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The Australian and New Zealand Dental Implant Registry: Regulatory Requirements and Registry Development

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ABSTRACT

Background: The Therapeutic Goods Administration is responsible for the Regulation of manufacture and supply of all medical devices including dental implants. Medically, the patient is given a 'Patient Implant Card' (PIC). It is recommended to monitor the performance of devices in an implant registry.

Methods: The TGA Regulations were reviewed. The detailed methodology to establish a National Dental Implant Registry is presented and initial analysis performed.

Results: The placement of dental implants in Australia is not as regulated as other comparable medical devices. Currently the Registry has 43 clinics with 44 participating dental practitioners. The DIR has recorded dental implant related information from 4842 patients with 9429 devices (Australian and New Zealand data). Patients were usually over 60 years of age, more female and more implants were placed in the maxilla. The Australian replacement rate of dental implants was 1.83% and 1.42% for prostheses.

Conclusions: Improving the regulatory framework by introducing the issuing of Patient implant cards (PICs) so the specific device information type is transferable and retained long term and establishment of long-term independent monitoring in a Dental Implant Registry, crucial in identifying problems with the aim of improving outcomes for patients and dental professionals should be considered.

1 | Introduction

Dental implants have revolutionised the practice of dentistry by allowing dentists to permanently replace extracted teeth and thus allow patients to maintain normal oral function. The concept of dental implant placement by osseointegration between alveolar bone and titanium was demonstrated over 50 years ago. The initial work was developed in academic institutions with well-trained surgeons performing the surgery and well-trained prosthodontists completing the restorative component. This resulted in excellent results with over 95% success rate being achieved [1].

Since those early days, the use of dental implants has exploded with an estimated 12–18 million implants having been placed per year with several hundred million being placed in the last

Abbreviations: ADA, Australian Dental Association; ADIA, Australian Dental Industry Association; AOANJRR, Australian Orthopaedic Association National Joint Replacement Registry; ARCR, Australian Register of Clinical Registries; ARTG, Australian Register of Therapeutic Goods; CE, Conformité Européenne (European Conformity); CPD, Continuing Professional Development; DIR, Dental Implant Registry (of Australia and New Zealand); DIR-PIC, Digital Patient Implant Card (issued by the DIR); FDA U.S, Food and Drug Administration; FDI, Fédération Dentaire Internationale (notation system for tooth location); Medsafe NZ, (Medicines and Medical Devices Safety Authority of New Zealand); PIC, Patient Information Card; PID, Patient Information Document; PIL, Patient Information Leaflet; TGA, Therapeutic Goods Administration (Australian Commonwealth); TMJR, Temporomandibular Joint Registry.

Clinical Relevance

- The placement of dental implants in Australia & New Zealand is essentially unregulated. Follow up to determine the medium to long term outcome is dependent on the individual dental professional and a compliant patient who keeps returning to the same dental clinic. Commonly this doesn't occur.
- The dentist can be unaware of how successful their medium to long term success rate is and if the patient goes to a different dentist, then the type of implant and abutment is usually unknown.
- The solution is for the dentist to voluntarily record the details of their cases in an independent, ethically approved, well governed Dental Implant Registry. The service is free and provides each patient with an electronic Patient Information Card which gives the full details of their device.

decade [2]. Similar trends have been observed in Australia. In a 2017 survey it was found that over two thirds of General Dentist's place implants and over 80% of specialist Periodontists, Prosthodontists and Oral Maxillofacial surgeons place implants [3]. There were wide differences in the frequency of which implants were placed. Specialist Periodontists and Oral Maxillofacial surgeons place implants on a weekly basis in over 70% of respondents. Whereas with General Dentists only 30% place implants weekly. Similarly, there was a variation in practice with specialist Periodontists and Oral Maxillofacial surgeons predominately completing the surgical phase of implant placement and then referring to a General Dentist or Prosthodontist for the prosthetic component. Conversely, fewer General Dentists and Prosthodontists perform both the surgical and prosthetic phases.

The question then arises as to whether this greater frequency and wider involvement results in the same high rate of success as seen in the initial academic studies? This is what is expected by the patient and the dental professional. The real answer to this question is largely unknown as Dentistry is largely practiced on an individual short term episodic basis with minimal follow up. Certainly, the patient expects that given the high financial outlay and extended chairside procedures the implant should be trouble free for the rest of their life. They also expect that if for any reason they change dentist the new dentist will be able to identify the system and resolve any problems in a short period of time without delays regarding record procurement from the original treating clinician.

