

A far-reaching Regulation for the Italian National Registry of Implantable Prostheses: a possible model for other health registries

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Abstract

Medical device registries are major tools for public health, able to provide early warning systems for increasing the patient safety. We are now at the forefront of a final legal and procedural step to design the Regulation of the Italian Implantable Prostheses Registry (RIPI) and to make data collection mandatory. This can ensure prostheses traceability, recall of patients and fuel biomedical and epidemiological research. Data completeness will be greatly improved when the Regulation is issued. At that time, rules for accessing data and subjects/entities allowed to access the Registry will be clearly defined. Therefore, the Regulation content is crucial, with no chance to fail in its design. The thorough expertise gained at the Italian National Institute of Health (Istituto Superiore di Sanità) by the Italian Arthroplasty Registry in terms of scientific, technical and privacy management may represent a prototypical model for other registries. Our aim is to identify a few key issues to shape a far-reaching Regulation that might permit the flexible and dynamic functioning of RIPI providing suggestions for other registries at national and international level.

Key words

- registries
- government regulation
- medical device legislation
- prostheses and implants
- patient safety

INTRODUCTION

The important role of the medical registries has been widely recognized from a public health perspective [1]. Medical device registries are major tools for decision-makers and managers as they potentially provide an early warning system for identifying patients at risk, shortening the time before health hazards can be widely perceived. Furthermore, they are recognised as useful tools for collecting post-market surveillance data and, in case of implanted devices, they may allow to understand if a complication is related to the surgical procedure or to the implant type [2, 3]. Therefore, they allow to improve the quality of medical treatments and procedures, as devices failure can be rapidly detected, and potentially dangerous implants averted [4]. Such registries are also able to provide data for research, to test epidemiological and biomedical hypotheses and to avoid useless and costly surgical procedures for national health services. All these roles are well recognised in the European Medical Device Regulation issued in 2017 (Table 1, n. 9).

In Italy, as well internationally, the number of implants is increasing together with the potential revision procedures, therefore, the limitation of the number of revisions is a prior objective to be pursued. To provide an example, if only the number of revisions of hip and knee arthroplasties in Italy might be reduced even by 1% (in 2019, 15,043 hip and knee revisions were performed), the total cost saving would be more than 1.8 million euros per year, taking into account the only surgical DRGs. There is no doubt that thanks to a good working registry, the burden of revision procedures can decrease dramatically [5]. More importantly, to achieve this result and have the best impact on public health, an efficient registry needs to be based on a standardized high-quality data collection [3, 6]. In this regard, we have now a unique opportunity to make a final step from a legal and procedural point of view towards the best realization of the Italian Implantable Prostheses Registry (RIPI). The aim of this paper is to identify a few key issues to shape a far-reaching Regulation for the RIPI dynamic functioning at national and international

level that might serve as a reference for the implementation of other registries in Italy as well as in other European countries with similar governing structures.

THE NATIONAL REGISTRY OF IMPLANTABLE PROSTHESES IN ITALY: THE STATE OF THE ART

RIPI is in the provision of a Governmental Decree issued in 2017 (hereinafter “DPCM”) (*Table 1*, n. 6) that addresses 38 national surveillance systems and 28 national health registries. Most of them are operating on the basis of already existing legal norms or research initiatives of the Italian National Institute of Health (Istituto Superiore di Sanità, hereinafter ISS) jointly with the Ministry of Health [7]. Actually, the DPCM lays the basis for an unprecedented functional framework for these registries and surveillance systems, taking into account the European personal data protection regulation (EU GDPR/2016) (*Table 1*, n. 2) and domestic privacy provisions (*Table 1*, n. 1, 3).

RIPI is conceived as an umbrella structure of specific registries of high risk- and high health-impact implantable prostheses. Following specific agreements between the Ministry of Health and the ISS, a few studies started at the beginning of 2019 [8] to empower the already existing registry of joint prostheses, the Italian Arthroplasty Registry (RIAP), and to launch the new registries of spinal implants, of pacemakers and defibrillators, and of heart valves.

