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# Development of the stakeholder communication strategy for a public health registry based on communication effectiveness criteria

## A study based on the case of the Italian Implantable Prostheses Registry (RIPI)

Department of Communication and Social Research (CoRiS)

PhD in Communication, Social Research and Marketing – XXXV cycle

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Development of the stakeholder communication strategy for a public health registry based on communication effectiveness criteria. A study based on the case of the Italian Implantable Prostheses Registry (RIPI). Ph.D. Thesis – Sapienza University of Rome

# Abstract

This PhD dissertation is the result of the research project in collaboration between Sapienza University of Rome and the Italian National Institute of Health (Istituto Superiore di Sanità, ISS). It was aimed at developing a model of a stakeholder communication strategy for the Italian Implantable Prostheses Registry (RIPI, ripi.iss.it). Effective communication is understood as such that meets both the needs of the audiences and the objectives of the organisation. The mixed methods approach was chosen as it is particularly relevant for multi-component research projects. RIPI stakeholders were identified and their communication priorities were studied. A model of effective communication strategy for a registry in public health was proposed. Its key elements are research-based understanding of stakeholders' priorities and of registry's objectives, stakeholder-oriented objective setting, and effectiveness evaluation on different levels of communication plan.

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Questa tesi di dottorato è il risultato di un progetto di ricerca in collaborazione tra Sapienza Università di Roma e l'Istituto Superiore di Sanità (ISS). L'obiettivo di questo progetto è di sviluppare un modello di strategia di comunicazione centrata sugli stakeholder del Registro Italiano di Protesi impiantabili (RIPI, ripi.iss.it). Si applica il concetto di comunicazione efficace, inteso a soddisfare le esigenze del pubblico e gli obiettivi dell'organizzazione allo stesso tempo. L'approccio metodologico utilizzato per la ricerca, quello dei mixed methods, è stato scelto inquanto particolarmente rilevante per i progetti di ricerca multicomponente. Inizialmente sono stati identificati gli stakeholder RIPI e le loro priorità di comunicazione. In seguito, è stato proposto un modello di strategia di comunicazione efficace nell'ambito dei registri nella sanità pubblica. I suoi elementi chiave sono: individuazione delle priorità degli stakeholder e degli obiettivi del registro basata sulla ricerca, predisposizione di obiettivi orientati agli stakeholder e la valutazione dell'efficacia a diversi livelli del piano di comunicazione.

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# List of abbreviations

| | |
|---|---|
| AIAC | Associazione Italiana di Aritmologia e Cardiostimolazione, Italian Association of Arrhythmology and Cardiac Pacing |
| AISOT | Associazione Italiana Specializzandi in Ortopedia e Traumatologia, Italian Association of Orthopaedics and Traumatology Residents |
| AMEC | International Association for Measurement and Evaluation of Communication |
| APMARR | Associazione Nazionale Persone con Malattie Reumatologiche e Rare, National Association of People with Rheumatological and Rare Diseases |
| ASL | Azienda Sanitaria Locale, Local health authority |
| CND | Classificazione Nazionale dei Dispositivi Medici, Italian National Classification of medical devices |
| CRM | Customer Relationship Management |
| CSot | Customer satisfaction |
| DGDMF | Direzione generale dei dispositivi medici e del servizio farmaceutico (Ministero della salute), Directorate General for Medical Devices and Pharmaceutical Service of the Ministry of Health |
| DPCM | Decreto del Presidente del Consiglio dei ministri, Prime Minister Decree |
| DRG | Diagnosis Related Groups |
| EC | European Commission |
| ECDC | European Centre for Disease Prevention and Control |
| EMDN | European Medical Device Database Nomenclature |
| Eudamed | European Medical Device Database |
| GLOBE | Gruppo di Lavoro Ortopedia Basata sulle prove di Efficacia, Evidence-Based Orthopaedics Working Group |
| HDR | Hospital discharge records (schede di dimissione ospedaliera, SDO) |
| IMD | Implantable Medical Device |
| LROI | Netherlands' National Registry of Orthopaedic Interventions |
| MD | Medical device |
| MDR | The European Union Medical Device Regulation |
| MDS | Minimum data set |
| MoH | Ministry of Health |
| NJR | National Joint Registry |
| NORE | Network of Orthopaedic Registries of Europe |