This is not a new issue. Nearly a century ago the American surgeon Codman said, 'The common sense notion that every hospital should follow every patient it treats for long enough to determine whether its treatment has been successful and then initiate a review to preventing similar failures in the future!' [4]. The medical response to this challenge has been twofold: regulation and registries.

Regulation by government agencies sets standards, for manufacturers and end users, which must be met. Registries established by medical associations or industry bodies collect data on implanted foreign body devices to monitor the long-term outcomes.

In Australia, the Therapeutic Goods Administration (TGA) serves as the regulatory authority and provides regular updates on requirements outlined in the 'Essential Principles' which govern medical devices, including implantable devices such as dental implants, to ensure their safety and performance [5]. The Essential Principles are outlined in section 1 of the Therapeutic Goods (Medical Devices) Regulations 2002, which are authorised by the Therapeutic Goods Act 1989, part of Australia's legislative framework [5]. The TGA also monitors outcomes and produces advisories if the standards are not met, can take regulatory action, such as the removal of products from supply in Australia.

Regulatory requirements on behalf of manufacturers and sponsors (distributors into Australia) Data regulations specific to Dental Implants primarily relate to requirements for clinical evidence, patient information materials, post-market surveillance data and registries. The TGA requires clinical evidence (data must demonstrate safety and performance) Risk Management Data (data covering hazards like infection, implant failure, or allergic reactions) and Labeling and Instructions (Data on device identification, usage and warnings) with devices that are successfully added to the ARTG [6].

In the first 2024 newsletter published by the Dental Board of Australia [7], the Chair attached the 'Regulatory basics on medical devices for health practitioners' guidance issued by the TGA that shows that dental implants are generally defined as Class 2b devices, which pose a moderate to high risk to the patient (S 1). For Class 2b devices, manufacturers are required to produce a generic Patient Implant Card (PIC) and a Patient Information Leaflet (PIL), both of which must be included with the device at the point of sale. The surgeon is then responsible for completing the PIC and providing both the PIC and PIL to the patient. Together, these documents outline the type of device used, guidance on its safe use and instructions on how to report any adverse events or concerns [8, 9].

Dentistry in general has not been involved in the development of registries. Indeed, in the past when individuals have suggested to professional organisations that implants should be registered the concept was resisted.

The Australian Framework for National Clinical Quality Registries sets the standards applicable to all health registries which include dental, although currently there are no specific standards set for dental implants. Dental implants are part of health and are not unique. The framework sets principles for data management for all registries and the DIR is set up to conform with the guidelines [10].

A medical device registry is a scientific body that systematically collects information and data related to medical devices used in clinical practice. Analysis of the information collected serves several key purposes including but not limited to: Data Collection, Monitoring, Safety and Effectiveness, Regulatory Support, Research and Development, Improving Patient Outcomes, Patient Transparency and public Health

[4]. Registries independently collect data on specific devices. Australia hosts a substantial number of clinical registries, reflecting its commitment to improving healthcare outcomes through systematic data collection and analysis. Over 120 clinical registries are listed on the Australian Register of Clinical Registries, encompassing a wide range of clinical domains [10]. The majority have been established by the relevant surgical associations; however, in certain cases, such as with pelvic mesh registries, have been initiated following recommendations from regulatory authorities in response to significant concerns regarding poor clinical outcomes.

The classic example of a successful device registry is the Australian Orthopaedic Associations National Joint Registry (AOANJRR) which has collected over two million knee, hip, shoulder and other joint replacements to date [6]. Although voluntary, the AOANJRR currently captures around 98.8% of all hip, knee and shoulder replacements in Australia [6]. The value of this approach was exemplified by Australia's early detection of the crisis associated with cobalt–chrome joint replacements, making it the first country globally to identify the issue. All patients in Australia who received this type of device were identified, monitored and if needed the implant was removed and replaced. The Australian and New Zealand Association of Oral & Maxillofacial Surgeons, the association covering all Oral and Maxillofacial Surgeons has established a Temporomandibular Joint Registry (TMJR) for all temporomandibular joint replacements placed in Australia and New Zealand. Registries are powerful tools to monitor, educate but importantly protect the public.

Currently there are a limited number of operational dental registries, independent of implant manufacturers, either internationally or in Australia [11–17] (Table 1).