ISS can provide an effective contribution to the achievement of this goal, thanks to the multi-faceted expertise, practice and procedures already operating at national level for RIAP, whose effectiveness has rapidly improved over the past decade [9]. Accordingly, the pioneering activities of RIAP will be able to speed up the implementation of the forthcoming RIPI, structured as a federation of regional registries under the coordination of ISS. In fact, RIAP has already established a strong and successful collaboration with several Italian Regions that were able to develop or improve their own data collection, launch registries at regional level and, in some cases, elaborate specific safety indicators (e.g. prosthesis revision rate). Moreover, RIPI will adopt the same architecture of data collection process of RIAP, based on electronic Hospital Discharge Records (e-HDR) routinely collected in all Italian hospitals. Associated with a minimum dataset of additional variables (MDS), these provide crucial data that make it possible to perform outcome studies, assess device safety and assure its traceability [10]. Therefore, the conceptual and organizational heritage of RIAP will be transferred into a comprehensive system of several registries (one for each implantable prosthesis). It will involve the following actors (*Figure 1*):

- hospitals that record MDS in the Platform;
- Regional Centres that access the Platform, link MDS to HDR and send the linked data to RIPI Surgical procedures database;
- manufacturers that upload in the RIPI Medical Device Database all the information needed for device identification and characterisation.

Currently, this model seems to be the most cost-effective

way to easily integrate the registry data collection into the regional/national health information systems. Indeed, it allows to re-use the already existing information technology infrastructure and, therefore, requires only minimal investments by both regional and national governments. In the meantime, it makes it possible to assure patient and implanted device traceability. Finally, it is designed to be easily integrated, in the near future, into the data flows of the National Health Service (SSN) and to allow for benchmarking with data collected by other similar registries in Europe and for interconnections with international databases, to associate more detailed technical information to each device.

THE IMPACT OF A STREAMLINED AND EFFECTIVE REGULATION

The establishment of a registry has to cope with administrative and practical challenges, in particular in Italy. In other international contexts, such initiatives have followed simpler paths [11-13]. For what concerns RIPI, the final step of a legal production, that has lasted 14 years (*Table 1*), is the establishment of an operating Regulation (hereinafter, “Regulation”). Focussing on the impact of a clear, comprehensive and prompt Regulation, a few key issues are at stake. The first is the *completeness* of data. Everyone knows there is a continuous threat to completeness when a registry is based exclusively on patients’ consent, as it currently is for many Italian registries and surveillances according to the provision of personal data protection legislation (*Table 1*, n. 1, 2). Completeness, therefore, will be greatly favoured by the issuing of the Regulation, because its coming into force will make the individuals’ consent not necessary any longer. Consequently, we can foresee that the lack of data might be eventually overcome in the medium term. The second key question is “governmental support”. Following the positive experience of the German Registry [14], the participation of all the hospitals might be achieved through a joint effort between the central government and other stakeholders including, as in our setting, the regional governments. Finally, following the example of well developed registries in other European countries [4, 12] the Regulation should consider the adoption of a unique “national patient identifier” (i.e. an alphanumeric code able to trace the patient, without infringing the privacy rules, throughout the health records collected by SSN). In the meantime, to achieve this purpose the pseudonymization procedures designed by ISS experts and successfully applied to RIAP, will be extended to RIPI.

In Italy, we are now on the threshold of the final important step to design the regulations for all the epidemiological surveillances and registries listed in the DPCM. This is, actually, the most important provision currently pending. In this enterprise, it would be advisable to involve all the stakeholders: patients’ representatives, policy makers, health managers, clinicians, researchers, and manufacturers when necessary, being all of them a real asset for this purpose.

