment expressing concern over the lack of QMS in facilities:

> *My experience with devices manufactured on site, is that there is often no initial contact with infection control to assess sterilising requirements. Traceability also has to be achieved for these items.*

Information about manufactured medical devices

We asked all 28 hospitals and healthcare facilities what information is provided to the patient/client when they are given a medical device. 24 of the 28 facilities (86%) advised that they provided at least one or more of the following four sources of information to their patients/clients:

- Instructions For Use
- A fact sheet incorporating instructions for use with clinical treatment information
- Post-operative/treatment care instructions
- Contact details to a specific service or facility are provided to patients to connect if something goes wrong.

The remaining four facilities (14%) were unsure what information is provided to the patient/client when they are given a medical device. One facility advised that the information provided varies as there is often no knowledge of requirements and no internal control systems in place.

The 28 facilities were asked if they provided any other sources of information to patients. One facility advised that they also provide a patient information card and patient information sheet for implantable medical devices. Further comments include:

> *Routinely nothing is given to the patient, they follow up with hospital or doctor if something goes wrong, and vice versa if a medical alert is triggered in the device implanted.*
>
> *In some cases a patient may be provided an information card with details of their implant but this is not common currently.*
>
> *It is my experience that this [information provided to patients/clients with medical devices] is very variable as there is often no knowledge of requirements. Post operative/treatment care instructions are often developed by clinicians with no version control and in many cases when I review this they are often out of date, there is no internal control systems in place. The same applies for fact sheets.*

Information relating to medical devices provided to patients/clients is:

- Recorded in the patients/client's file (25, 89%)
- Given to the patient/client (17, 61%)
- Recorded in an internal patient/client registry (14, 50%)
- Recorded in an external patient/client registry (5, 18%)
- Recorded in the patient/client's MyHealth record (2, 4%)
- Unsure (1, 4%)

The following additional information on record keeping was provided by respondents:

> *Information is often on file with the device company for Class III items, but the principle receptacle is the hospital and doctors records.*
>
> *The first 3 [methods] does occur but it is very variable in terms of consistency. Where required an implant registry is maintained. In our [state], our Licensing and Regulatory Unit assess compliance for maintaining an implant registry.*

An internal [state] health database (compliant with health information storage legislation) is used to store all case history for personalised medical devices. This includes the original request form, design history, quality assurance reports, and delivery information.

Different documents given depending on the device.

File should be in eMR [Electronic Medical Record that is sent to GP upon discharge] for specific items, Patient cards (supplier origin) are supplied for implantable items. Uncertain if all departments are following this process-they have been instructed to do so.

Information, regarding CPAPs and similar devices, issued to patients, is recorded in our [State] Local Health Network register.

Adverse events and reporting

The 16 facilities engaged in the manufacture of medical devices said the following measures for reporting adverse events are in place at their facility:

- Adverse events are either internally reviewed within the manufacturing/clinical team and/or reported through hospital reporting structures (15, 94%)
- A report is made to the TGA (5, 31%)
- A report is made to Ahpra (3, 19%)
- A report is made to the Commission (4, 25%)
- A report is made to the NDIS Commission (1, 6%)
- A report is made to a state/territory government (3, 19%)
- One facility advised that they were unsure what measures are in place for reporting adverse events.

Two facilities provided the following additional comments:

Facility incident register IIMS is available, however no adverse events have never occurred, and therefore none reported.

Patients are given registered medical devices, such as Continuous Positive Airway Pressure (CPAP) devices. These are made, and supplied to the hospital, by external organisations. Some surgical medical devices are made and used within the hospital. These are not issued to patients.

Communication and education

In response to being asked whether they had regulatory obligations to the TGA, respondents provided the following responses:

- Yes (16, 57%)
- No (2, 7%)
- Unsure (10, 36%)

We asked the 28 hospitals and healthcare facilities what would help them and their organisation with meeting regulatory obligations for medical devices.

The most requested/popular options for helping organisations to meet their regulatory requirements are:

- Greater clarity from the TGA about whether we have regulatory responsibilities
- Dedicated online training about regulatory responsibilities that can be undertaken at any time
- More information from peak/professional bodies about specific regulatory responsibilities to their members
- Knowing whether materials and equipment we're using are approved by the TGA
- Regular, direct engagement through presentations/webinars with the TGA

Themes

Overall, the survey results indicate a wide range of activities with medical devices are being undertaken in hospitals and health care facilities by a combination of Ahpra registered practitioners, relevant trained health professionals, engineers, and trained technicians. Results indicate most hospitals and healthcare facilities are only manufacturing devices for their own patients or clients (81%) – the remaining 19% are manufacturing devices for both their own patient/clients as well as for someone else's patients/clients.

Approval measures for medical devices manufactured on-site vary depending on the organisation and the risk level of the devices being manufactured. Generally, singular approval was obtained from either a clinical, engineering, or technical perspective. Only one facility advised that sign-off from both a clinical and engineering perspective was needed before manufacture could proceed.

With respect to the use of quality management systems (QMS), 16 facilities provided information about the risk management protocols and strategies they had in place:

- Only two of the 16 facilities that manufacture medical devices (13%) have independently certified QMS systems. Just under half of these facilities (7, 44%) had a documented internal QMS system (including the two facilities with certified QMS systems).
- Seven of the 16 facilities that manufacture devices (44%) indicated that they were unsure what risk management protocols and strategies are in place.

Survey responses indicate the processes and methods used to provide information to patients/clients about their medical devices and keep records of medical devices supplied to patients/clients varies (both between and within hospitals and healthcare facilities) and the methods used may not always meet current regulatory requirements. Similar issues were observed with responses relating to the review and reporting of adverse events:

- Most facilities either internally reviewed adverse events within the manufacturing/clinical team and/or reported adverse events through hospital reporting structures.
- Only a small number of facilities advised that they report adverse events to TGA (5/16, 31%) or to other relevant regulators including Ahpra (3/16, 19%), the Commission (4/16, 25%), NDIS Commission (1/16, 6%) or to state/territory governments (3/16, 19%).
- One facility was unsure what measures are in place for adverse event reporting.

More than half of the facilities identified that they do have regulatory obligations to the TGA (57%), 36% were unsure and 7% said that they did not have regulatory obligations to the TGA. Furthermore:

- Six facilities that manufacture devices said they were unsure if they had regulatory obligations to TGA and one facility that manufactures devices said they did not have regulatory obligations to the TGA.
- Six of the 16 facilities (38%) that manufacture devices in-house indicated that they were accredited under the AHSSQA scheme, noting that some facilities may not understand what the AHSSQA scheme is, as most hospitals and healthcare facilities should be accredited (excluding private dental clinics).
- Only three facilities (13%) advised that they trust their health practitioners and the staff operating manufacturing facilities to know what regulatory obligations they have. Five respondents (22%) did not provide a response.

Overall, the survey results suggest there is a need for increased communication and education of TGA regulatory requirements for hospitals and healthcare facilities.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Devices Emerging Technology Section Medical Devices Surveillance Branch	August 2023

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