In 2016, Derks conducted a study utilising registry data to assess implant performance and complications such as peri-implantitis [12]. This study highlighted the importance of registries in gathering long-term data, identifying risk factors and improving clinical outcomes. Key findings included the identification of specific implant types and patient characteristics associated with higher complication rates, potentially providing clinicians with important information that can be used to make clinical decisions to improve patient outcomes. Additionally, Klinge [2] further emphasised the importance of dental implant registries and underscored the role of registries in ensuring patient safety and enhancing the overall success rates of dental implants. The article advocated for the broader implementation of registries to facilitate continuous monitoring and early detection of potential issues. These articles and existing devices registries underscore the significant benefits of dental implant registries in enhancing patient safety, improving implant success rates and providing valuable data for ongoing research, assisting manufacturers in product development and improvements, improving regulatory frameworks and good clinical practice.

The aim of this paper is to describe the TGA regulations and to how they apply to dental implants and their development. We also include initial results of an Australian and New Zealand dental implant registry which helps practitioners comply with their regulatory requirements for the protection of the public.

TABLE 1 | Summary of registries.

References	Source	Type	Numbers	Outcome
Derks et al. Ref. [12]	Swedish National Data Registry	Retrospective Random sample	11, 311 implants 2765 patients 800 clinicians	At 9 years Early implant loss 4.41% Patients 1.4 implants Overall 7.6% implant loss
Derks et al. Ref. [13]	Swedish National Data Registry	Retrospective Random sample Periimplantitis	1578 implants 588 patients	Estimate of Periimplantitis, 9 years None 23% Mild 45% Mod/severe 40%
Berg et al. Ref. [14]	Norwegian Medical Registry	Retrospective Pilot study	1326 implants 781 patients	At 1 year Implant loss 2.9%
Guo et al. Ref. [15]	Royal Dental Hospital of Melbourne (Australia)	Retrospective Cohort study 2005–2009	1622 implants 406 patients	Follow up mean 2.18 years Implant failure 2.7% Complications surgical 11.97% Biological 17.97% Restorative 14.17%
Duong et al. Ref. [16]	Adelaide Dental Hospital Australia	Retrospective Cohort study	537 implants 320 patients	Failure 12.75% over 9 years
Liam Ref. [17]	Melbourne Australia	Proof of concept trial	15 patients 10 clinicians	Demonstrates a viable electronic web based prospective trial
Present study	Australian Private Clinics	Prospective Includes retrospective Electronic based	4158 implants 1268 prosthesis 2571 patients 41 clinicians	Implant failure 1.83% Prosthesis failure 1.37% Registrations covering 7.5 years (2017–2025)

2 | Methods

The various Dental Implant Registries World-wide which have been established either on a country wide or international basis were reviewed and classified.

The Dental Implant Registry (DIR) was first piloted in 2018 and progressively developed and fully established in January 2024. It has full Australian ethical approval (Project Number 2023-04-385). The DIR has begun the process of obtaining New Zealand ethics approval. The data collection consists of patient data including age, gender, location, contact details, treating practitioner and medical history. The implant data consists of the manufacturer, number, size and length, location, date of procedure, whether bone grafting required and whether primary or secondary loaded. The prosthetic data consisted of the abutment type, crown type, materials, manufacturer and date of placement. Failure was measured by replacement of either the implant or the prosthetic component and documented the time between the original placement and the replacement procedure. The replacement rates also captured same day replacement, which can be utilised to analyse effectiveness of implant/abutment delivery systems or operator related handling issues of devices.

The DIR is a not-for-profit organisation that was initially funded partially through patient fees and private funding. Moving forwards, funding sources will include sale of reports, research grants and donations. To ensure long term sustainability, additional funding sources will continue to be explored. DIR's sustainability strategy focuses on expanding stakeholder partnerships whilst delivering value.

Oversight is provided through several committees, including a DIR Steering Committee, Patient Advocacy Group and Research committee. In development is the formulation of the Manufacturers Steering Committee and Data Governance Committee.

The governing body has identified and operates in full compliance with all relevant laws, regulations and jurisdictional guidelines and policies applicable to Clinical Quality Registries.

A Registrar, appointed by Implant Registries Pty Ltd. (company that supplies the software application which collects registry data), manages the technical operation of the application and ensures data integrity.

From April 2025, registration fees have now been waived for both patients and practices [18]. It serves a dual purpose as a device register and a device registry (Figure 1). Participation in the DIR is voluntary and uses an opt-out consent method. A PIS is provided to each registered patient. Patients can withdraw their data from the registry at any time. All data is securely stored within Australia. Collected data is anonymised before statistical analysis is performed. Raw data is not sold or disclosed to third parties. There is a strict governance framework [19].