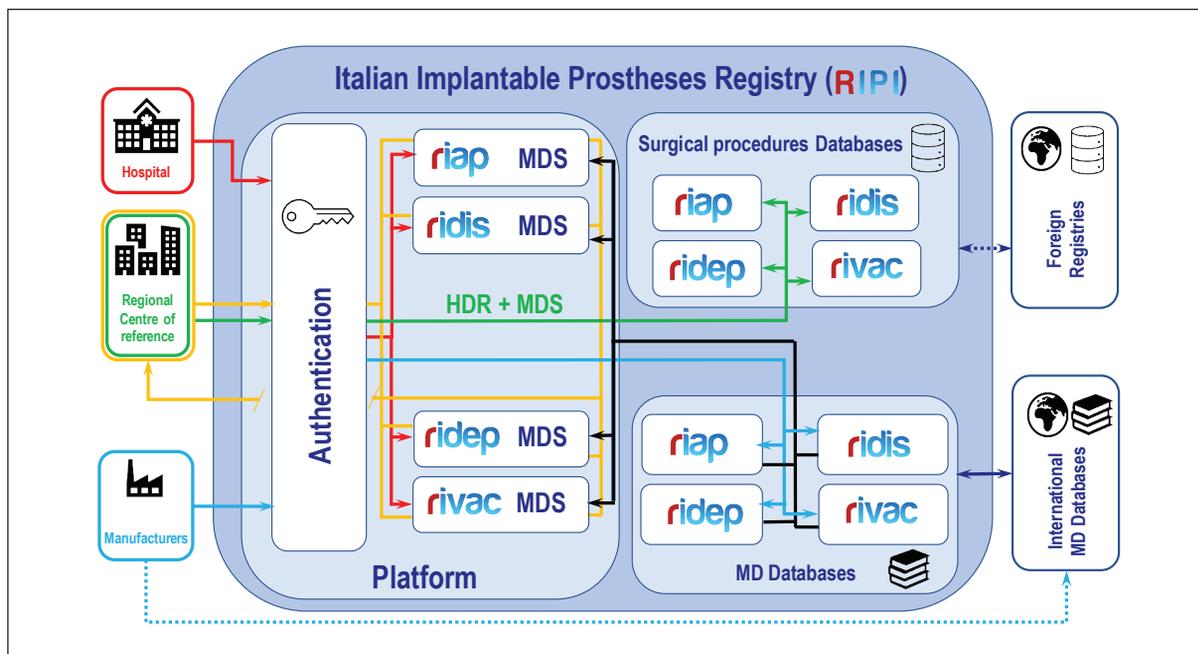
As for RIPI, the Regulation approval will mainly give rules for accessing the data, establish the subjects/entities allowed to access them, as well as the data that can

Table 1
Summary of the legal provisions impacting on the establishment and regulation of the Italian Implantable Prostheses Registry

Relevant to	n.	Provision	Title	Relevant issues
Personal data protection	1	Italian Law Decree 30 June 2003, n. 196	<i>Codice in materia di protezione dei dati personali. GU, Serie Generale n. 174 del 29 luglio 2003 - Suppl. Ord. n. 123</i>	
	2	Regulation (UE) 2016/679 of the European Parliament and of the Council, 27 April 2016	<i>Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, GDPR). Official Journal of the European Union L119/1, 4.5.2016</i>	Regulation (EU) 2016/679 (GDPR), together with the provisions of the Italian Legislative Decree 196/2003 (as modified by the Legislative Decree 101/2018), defines the framework for personal data protection procedures
	3	Italian Law Decree 10 August 2018, n. 101	<i>Disposizioni per l'adeguamento della normativa nazionale alle disposizioni del regolamento (UE) 2016/679 del Parlamento europeo e del Consiglio, del 27 aprile 2016, relativo alla protezione delle persone fisiche con riguardo al trattamento dei dati personali, nonché alla libera circolazione di tali dati e che abroga la direttiva 95/46/CE (regolamento generale sulla protezione dei dati). GU Serie Generale n. 205 del 4 settembre 2018</i>	
Registries establishment and implementation	4	Italian Law 27 December 2006, n. 296	<i>Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge finanziaria 2007). GU Serie Generale n. 299 del 27 dicembre 2006 - Suppl. Ord. n. 244</i>	It foresees funding to establish disease registries requiring the use of medical devices (Paragraph 825)
	5	Italian Law Decree 18 October 2012, n. 179 Converted with amendments by the Law 17 December 2012, n. 221	<i>Ulteriori misure urgenti per la crescita del Paese. GU Serie Generale n. 245 del 19 ottobre 2012 - Suppl. Ord. n. 194/L GU Serie Generale n. 294 del 18 dicembre 2012 - Suppl. Ord. n. 208</i>	It establishes surveillance and registry systems, among them the registries of prosthetic implants (Art. 12 paragraphs 10-14)
	6	Italian Decree of the President of the Council of the Ministers (DPCM), 3 March 2017	<i>Identificazione dei sistemi di sorveglianza e dei registri di mortalità, di tumori e di altre patologie. GU Serie Generale n. 109 del 12 maggio 2017</i>	Following the provisions of Law 221/2012, this Decree addresses 38 surveillance systems and 28 registries. It defines the national and regional institutions in charge for their management and maintenance and states that their final operativity will be achieved when their own Regulations are approved
	7	Italian Law 30 December 2018, n. 145	<i>Bilancio di previsione dello Stato per l'anno finanziario 2019 e bilancio pluriennale per il triennio 2019-2021. GU Serie Generale n. 302 del 31 dicembre 2018 - Suppl. Ord. n. 62/L</i>	Data collection is mandatory for regions and health operators. "Implantable medical devices" registries are introduced for the first time besides the "prosthetic implants" registries (Paragraph 558 modifies paragraph 11 of Law 221/2012 and introduces paragraph 11-bis)
	8	Italian Law 22 March 2019, n. 29	<i>Istituzione e disciplina della Rete nazionale dei registri dei tumori e dei sistemi di sorveglianza e del referto epidemiologico per il controllo sanitario della popolazione. GU Serie Generale n. 81 del 5 aprile 2019</i>	The transmission of data to the national registries by the regions is a prerequisite for the distribution of funds to the regional health services (Art. 5)
EU Regulation for Medical devices	9	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017	<i>Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Official Journal of the European Union L117/1, 5.5.2017</i>	This Regulation is centered on the improvement of patient safety. In particular, it recognizes the medical device registries as important tools to achieve this aim (Art. 108 Device registers and databanks)