| | |
|---|---|
| OECD | The Organisation for Economic Co-operation and Development |
| PA | Public authorities |
| PIAO | Piano Integrato di Attività e Organizzazione, Integrated Plan of Activities and Organisation |
| PNRR | Piano Nazionale di Ripresa e Resilienza, The National Recovery and Resilience Plan |
| PO | Participant observation |
| PSC | Public sector communication |
| PTA | Piano Triennale di Attività, Triennial activity plan |
| RG | Research group |
| RIAP | Registro Italiano ArtroProtesi, Italian Arthroplasty Registry |
| RICRAF | Registro Italiano Impianti Cranio Facciali, Registro Italiano impianti Cranio Facciali |
| RIDEP | Registro Italiano Defibrillatori e Pacemaker, Italian Implantable Cardioverter-defibrillator and Pacemaker Registry |
| RIDIS | Registro Italiano Dispositivi Impiantabili per chirurgia Spinale, Italian Spinal Implants Registry |
| RIDIU | Registro Italiano dei Dispositivi Impiantabili Uditivi, Italian Implantable Hearing Device Registry |
| RIPI | Registro Italiano delle Protesi Impiantabili, Italian Implantable Prostheses Registry |
| RIVAC | Registro Italiano Valvole Cardiache, Italian Heart Valves Registry |
| RNPM | Registro Nazionale degli impianti protesici mammari, National Breast Implants Registry |
| SC | Science communication |
| SC RIAP | RIAP Scientific committee |
| SCS | Scientific Communications service of ISS |
| SDGs | Sustainable development goals of the United Nations |
| SIFO | Società Italiana di Farmacia Ospedaliera e dei Servizi Farmaceutici delle Aziende Sanitarie, Italian Society of Hospital Pharmacy and Pharmaceutical Services of Health Authorities |
| SIOT | Società Italiana di Ortopedia e Traumatologia, Italian Society of Orthopaedics and Traumatology |
| SSN | Servizio sanitario nazionale, National healthcare service |
| URP | Ufficio relazioni con il pubblico, Public relations office |
| WHO | World Health Organization |
| WoS | Web of Science |

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# Introduction

## Preamble

This PhD dissertation is the result of the research project made in collaboration between Sapienza University of Rome and the Italian National Institute of Health (Istituto Superiore di Sanità, ISS). The initiative of this applied research project came from the management of Italian Implantable Prostheses Registry (RIPI) established in ISS. Their proposal to start research and collaboration with the Doctorate in Communication, Social Research and Marketing was motivated by the need to make the data and research produced by the Registry communicable and usable to a wide audience. In addition, RIPI's website was launched in 2019, with the aim of communicating with the external audiences. The communicative performance of the site with respect to the various audience segments needed to be evaluated and eventually improved. For this reason, it was proposed in 2019 to include a doctoral student in Communication sciences in the RIPI working group. Before, the Registry exclusively included researchers and PhD students from core disciplines such as biomedical statistics, engineering, computer science and epidemiology. With this in mind, the research project in Communication Sciences was supposed to bring applicable results.

RIPI is a registry, so more generally a monitoring system, that collects data on the interventions performed in Italy of implantation or removal of specific prostheses, for example joint replacement procedures, with attention to the characteristics of both the surgery and the implant. RIPI's objectives are twofold:

- to track patients in case of a recall of the prosthesis they have been implanted with,
- to perform and enable statistical analyses on the collected data, including the implant survival analysis.

These analyses allow for timely detecting of eventual problems that could otherwise endanger the health of many patients (Torre et al., 2021). Numbers of persons involved confirm the importance of the registries. For example, from 2001 to 2019 the total annual number of joint replacements in Italy more than doubled, reaching 220,447 interventions in 2019.

RIPI is an 'umbrella' structure that comprises Italian Arthroplasty Registry (Registro Italiano ArtroProtesi, RIAP), Italian Spinal Implants Registry (Registro Italiano Dispositivi Impiantabili per chirurgia Spinale, RIDIS), Italian Implantable Cardioverter-defibrillator and Pacemaker Registry (Registro Italiano Defibrillatori e Pacemaker, RIDEP), Italian Heart Valves Registry (Registro

Italiano Valvole Cardiache, RIVAC), Italian Implantable Hearing Device Registry (Registro Italiano dei Dispositivi Impiantabili Uditivi, RIDIU) and newly established Italian craniofacial implants registry (Registro Italiano Impianti Cranio Facciali, RICRAF).

These registries are at different development stages. To date, RIAP remains the pivotal and by far most advanced part of RIPI. Work on its development started in 2006 and later its engineering infrastructure was taken as a model for other registries.

After the first months of working on this project, which included participant observation, it was decided to widen its scope and to develop a stakeholder communication strategy.

## Communication in public health

The Italian Implantable Prostheses Registry is coordinated by the ISS and supported by the Ministry of Health, and as such its communication activities structurally fall within the scope of public sector communication.

Public health institutions establish communication with various stakeholders. In this relationship stakeholder groups take the role of audiences that can be classified using different taxonomies: internal/external audiences, specialists/general public, most relevant/less relevant groups, etc. Any of these dichotomies is made up of very different profiles, which makes the development of a comprehensive communication strategy a complex task.

Authors in this field note two characteristics of contemporary society that add up to the complexity of communication practice in public health and its research. First is the general crisis of trust, both in institutions and in the credibility of scientific research, which has developed in late modernity as stated by many scholars (Beck 2000; Lorusso 2018; Nickols 2017).