The DIR device register is accessible online to participating clinical practices allowing flexibility to enter data directly or to securely submit information to the DIR team for registration. Participants have access only to their own patient information. Patients can access their own information online and are also issued an electronic 'Patient Implant Card' (PIC) post registration.

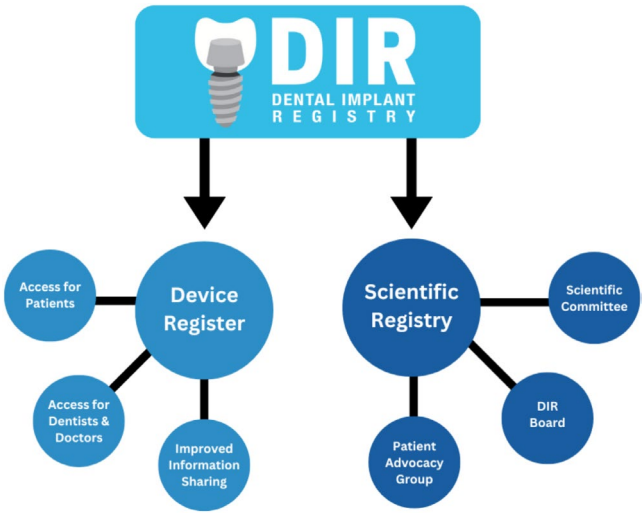


FIGURE 1 | Structure of the dental implant registry and its dual role as a register and device registry.

2.1 | Access to Identifiable Data

- *Patients*: can access their own implant records via a secure online portal. They may authorise new treating practitioners to access their records.
- *Treating Dental Professionals*: can only access patient data for patients they have treated (or been authorised to access by the patient).
- *DIR Staff*: may access identifiable data solely for registry management and analysis.
- *Manufacturers*: may request performance reports about their products, but only in aggregate and where confidentiality of other manufacturers is protected.

Consistent with the Australian Framework for National Clinical Quality Registries (2024) and Bellberry HREC requirements, identifiable data within the Dental Implant Registry (DIR) is securely stored within the registry platform, with access strictly restricted to authorised DIR staff. Access permissions are role-based and granted only to individuals who require identifiable data to perform approved operational, analytical, or governance functions to ensure the lawful and ethical handling of identifiable information.

The DIR acknowledges that health data inequities exist across the board and is committed to addressing these through culturally appropriate governance and endeavours to adhere to internationally recognised frameworks such as the OCAP principles (Ownership, Control, Access and Possession) and relevant Australian guidelines for Aboriginal and Torres Strait Islander data governance.

The DIR plans to actively engage with Indigenous communities and representative bodies to ensure that any data relating to these populations is collected, managed and used in a way that respects their rights and cultural values and supports equitable health outcomes.

Ongoing activities of the registry include:

- Exploring cultural data considerations in data governance
- Seeking representation from Aboriginal, Torres Strait Islander and Māori/Pacific Islander health and consumer advocates; and
- Engaging Indigenous and cultural advisors as required to ensure appropriate guidance and oversight
- Ensuring patient-facing documentation and information materials are culturally appropriate and available in multiple languages to support equitable participation

These actions support fair representation, culturally safe participation and alignment with Indigenous Data Sovereignty principles across all registry operations.

3 | Results

A review of the current regulatory frameworks in Australia and overseas and various Registries data was carried out and is presented in Supporting Information S1 and Table 1.

The Regulatory framework in Australia closely follows overseas regulators. Medically, the regulations around medical devices are well defined and recommend issuing PICs and PILs for patients. Currently, dental implants are exempt from this level of regulatory requirement in several countries including Australia.

When considering device registries, the largest dataset was seen from the Sweden National Data Registry which recorded 11,311 implants across 2765 patients, showing broad national coverage and strong statistical power [12, 13].

The smallest dataset was produced by a proof of concept trial, which involved 15 patients, demonstrating feasibility rather than population-level insights [17].

The present study had the second most dental implants recorded (8048 implants), with 43 clinics and 44 practitioners participating actively. A mixture of specialist and general dentists made up the participating practitioners (Table 2). This Australia/New Zealand wide prospective and retrospective study sits between national-scale registries and institutional cohorts, offering a real-world snapshot over 7 years (Table 3).