be accessed. Moreover, it will allow the registry to work as a mandatory system of national and regional registries. From the juridical perspective, in fact, there will be an important shift from individual patient's consent to a mandatory collection of data for the following spe-

cific recognised purposes: traceability of the implanted prostheses, recall of patients by the competent authority when a high number of adverse events are reported, and epidemiological and biomedical research. It is important to underline that, according to personal data

**Figure 1**

Italian National Registry of Implantable Prostheses (RIPI): data collection flow.

MDS: Minimum Data Set; HDR: Hospital Discharge Record; RIPI: Registro Italiano delle Protesi Implantabili;

RIAP: Registro Italiano ArthroProtesi (Italian Arthroplasty Registry); RIDIS: Registro Italiano Dispositivi Implantabili per Chirurgia Spinale (Italian Spinal Implants Registry); RIDEP: Registro Italiano Defibrillatori e Pacemaker (Italian Implantable Cardioverter-Defibrillator and Pacemaker Registry); RIVAC: Registro Italiano Valvole Cardiache (Italian Heart Valves Registry); MD: Medical Device.

protection legislation, information regarding RIPI procedures and aims shall be always given to the patients, in spite of the fact that their informed consent will be no longer necessary.

Actually, there is still a long way to go before the Regulation is officially adopted. In fact, it will require a proposal by the Ministry of Health, an agreement by the Permanent Conference of the Regions and Autonomous Provinces, the approval of the National Authority for Personal Data Treatment and, eventually, of the Council of State, after a deliberation of the Council of Ministers. Lastly, it will be adopted by means of a Decree of the President of the Italian Republic.

TEN RECOMMENDATIONS FOR BETTER FUNCTIONING OF A HEALTH REGISTRY

Registries and surveillance systems at national and European level are based on directives and regulations common to all the Member States. In this framework, the thorough experience in RIAP scientific, technical and privacy issues allowed to identify the following 10 key points that a Registry Regulation, particularly for medical devices, might consider:

1. To define the specific aims and objectives of the Registry, at national and regional levels [3].
2. To settle the whole Regulation on general principles that can maintain their universal validity over time and over different scenarios. For example, prostheses are subject to rapid technical and technological development. Likewise, the Regulation should not restrict the Registry's functionality when new tasks emerge from epidemiological and public health per-

spectives. There might be the need for international benchmarking requiring the availability of individual records or for eventual inclusion of other "items"[3].

3. To introduce specific terms clearly addressing the data needed for the medical devices traceability (i.e. Unique Device Identifier – UDI; manufacturer; product catalogue code; serial number; lot) and to provide a set of key words to which the Regulation will make reference. These key words will be used to describe the Registry's objects, tools and pathways. They will prevent anyone, among different stakeholders, from misinterpreting and making ambiguous the meaning of the rules. For example: i) the terms addressing the subjects/entities in charge of the data collection and of the data flow implementation like "National Registry" and "Regional Registry"; ii) the specific objects to be dealt with by the specific Registry, for example "implantable prosthesis" which is different from "implantable device"; iii) the terms related to the main purpose of the Registry.
4. To establish a Registry's governing body, like a scientific board. Its composition, in terms of expertise and tasks, should be clearly addressed. The role of this board is to take necessary measures for updating the Registry, easily placeable within the framework provided by the Regulation. The Regulation, in fact, to be fully applied, has to rely on the judgment of this specific governing body whose choices are of highly technical and scientific value and may assure a dynamic and evolutionary functioning of the Registry in step with the times [3].