The lack of trust was confirmed by the sociological surveys' findings. In the Eurobarometer survey "European citizens' knowledge and attitudes towards science and technology" (European Commission, 2021) a half of respondents across Europe agree that we can no longer trust scientists to tell the truth about controversial scientific and technological issues because they depend more and more on money from industry. Italy was one of three EU Member States with the highest agreement (44%) on the statement "nowadays, the problems we are facing are so complex that scientists are no longer able to understand them", while the average agreement rate on this was 32%.  As Lovari (2020) writes, in recent years Italy has increasingly had to deal with anti-science movements that have cast doubt on the value of experts and scientists and that this is one of the main effects of a postmodern conception of health.

Another relevant societal condition is the technology-caused change in the nature of communication between institutions and citizens. In the age of social media, the traditional non-participatory mass communication with its one-way information flow is no longer possible when communicating with the general public. Citizens and other stakeholders of public sector communication become co-protagonists of the communication interventions (Comunello, 2014).

Both these trends have manifested so strongly during the Covid-19 pandemic that the UN have called this condition an 'infodemic'. 132 States including Italy ratified the Cross-Regional Statement on “Infodemic” in the Context of COVID-19, that says: “We remain committed to creating a healthy information environment at the national, regional and global levels, in which the “infodemic” is countered by scientific, evidence-based information and facts” (UN 2020)

Public health institutions give more and more importance to communicating knowledgeably and with attention to the impact. The 'WHO Strategic Communications Framework for effective communications' of the World Health Organization (2017) and the “Toolkit for the evaluation of the communication activities” by the European Commission (2017) are the reference documents at international level. At national level a use case is provided by the Ministry of Health of Portugal: The Portuguese National Health Plan 2021-2030 for the first time contains a separate chapter Plan of Strategic Communication.

In the scholarly perspective, research aiming at finding the ways to increase communicative effectiveness in public health is relevant in the post-pandemic period more than ever, also in the light of two above-mentioned societal trends.

I used the advanced search function of the Web of Science (WoS) database to roughly assess the amount of literature published by 2022 on the following subjects: public sector communication (also in public health), communication effectiveness evaluation, and implantable prostheses registries. The WoS Core Collection contained 7,151 documents (mostly articles and proceeding papers) on “public sector communication”. One third of them (2,199, or 31%) appeared to be related to “public health”. Only 105 items remained when results were refined by including “Italy”. 10,476 results were found for the topic “communication effectiveness evaluation”, yet after adding “public health” and restricting search areas to exclude computational and engineering interpretation of ‘communication’ only 688 relevant results remained.

Scarce results were obtained when adding the “registry” into different queries. The query “implant* registry AND public health AND information” generated only 41 items, while changing “information” to “communication” gave almost no relevant output.

We can see that the general area is widely researched, but when delving into specific arguments much less is found. Also in the Italian context there are no studies explicitly elaborating on the evaluation of communication in public healthcare in contexts similar to RIPI. There is therefore an opportunity to contribute to the research by proposing a communication strategy for an exemplar case.

At the same time, the ‘grey’ literature is represented by numerous practically oriented manuals and guidelines. These rarely make an explicit reference to some methodological background, so the question remains how theoretically and methodologically informed they are. In digital communication, the reference document for Italy is Linee guida di design per i siti internet e i servizi digitali della PA (AGID, 2022) with the associated Manuale operativo di design that explains the design process of PA websites and digital services and contains a practical toolkit. In public health, an official tool is Linee guida del Ministero della Salute sulla comunicazione online in tema di tutela e promozione della salute developed 13 years ago (Ministero della Salute, 2011).

In the general area of institutional communication in public health the academic literature is extensive and growing, but only limited research can be found on the evaluation and criteria of its effectiveness. The evaluation of institutional communication in public health would be an ambitious research task due to its interdisciplinary nature between mass communication theories, evaluative sociology, government efficiency studies, health communication and epidemiology.

A prospective opens up for the development of interdisciplinary approaches in public health communication. The interest in it is confirmed by the trends in academia, in the scientific societies and in the institutions themselves.

In academia, new courses and curricula of "hybrid" profiles are launched, such as: a joint course of Faculty of Pharmacy and Medicine and Faculty of Political Science, Sociology and Communication at Sapienza University ‘Comunicazione Scientifica Biomedica’, or an advanced training course ‘Comunicazione in sanità e Bioetica’ at Bologna University. Master's courses in Scientific communication often dedicate significant space to the medical field (e.g., Scuola Internazionale Superiore di Studi Avanzati in Trieste or University of Parma).

In the International Communication Association, Health Communication Division is one of the major thematic divisions. It embraces multiple areas of research under the common definition "communication in health promotion and health care": provider-patient interaction, social support networks, health information systems, medical ethics, healthy policy and health promotion (icahdq.org/group/health). Also, in the European Communication Research and Education Association (ECREA), Heath Communication in 2021 from a temporary working group became a permanent section. At least 37 contributions at the ECREA's European Communications Conference 2022 explicitly mentioned "public health" in a variety of thematic areas from Audience and Reception Studies to Communication and Democracy to Crisis Communications (ECREA, 2022). From the other side, at the annual congress of Società Italiana di Ortopedia e Traumatologia (SIOT) in November 2022, the roundtable on health communication "Primum non tacere" became one of the central events.