The Registry analysed that the average age of the patients was 60.8 years but with a wide age range. Over 80% of the patients were 50 years or older and there was a slight female preponderance (Table 3).

The distribution of dental implant placement by tooth location is presented in Figure 2, with prosthetics by tooth location in Figure 3. More dental implants and hence prostheses were recorded on the DIR cohort in the maxilla than the mandible. Upper anterior teeth and 1st and 2nd molars were the most frequently replaced teeth. The majority of dental implants (65.58%) were used in single fixed implant restorations.

TABLE 2 | Practitioner type.[a]

Practitioner type	Number of practitioners
Oral Maxillofacial Surgeon	5
Periodontists	13
Prosthodontists	5
General Dentists	21

[a]Active users, some clinicians only record intermittently.

Implant failure rates ranged from the lowest reported in the present study 1.83% implant failure (Table 4), 1.47% prosthesis failure, over 7 years. The highest failure rate was noted in the Adelaide Hospital based study with 12.75% failure over 9 years. The Derks et al. [13] a 7.6% overall implant loss after 9 years, with early loss at 4.41%.

4 | Discussion

This paper presents the TGA regulatory requirements for permanently implanted foreign bodies in humans. The legislation requires the manufacturer or sponsor of the implantable medical device to report adverse events in compliance with the essential principles within 20 working days. They are also required to provide annual reports, retain retention of supply and distribution data. These regulations are designed to protect the public from harm. The way in which implanted foreign bodies can be monitored for the whole of the life of the device or patient's life is by means of independent registries. This concept has been embraced and adopted by the medical profession with there being over 120 registries in Australia listed on the Australian Register of Clinical Registries (ARCR). The ARCR is a voluntary register of registries, so the actual number is estimated to be higher at over 200. Examples include the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) which has over 2 million hip, knee, shoulder and other joints registered. This model was followed when adverse reactions to pelvic mesh were identified. The Australian Government recommended that a Pelvic Mesh Registry be established and funded it [18]. Another example was the Intensive Care Registry which identified the number, location, type and status of all ventilators in Australia. This was invaluable information when the Covid pandemic struck. It is noteworthy that involvement of Health professionals in Registries is voluntary but under Commonwealth Quality Assurance Status rules there can be specific protections afforded to both the data and the health professionals who include their data in a Registry.

Dentistry has only partly embraced the concept of TGA regulations and the need to monitor the outcome of dental implants. There are a number of reasons for this. Dentistry often views itself as independent of mainstream health, usually operates in

TABLE 3 | Overall dental implant registry characteristics (AU data).

Total number patients	**2571**
Males	1112 (43.25%)
Females	1283 (49.90%)
Not known	176 (6.85%)
Age average and range	60.8 (19–96) years at time of procedure
Mean	63 years
Less than 50 years	521 (20.26%)
50 years or more	2065 (80.32%)
Total devices	5426
Total implants	4158
Number of implants per patient	1.8
Less than 50 years	1.53
More than 50 years	1.85
Total prosthesis	1268

Implant purpose	**Total**	**< 50 years old**	**50+ years old**
Single fixed crown	2721 (65.58%)	421 (77.11%)	2300 (63.84%)
Multiple implant bridge (partial arch)	721 (17.38%)	62 (11.36%)	659 (18.29%)
Full arch	453 (10.92%)	47 (8.61%)	406 (11.27%)
Over denture	127 (3.07%)	7 (1.28%)	120 (3.33%)
Other (zygomatic and extra oral)	127 (3.06%)	9 (1.65%)	118 (3.28%)

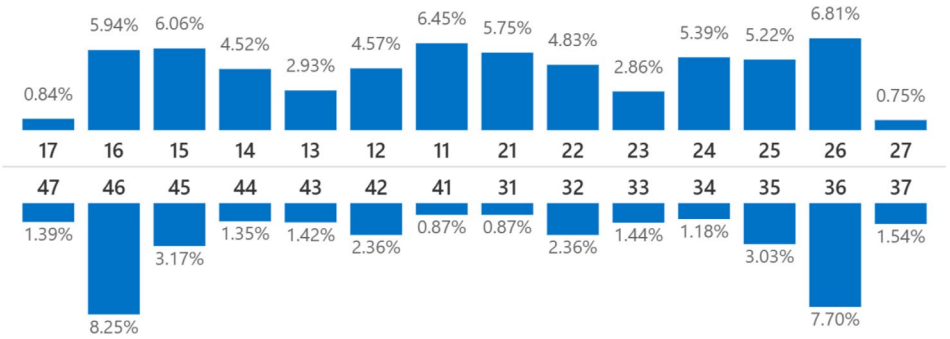


FIGURE 2 | Dental implants placed by tooth location (FDI).