5. To define the type of data to be collected and processed. Data should not be restricted or fixed in a non-reversible way. It is advisable to make a list of data which is as much as possible all-encompassing (e.g. the data collected by PROMs, i.e. questionnaires measuring the quality of life of patients, should be included). The list can be updated on the basis of the indications given by the Scientific Board [3].
6. To adopt updates, when needed, on different issues like “sources” and “type” of data and “subjects admitted” to access the data, following the Scientific Board advice.
7. To delimit the procedural steps for accessing the data and to outline access in relation to the hierarchical levels established for specific subjects. This means to discriminate “individual pseudonymized data”, subjected to restricted access, from “aggregated data” that is possible to share upon request by each recognized subject, and, finally, from data defined as “open data”.
8. To update the list of Institutions, at national and international level, that can be included as partners for data sharing and/or data analyses, with the clear definition of each data controllers’ roles and of the specific data to be treated, under the general provision of the Regulation.
9. To outline the specific tasks that national and regional data have to accomplish and which data they govern in their specific context. According to GDPR, in fact, the data controller is “the legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data”.
10. To clearly address the deontological rules that medical, biomedical and epidemiological research activities – to be performed on data released by the Registry – have to refer to, on the basis of specific objectives and protocols and according to national rules for data protection, when available.

THE CRUCIAL GOAL: TO IMPROVE PATIENT SAFETY

According to the European perspective (EU Regulation 2017/745) (*Table 1*, n. 9), in the future RIPI should be encompassed within the widest Registry of the “Implantable medical devices” – for the first time mentioned in Italy by the law 145/2018 (*Table 1*, n. 7) – expanding, indeed, the monitoring to all kinds of implanted devices. Therefore, the work to be done immediately, for a prompt issuing of an effective Regulation, will perfectly fit in the new defined legal European framework which will come into force in a very short time (the initial May 26th 2020 deadline was postponed to May 26th 2021, due to the COVID-19 pandemic challenge). As a matter of fact, Europe underlines the importance of establishing these registries as their role is central to improve patient safety. Hence, we have to take into account this urge that commits several important stakeholders as well, like Competent Authorities on Medical Devices, implantable devices Manufacturers and Notified Bodies. The boost given by the EU is

consistent and demands smooth functioning registries as strategic tools for further post-marketing surveillance as well as for implantable devices safety monitoring improvements [15]. As a matter of fact, medical device registries should be considered a structured piece of the whole national health service that might be empowered when different data collection flows are interconnected.

The recent, unprecedented COVID-19 pandemic has strongly underlined that Public Health needs rapid interventions, high quality data, as well as the most efficient working of networks operating for health-related activities and data flows: Health Registries - and RIPI can be a good reference - are, in fact, valuable health networks for epidemiological monitoring. To speed up RIPI implementation, it is unavoidable to put in practice the surveillance on prostheses and provide sound data to epidemiological monitoring; it will then be possible to translate the new knowledge, continuously gathered, into effective public health actions. It is a virtuous circle for which the legal norms are to be a driving force not a hindrance. If there is indeed room for maneuver in defining the rules, it is necessary to proceed rapidly, and adopt them. We have to reflect on the fact that the first attempt to rule health registries in Italy was made in 2006, a long and complex path requiring more than 14 years. On the contrary, in 2019, the German government, on the basis of huge experience of the National Orthopaedic Registry [14], in less than six months proposed and approved the law establishing and ruling the German Registry of Implantable Devices (Implantateregister Deutschland) as mandatory [16]. As stated by Steven Graves, Director of the Australian Joint Replacement Registry: «Change occurs most effectively when all relevant stakeholders have ownership of data. This is why it is so important that Italy has its own registry. Italian data is necessary to improve Italian outcomes» [17]. The time has come for Italy to make fully operational its own national registry to further improve the safety of implanted patients. Hopefully, the ten key points of the Italian experience we describe might be a model for the establishment of national registries in those countries with similar governing structures.

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Authors’ contributions

VT pictured the study conception and drafted the

manuscript. MT contributed to the study conception, provided data, revised the manuscript for important intellectual content.

Conflict of interest statement

Virgilia Toccaceli is a member of the Italian Arthroplasty Registry (RIAP) Steering Committee as the ex-

pert of personal data protection. Marina Torre is the Scientific Director of the Italian Arthroplasty Registry (RIAP) and of the Italian Implantable Prostheses Registry (RIPI).

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