As for the Italian public health institutions, in October 2019, the ISS hosted a discussion on the role of social marketing at the workshop "Marketing and social communication for health promotion". In 2021, followed a series of webinars co-organised by the ISS "Salute e società" that tackled the problem of healthcare communication.

## The complexity of evaluation

How can we define what good public sector communication actually should be?

In Italy, the underlying law (Law No. 150 of 7 June 2000) indicates communication as an obligation of the public authorities (PA) but does not include a definition of communication in the text; its Article 13 deems it desirable to achieve maximum effectiveness of communication but does not contain any mention of its evaluation, although it may be considered implied. Four years after the publication of Law 150/2000, it was estimated that only 30% of Italian public administrations had tackled the problem of adopting evaluation methods for the communication activities carried out (Rolando, 2004). The Italian National Agency for the Evaluation of Universities and Research Institutes (ANVUR) developed the Guidelines for the evaluation of public research institutions, including the ISS. This document, too, does not contain evaluation criteria, limiting itself to prescribing their existence in three-year Action plans developed by the institutions themselves (ANVUR, 2016). Communication effectiveness can be understood pragmatically as the degree to which the objectives of an intervention have been achieved or the needs that originated it have been satisfied (Palumbo, 2001). In the case of institutional communication, the determinants of the effectiveness evaluation are, on the one hand, the objectives of the organisation as a communicating party and, on the other hand, the communicative needs of the audience (also interpreted by the communicating party). Without predetermining the objectives and key indicators, we can only estimate the degree of effectiveness of communication intuitively, guided by the theories of communication, social research and social policy evaluation.

Klein-Dossou Leeuw & Fava (2001) list good reasons to evaluate communication in, and of, institutions, from more macro-social levels (in the logic of the development of social processes) to more specific levels concerning the functioning of public administrations and intrinsic to communication activity. They claim that effective organisational performance and management are not possible without efficient and effective communication performance. (Klein-Dossou Leeuw & Fava, 2001).

Significant was the contribution of evaluation sociology in the USA to the development of communication research, with particular regard to the development of applied evaluation instruments. In 1988, "Communications Audits" by Cal W. Downs was published, in which the need for regular audits of organisations' communication activities was emphasised, following the approaches developed in the financial sphere (Downs, 1988). During the 1990s and 2000s, several American authors developed the idea of the need for audit processes as part of an organisation's internal reporting. Henderson (2005) argues that an audit should, among other, identify the strengths and weaknesses of the communication programme, determine the effectiveness of the key message, establish a baseline for further evaluation, and provide a plan of necessary changes to the communication programme. These researchers claimed that the audit of communication activities is feasible both within a private organisation and in the public sphere.

In Italy, to the moment, the evaluation of public communication, including that in public healthcare, has not been of particular interest to scholarly research. Claudio Bezzi, director of the Italian Institute of Evaluation, in 2001 considered this subject to be 'niche", claiming that in the evaluation literature the topic of communication is almost totally absent" (Bezzi, 2001, p. 49). Paradoxically, he sustained this point of view precisely in the volume of Rassegna italiana di valutazione dedicated to this very argument and rich in reflections on methodology. Mauro Palumbo in the same volume describes the evaluation of public communication as "an extremely stimulating theme, due to the growing relevance of the subject and the methodological complexity it presents" (Palumbo, 2001, p. 107). However, Bezzi confirmed the lack of research in 2022 when asked directly about it: “There is little interest in the subject, and it is really strange, because there are so many communicators, a lot is invested in communication (public, institutional) but then the subject of its effectiveness does not seem to interest. That is to say: it probably does interest but is dealt with in a pre-scientific way” (email interview to the author, September 2022). A recent Italian study (Massa et al., 2022) reflects on the concept of quality of the public sector communication in the pandemic context and uses the DeLeone and McLean’s model of information systems success proposed based on the quality of the system, of information and communication themselves, and on perceived usefulness of the information and communication for the users (DeLeone & McLean, 2003).

In order to answer the question "How effective communication activities are" we should be able to assess them consistently, using robust criteria developed from a strategic perspective. This opens up a research perspective for both the means of evaluation and the development and practical implementation of new communication approaches.