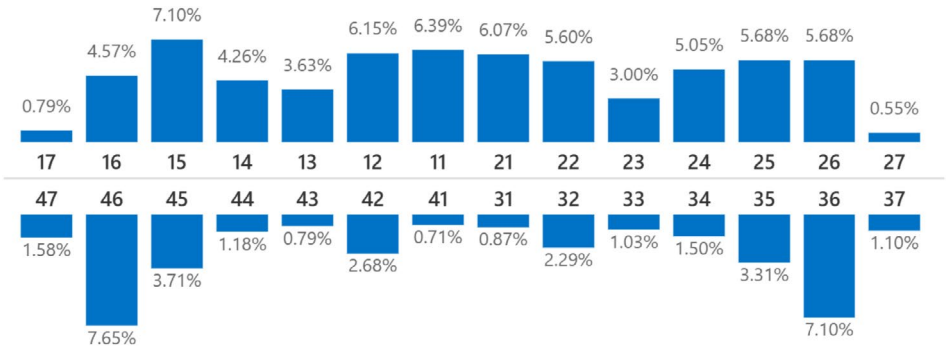


FIGURE 3 | Prosthesis placed by tooth location (FDI).

TABLE 4 | Dental implant and dental prosthesis removed and replaced.

		All complications		Complications within first year	
Device type	**Total**	**Replaced (including same-day)**	**Replaced (excluding same-day)**	**Replaced (including same-day)**	**Replaced (excluding same-day)**
Implants	4158	87 (2.09%)	76 (1.83%)	68 (1.64%)	57 (1.37%)
Prosthetics	1268	40 (3.15%)	18 (1.42%)	37 (2.92%)	15 (1.18%)

Note: Same-Day is registered as the same device type being registered on the same day, for the same patient, for the same tooth location.

isolated small practices and provides episodic treatments. The argument is also made that dental implants are highly successful and rarely cause issues [20]. These arguments are increasingly less tenable as clearly dental implants are permanently placed foreign bodies which can have significant adverse reactions [20]. It must be noted that the Therapeutic Act and Regulations apply to all suppliers in Australia even if the health practitioner considers they are independent of mainstream health. Recently two Dental Practitioners were prosecuted for failure to meet their regulatory obligations [21, 22].

Class III devices are defined as 'those that support or sustain life and are of substantial importance in preventing, improvement of human health or which prevent potential unreasonable risk'. Schedule 2 of the Therapeutic Goods (Medical Devices) Regulations 2002 contains the full classification rules which are extensive and complex [4]. Examples include hip and knee prostheses and prosthetic heart valves. Dependent on ones' view of the importance of mastication to human health and the prevention and resolution of dental disease then one could argue that dental implants should be considered as type 3 devices. Some extensive dental implant systems for example zygomatic implants meet the Type 3 criteria.

There is also the problem that when the patient changes dental practitioner the precise type of implant and prosthetic devices (with varying screw types and insertion torques) are not known to the patient or to the new practitioner so implant maintenance is difficult and, in some instances, lead to damage of the implant or prosthetic components. It was for this reason that Patient Implant Cards (PIC) are mandated for medical devices. If for example, you have a prosthetic hip that requires replacement or revision, understanding which device you received assists the surgeon in managing and treating the patient effectively and efficiently.