As we have seen, the registries in public health have not yet been significantly researched, although they interact directly with many heterogeneous stakeholder groups (healthcare professionals, researchers, decision-makers, patients) and therefore could need a distinct communication strategy even being a structural unit of an institution. One of the reasons why registries still haven’t been sufficiently studied as agents of communication process could be that they themselves did not claim the interest in this argument. The first medical devices registries in contemporary understanding appeared in the 1970s. For a long time, they kept to core activities and to a specialist-to-specialist communication. This is now changing, as the well-established registries include communications into their working plans with dedicated specialists, starting with the biggest medical device registries. The NJR (National Joint Registry, UK) that in many ways is a benchmark for other orthopaedic implants registries across Europe is now working on its communication strategy, designing it as a separate comprehensive document. The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) since 2016 provides the Lay summary to its Annual report (issued since 2000) in order to ensure that a clear, concise, and easily understood explanation of the published findings are available to all those who may be interested: “The Australian Orthopaedic Association believes this is especially important because of the high level of community interest in the Registry and the need to ensure that reports are accessible to all” (AOANJRR, 2022).

## The research idea

The present research aims to develop a model of a communication strategy for the Italian Implantable Prostheses Registry (RIPI) based on the evaluation of communication effectiveness. The research assumes that effective communication, i.e., communication that meets both the needs of the public and the objectives of the registry, should be based on the robust assessment of its effectiveness. The research is grounded in mass communication theories, evaluative sociology and studies on the efficiency of public administration.

The main research questions were set as follows:

RQ1: How can the technical and scientific results of the implantable medical device monitoring activity be effectively communicated to the stakeholder groups?

RQ2: What should be the criteria of communication effectiveness in the case of RIPI?

RQ3: Is it possible to build a model of effective communication strategy for a public health registry?

In the hypothesis, the findings could be extended to other projects and units in the public healthcare system which share a number of characteristics with registries.

The methodological approach of the research was defined in the framework of mixed methods (Creswell & Plano Clark, 2017; Mauceri, 2019).

Given the 'intangibility' of communication, by its nature qualitative methods are better suited to its evaluation, and quantitative methods can complement the work of interpretation or allow certain outputs to be evaluated with tangible indicators. This often happens in practice. Henderson lists among the most widespread research methods used for communication audits: surveys; focus groups; content analysis; readability studies and reader surveys (Henderson, 2005). Some tools developed in web marketing are perfectly usable, such as tracking and analysing a website user's customer journey, tracking metrics of social media interactions, and online surveys (Comunello, 2014; Lovari, 2017).

Since the 1990s, multidimensional evaluation approaches have been preferred in the international context and interest in mixed methods has grown. This methodology originated in the US research context makes it possible to exploit the strengths of qualitative and quantitative methods by applying them to the various stages of research and obtaining a result that is broader than the simple sum of the two methods.

Particularly appropriate becomes the use of mixed methods in projects that have many components, such as multi-stage evaluation studies in which the researchers may need to link several studies to achieve an overall goal. As in the case of the present study comprising the elements of evaluative research, case study, and model proposition.

The latter follows the logic of developmental research introduced by William J. Reid in "The Model Development Dissertation" (1979) claiming its recognition as a valid research design for PhD dissertations. The aim of such research is to put an inchoate model into shape for use in practice and for further testing. Models organise otherwise discrete principles, methods, and procedures into coherent strategies. The main product of such dissertation is not a set of findings and conclusions, but rather, a set of guidelines for practice.

The research work consisted of the following stages:

**Stage 1.**

Participant observation and literature analysis.

Initial development of criteria and indicators of communication efficiency and effectiveness, on the basis of participant observation and literature.

Definition of stakeholders and target audiences.

Comparative analysis of communication activities in the similar projects (implant registries in other countries, other registries and surveillance systems in the Italian public health system).

**Stage 2.**

Semi-structured interviews with RIPI stakeholders.

Website user experience analysis with web survey and Google Analytics tools.

Web survey of the RIAP Scientific Committee.

Hands-on activities in the RIPI research group: co-writing of RIAP annual reports and dissemination materials.

**Stage 3.**

Development of the communication strategy, both as a model and as a program, with a view to its applicability to other similar entities. Implementation test of several elements of the communication strategy.

This design retained a certain flexibility. As in the logic of qualitative methods, the design is built into the research, which can be changed according to progress and intermediate results (Izzo, 2020). It has to be mentioned that the Covid-19 pandemic period added a new dimension to the research work. It gave the possibility to observe emergency communications of RIPI and to co-author a Report on the orthopaedic surgery interruption in spring 2020 (Torre et al., 2021). At the same time, Covid-related restrictions of 2020-2021 naturally slowed down and changed my research work: the stakeholders were not always available for interviews, communications within the RIPI working group and between RIPI and ISS went completely online, and some planned outreach events and scientific conferences were cancelled.

## Outline of the dissertation

**Chapter 1** provides an overview of key concepts and the theoretical framework in the research of communication effectiveness and its evaluation. It then reviews the approaches to communication effectiveness evaluation in public health, and in particular in medical devices registries, both internationally and in Italy.

In **Chapter 2,** the case of Italian Implantable Prostheses Registry is outlined in detail, with the emphasis on identifying and mapping the Registry's stakeholder groups and audiences.

**Chapter 3** is dedicated to the research undertaken. It starts with a subchapter on the choice of mixed methods and the characteristics of the research design. Follow the subchapters analysing the results of the parts of research that applied different methods: semi-structured interviews with RIPI stakeholders, website user experience analysis with web survey and Google Analytics tools, a survey of the RIAP Scientific Committee, and participant observation applied from November 2019 to November 2022. The key findings here are the insights into the communication agendas of different stakeholders.

**Chapter 4** contains the central part of the research: a proposal for the communication strategy for RIPI. The chapter starts with identifying the objectives of the strategy and continues with the detailed description of its structural elements. Second part explores possible criteria of communication effectiveness and the approaches to its evaluation. In the **Conclusion** chapter, I elaborate on the applicability of this study to other similar projects and on its limitations. Indeed, the proposed model should yet be tested and adjusted if necessary, taking into account the resources actually available for its implementation.

**Appendices** contain the Questionnaire of the survey of the RIAP Scientific committee, the Survey of user experience conducted on the RIAP website, and an example of an interview guide used for the expert interviews.

**Notice**

This dissertation has been written in English both for ergonomic reasons and to make it easier for it to enter a broader international discussion (hopefully). The author is not Italian nor an English native speaker. The context of the Italian public health institution was new to the author, which made it possible to take a relatively unbiased, external perspective towards the mechanisms and the common practices. For this reason, the dissertation may have an unintentional ethnographical flair of explaining Italian public administration functioning to the foreign public, while being a foreigner myself.

The translations between Italian and English were made by the author consulting the European Union terminology portal[1], DeepL software, and relevant literature.

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[1] https://iate.europa.eu

# Chapter 1. Communication effectiveness criteria and evaluation

## 1.1. Public sector communication (PSC) in public health: Theoretical framework and key concepts

The aim of this chapter is to identify a theoretical framework relevant to develop communication strategies for the projects like RIPI. To do this, the analysis is required of where to place RIPI communications in the bigger picture of national healthcare communications and what is the actual stage of research and practice in PSC evaluation.

First of all, key notions such as public health communication and health communication in the context of public sector communication should be conceptualised and delimited.

In a famous definition attributed to J. D. Millet, communication is a shared understanding of a shared purpose. According to Cunning, "the word 'communication' describes the process of conveying messages (facts, ideas, attitudes and opinions) from one person to another so that they are understood." For the OECD expert group, communication is the discipline of packaging and delivering information strategically to achieve the greatest impact (OECD, 2021, p. 14). Schirato and Yell (2000) add an important dimension saying that communication as a "practice of producing and negotiating meanings (...) always takes place under specific social, cultural and political conditions". Communication as a social phenomenon and as research is culture-specific and sector-specific.

In this dissertation, communication is framed as a practice of information exchange between an institution and social groups as key actors, in the public health setting in Italy.

The Italian term 'comunicazione pubblica' is the closest equivalent of 'public sector communication' (not of 'public communication'). According to OECD's definition, public communication, in its turn, is the government function to deliver information, listen and respond to citizens in the service of the common good (OECD, 2021). It is distinct from political communication, and near to the concept of institutional communication as conceptualised in the section 1.1.2.1.

### 1.1.1. Communication vs Public relations

A comprehensive normative theory of public relations (PR) of an organisation has been developed by James Grunig, known as four models of public relations: press agentry model, public information model, two-way asymmetrical and two-way symmetrical model (Grunig & Jeong-Nam, 2021; Grunig et al., 2002). The two-way symmetrical model of public relations was proposed as a normative standard par excellence for PR practice. In a symmetrical position, an organisation communicates with the understanding that the interaction could change either or both parties; in an asymmetrical position organisation aims at changing attitudes, or behaviour of another party while staying unchanged itself. The theory was widely discussed and also criticised, but evolved successfully from when it was first conceptualised in 1984 until today, due to its flexibility. Authors wrote about the private sector but implicitly the model embraced communications of government agencies as well.

However, the model that turned out to be the best fit for the public authorities, in Grunig's reasoning, was that of public information. In this model, the function of the public relations practitioners is to produce and disseminate information to the media, and the information must be factual and consciously oriented to influence public opinion in favour of the organisation's objectives. It was proved especially true for scientific organisations, where journalistic training and norms were emphasised (Grunig & Jeong-Nam, 2021). Muzi Falconi confirms: "The best part of today's public sector communication can be ascribed to this model" (Muzi Falconi, 2015, p. 12). At this point it becomes clear that the concepts of public relations and communications cannot be equated. If PR is communication to the mass media and/or to other audiences by means of mass media, then the concept "communication" is wider as it also includes direct stakeholder communication and internal communication (between the organisation and its employees).