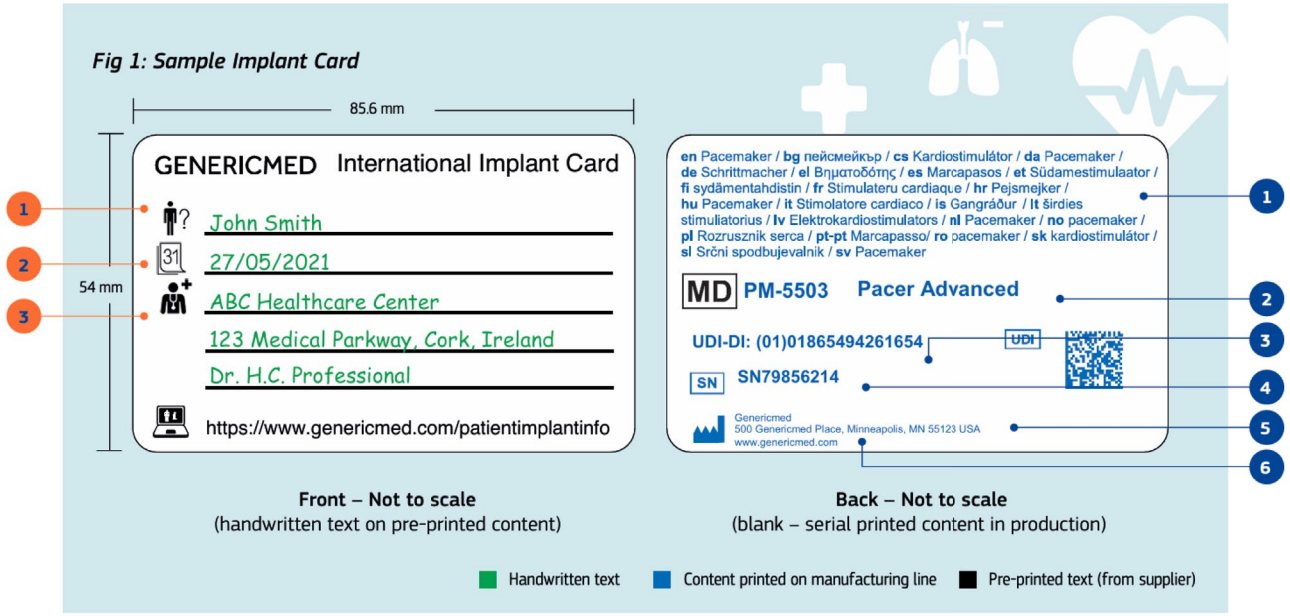
A decade ago, the European Union started consulting with manufacturers, professional organisations and responsible Government agencies including the Federal Drug Administration (FDA) of the USA, the TGA of Australia and MedSafe of New Zealand. The EU regulations requiring all implant patients have a PIC was legislated in 2021 [23], however, following a recommendation from Team NB, a European group that supports the regulatory and assessment bodies, published a paper released in March 2020, arguing that the entire dental implant system was classed as an excluded system [24]. This European Position paper is currently under review with an unknown release date [25]. Following review of these papers, there are several assumptions made, in particular about dental abutments, in these papers that the current authors contend are outdated or incorrect.

In Australia in 2017, the Therapeutic Goods Administration (TGA) initiated a public consultation process to evaluate the potential implementation of Patient Information Cards (PICs). Within the dental sector, the Australian Dental Industry Association (ADIA), the principal representative body for manufacturers and suppliers of dental products and services in Australia, was the sole respondent. The ADIA expressed opposition to the introduction of PICs for dental implants, primarily citing the low incidence of reported adverse events and the anticipated financial burden on both industry stakeholders and patients [26]. As a result of this feedback, the TGA ultimately granted a sector-wide exemption for dental implant systems from the PIC requirement at the conclusion of the consultation. At the time, this position was arguably justified. Assigning responsibility to manufacturers for the administration of data collection and the production of PICs and Patient Information Leaflets (PILs) represented a considerable logistical and financial challenge. However, since the 2017 consultation, the development of the Dental Implant Registry (DIR) has significantly mitigated these concerns. The DIR provides a digital alternative to traditional PICs at no cost to the patient or clinician, thereby reducing the regulatory and administrative burden previously anticipated by manufacturers. While dental implants continue to exhibit a high rate of clinical success when placed under appropriate conditions, the occurrence of failures, though infrequent, remains a reality that warrants systematic documentation and monitoring, particularly as new products are released into the market.

If a patient presented to a new clinician or even to a clinician within the same practice, as records may not be accurate or retained in the long term, especially with sales of practices and had a PIC, then the precise type of device, including the implant, abutment and screw type would be known in detail.

The requirements of a Patient Information Card include as a minimum, the name of the device, the model of the device, the batch code, lot number or serial number of the device, the manufacturer name, address or website (Figure 4). Regulations allow for these to be provided by the manufacturer in hard copy or electronically by a third party such as a Registry [27].

This paper shows the development and initial results of the DIR. Nine thousand four hundred and twenty-nine devices have been entered and followed from across Australia and New Zealand (as of June 2025). There is no doubt that this Registry data is biased and does not reflect the situation in the wider dental community. All the participants in the DIR are experienced practitioners committed to long term independent monitoring of their results [28].