Linguistic nuances should also be considered. The authors of the well-known study on European PR published as The Bled Manifesto claim that "in many countries it is even not possible to talk about public relations, when speaking in their own languages (especially the northern and the northwestern and central European countries)" (Verčič & Ruler, 2002). In Italian, relazioni pubbliche is more likely to evoke professional profiles like interactive direct marketing and client engagement. The concept used by the institutions is 'relazioni con il pubblico' as the PA in Italy are obliged to have the dedicated offices - URP with the functions of direct response to the citizens, so again this is not what public relations intend. Not occasionally, the professional association in Italy is called Comunicazione pubblica - Associazione Italiana della Comunicazione Pubblica e Istituzionale.

But if 'public relations' is interpreted as a relationship management activity - which is the case in many publications - communication is only its (fundamental) part.

The Bled Manifesto authors group found that in European countries both public relations and communication are commonly used terms to name the field, the first being more usual in practice while the second more common in science ("public relations practitioners" but "communication studies"). "We believe that it has no use to make a distinction between communication and relationships. From our research it is obvious that - at least in Europe - even public relations researchers cannot make any clear difference between communication and relationships (...). What one sees as communication is what another uses the word relationships for" (Verčič & Ruler, 2002, p.6).

This interchangeability might be due to the absence of demand for a single industry-wide term. The absence of demand, in turn, might be due to the fact that on a practical level, problems do not arise stemming precisely from different interpretations of the terms. Apparently, terminological uniformity at the level of national academia and practice is not an urge, and mutual understanding at the international level is sufficient.

The epistemological profile of communication of a public health institution (and of any of its divisions) should be defined at the crossroads of two perspectives: the public sector research and health communication research.

### 1.1.2. Public sector communication (PSC) in public health

In the public sector, three kinds of communications are usually recognised, but the boundaries between them are disputable: institutional, social (or that of public utility) and political communication. Recognising that it would be difficult to give an unambiguous definition of what is meant by social communication, the educational web portal Pubblica Amministrazione di Qualità still tries a simplified description of 'comunicazione sociale': in the PA, this would comprise activities aimed at bringing citizens closer to rules and services: "social communication campaigns aim to raise public awareness in addressing problems of a collective nature and interest by modifying and changing the attitudes and behaviour of individuals and social groups"

(Pubblica Amministrazione di Qualità, 2014). So, for public health authorities, social communication would be very near to the sector-specific health communication.
The fluidity of boundaries between institutional, social and political communication is considerably pronounced in Italy and became particularly evident in the first years of social media use by PA. Social media, especially, created confusion in the perception of connected citizens between public utility communication flows and window-dressing messages from the political leadership (Comunello, 2014; Lovari, 2022).

Although often in the research the concept 'institutional communication' is used as a synonym for general concept 'public sector communication', it is more correct to understand it as one of three main kinds of PSC. In this meaning, institutional communication is aimed at positioning the institution in a favourable way highlighting its certain characteristics. In terms of the requirements for government information transparency, the mechanisms and outcomes of an institution's activity must be communicated to the general public, or better say in this perspective, to taxpayers. So, it can be claimed that two main functions of institutional communication are to meet the transparency requirements and to maintain the reputation, and the key messages are about the institution's performance.

In Italian research, there was a lively conceptual discussion in the beginning of 2000, in search of definitions. Faccioli defines 'comunicazione pubblica' as a set of processes oriented towards the enhancement of the public sphere: "that framework of processes enabling the various actors intervening in the public sphere to enter into relations with each other, to compare points of view and values in order to contribute to the common goal of achieving the general interest" (Faccioli, 2002, p. 2). For Klein-Dossou Leeuw & Fava, on the other hand, 'comunicazione pubblica' is simply communication of the institution directed externally (2001, p. 17). Paoletti (2001, p. 32) agrees that 'comunicazione pubblica' is an ambiguous concept and proposes a subdivision of the forms of institution's communication into: external communication (including every announcement published); internal communication; citizens' communication towards the institutions (including the activities of the public relations office - URP). However, this classification uses different bases, combining tools with processes and with objectives. I believe that the category of citizens' communication towards institutions falls within the scope of external communication, as the feedback is an integral part of the communication process.

For Simonetti, in the PSC the aim is to increase the level of trust, satisfaction and perceived value for users, with a view to better governance. In relationship with the PA, the citizen is not merely a service user, he is a bearer of interests and holder of rights. As Simonetti writes: experiences and technologies borrowed from the private sector can be good starting points for defining the CRM strategies - where "C" stands for "Citizen" not for "Customer" - in a public administration (Simonetti, 2003).

For Italian public administration, the reason and the sense of communicative activities is prescribed by law, which stipulates the obligation to inform, to be transparent, and to be subject to accountability and scrutiny on the part of citizens. Vast literature reflects on the duty to inform, from a legal point of view (e.g., Merloni, 2002; Mancini, 2002). It is since the early 1990s that the communication of public authorities with citizens has been gradually contextualised by the legislation.

The basic premise is that communication is more than dissemination of information. Communication would mean that the audiences and stakeholders have an important active role and their response, as well as communication on their initiative, should be taken into account in policymaking. Arena in a document dedicated to PA officers in the 'URP of the URP' project distinguishes the two notions in a popular but also philosophical way: "The main difference between communicating and informing lies in the purpose: one communicates to give a meaning to the reality, while one informs to give it a structure, a form" (Arena, 2005). In informing there is a unidirectional relationship based on the transmission of information, while in communication all subjects are active participants.