1. Name of the patient or patient ID
2. Date of implantation
3. Name and address of the healthcare institution that performed the implantation

1. Device name
2. Device type
3. Unique device identification (UDI) – the UDI should be in automatic identification and data capture (AIDC) format, e.g. linear or 2D-barcodes, and the UDI device identifier (UDI-DI) should be in human-readable format
4. Serial number or, where applicable, lot or batch number
5. Name and address of the manufacturer of the medical device
6. Website of the manufacturer of the medical device

FIGURE 4 | Sample Printed Patient Implant Card (PIC) for the European Union. *Source:* https://health.ec.europa.eu/system/files/2021-11/md_implany-cards_factsheet_en_0.pdf.

This study uses a simple definition of failure. Namely, that a device was removed and replaced (which was not recorded in the Registry directly), but was defined as a second device being placed in the same tooth location as a previously registered device (Table 4). Clearly this is an underestimate of total implant failures, as some may still be present in the mouth but exhibiting complications, or an original device that failed having not been initially recorded in the Registry, only it's replacement, means that a failure is not recorded in the registry.

Updating the data entry application to facilitate biologic (lack of integration, peri-mucositis, peri-implantitis), mechanical/technical complications and associated devices, procedures and patient factors is one of several upgrades to the application being rolled out in 2026 to DIR participating practices that addresses the short fall in the dental implant complication data set.

To date the placement of dental implants in Australia, requires that the individual be a registered dentist. There are no minimum training or ongoing CPD requirements for those engaged in implant dentistry. In the last three decades hundreds of thousands of dental implants have been placed by many different operators varying widely in skill and experience levels. The number of dental implants placed in Australia and New Zealand is not known. In informal discussions with the main manufacturers, it can be 'guess estimated' that between 150,000 to 200,000 implants are sold per year. There are no official estimates.

There are considerably fewer prosthetic components rather than implants recorded in the registry. This is because if the dental implant is placed by a specialist who then refers the patient back to a general dentist for the prosthetic component, unless that general dentist also contributes to the registry, then the

prosthetic component will not be recorded. Again, prosthetic failure is recorded by that component being removed, replaced (excluding temporary devices) and all recorded in the registry. This again is an underestimate.

Currently a more detailed analysis of the Registry is being undertaken to determine which factors contribute to success or failure. The purpose however of this paper is to determine the regulatory environment and demonstrate the fundamental role of the Registry.

Capturing past data can assist clinicians in identifying dental implants in patients, moving forward by involving as many dentists as possible in the ongoing DIR. This both protects the profession and more importantly patients. It is best to do this voluntarily rather than have it mandated.

5 | Conclusions

There is a need to update the regulatory framework for dental implant devices. Ideally, all dental implant devices placed into patients should be accompanied by issuing PICs and PILs and should be independently monitored in a device registry.

There are a number of future ambitions for the DIR.

1. To expand the DIR to include the maximum number of dentists so it wholly represents the full spectrum of the profession and all the diverse range of different implant suppliers in Australia and New Zealand. This will allow for the analysis of the various parameters of success and failure both with the implant and prosthetic component.
2. Developing predictive models to guide practitioners towards more successful patient outcomes.
3. To foster international collaboration with other National Registries as they are developed. Australian dentists have shown strong support for practice accreditation with approximately 50% voluntarily participating even though it represents a significant cost financially and in time required to comply. This is the highest participation rate in the world for a voluntary dental practice accreditation scheme. If that same behaviour was applied to a DIR, it would go a long way towards meeting the goals of the DIR.
4. Continued refinement of the registration process to make it simple and fast to participate plus the recognition by dentists of how patient costs and dentist's lives would be improved by a comprehensive DIR.
5. Integration with the TGA is an important goal, the DIR will provide a portal to TGA representatives. This portal will include a reporting system that provides information on device usage and complication rates, facilitating post market surveillance.

Author Contributions

S. Soukoulis: Conceptualisation investigation, initial draft, data development, data analysis review and finalisation. S. Davis: Investigation, advice review and finalisation. A. Goss: Conceptualisation, investigation, initial draft, data analysis, review and finalisation.

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Conflicts of Interest

S. Soukoulis Founder and Director DIR (The DIR is a non-profit funded by Implant Registries P/L.). Considerable financial investments in the development of the DIR for no personal financial gain. S. Davis and A. Goss no financial interest with the DIR.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Table S1:** TGA classification of medical devices. Medical Devices are allocated to one of five main classifications depending on the level of risk they pose.