The logic and bases of communication activities are the same among the Italian PA, but every institution can put emphasis on different kinds of communication. The Ministry of the Interior should pay more attention to risk communication as its competencies include emergency management, while the Ministry of Health (MoH) and the structures of the National Health Service (SSN) would obviously focus more on health communication, including health literacy.

It was in the 1980s that, stimulated by economic growth, the need for modernisation of PA in Italy became evident, including its relations with citizens. A role of business communicator already existed while a figure of a public communicator needed to be created yet. But the PA system was somehow disinterested to change, argues Rolando (2004). He attributed it to the bureaucracy's reluctance to be judged and evaluated, to the conviction that nothing had to be explained so as not to increase the already onerous amount of work and not to have to test each other's skills and, finally, there was an the idea that knowledge within the PA should not be dispersed nor widespread.

Law 214/90 sanctioned the principle of transparency and access to administrative acts marked the beginning of change. In 1993, Law 29/93 prescribed the creation of Public Relations Offices (art. 12), the purpose of which is to provide information to users on acts and the status of proceedings. Subsequently, communication in the PA was regulated by Law No. 150 /2000 'Disciplina delle attività di informazione e di comunicazione delle pubbliche amministrazioni'. This law attempts to make PA accept that communication is a transversal component of its identity. In fact, as mentioned in the Introduction, it defines communication as an obligation of the PA and establishes press offices in public administrations. Dwelling on the formulations, one can notice that the Law 150/2000, however, does not state in the text either the definition of communication or its distinction from the concept of information.

> "...sono considerate attività di informazione e di comunicazione istituzionale quelle poste in essere in Italia o all'estero dai soggetti di cui al comma 2 e volte a conseguire:
> a) l'informazione ai mezzi di comunicazione di massa, attraverso stampa, audiovisivi e strumenti telematici; b) la comunicazione esterna rivolta ai cittadini, alle collettività e ad altri enti attraverso ogni modalità tecnica ed organizzativa; c) la comunicazione interna realizzata nell'ambito di ciascun ente" (Art.1)

The Law 150/2000 lists six aims of information and communication activities of PA, articulating them in three functions: to illustrate, to promote, to facilitate.

> Le attività di informazione e di comunicazione sono, in particolare, finalizzate a:
> a) illustrare e favorire la conoscenza delle disposizioni normative, al fine di facilitarne l'applicazione;
> b) illustrare le attività delle istituzioni e il loro funzionamento;
> c) favorire l'accesso ai servizi pubblici, promuovendone la conoscenza;
> d) promuovere conoscenze allargate e approfondite su temi di rilevante interesse pubblico e sociale;

e) favorire processi interni di semplificazione delle procedure e di modernizzazione degli apparati nonché la conoscenza dell'avvio e del percorso dei procedimenti amministrativi;
f) promuovere l'immagine delle amministrazioni, nonché quella dell'Italia, in Europa e nel mondo, conferendo conoscenza e visibilità ad eventi d'importanza locale, regionale, nazionale ed internazionale. (Art. 1, comma 5)

The objectives thus described all fall within the scope of institutional communication, with exception of (d) that is the essence of social communication: promote broader and deeper knowledge on topics of relevant public and social interest.

Communications of a public health institution may be of several types, depending on their purpose. At the organisational level and in practice, we will find the elements characteristic for institutional communication, social (health) communication and, in case of a public health emergency, risk / crisis communication. For a research institution as ISS, scientific communication (towards researchers) and science communication (towards non-specialists) are also relevant. It needs to be determined whether the same types of communication are relevant for an individual project within a PA institution, such as RIPI.

### Institutional communication

67% of national Ministries of Health surveyed by the OECD across Europe confirmed that raising awareness of policies is the leading objective of public communication function (OECD, 2021). According to the Italian MoH report Relazione sulla Performance Anno 2021, one of key objectives of the Ministry's Directorate General for Communication and European and International Relations (DG COREI) was promoting the role of Italy for the health protection in the international international arena. In the PIAO 2022-2024, development of institutional communication policies (sviluppo di politiche di comunicazione istituzionale) is among nine macro-areas of health policy in these three years (Ministero della salute, 2022a, p.12).
Examples of the MoH's institutional communication are the following news items published in the News section of Ministry's web portal (dates, headings and the first paragraphs are provided):

04/01/2023. Programma EU4Health - Joint Actions 2023.

> La Commissione Europea ha richiesto al Ministero della salute di avviare le procedure per la Nomina della Organizzazione partecipante ("Competent Authority" - Coordinatore Nazionale) per ciascuna delle Azioni Comuni (Joint Actions-JA) e dei Finanziamenti Diretti (Direct Grants-DG) contenuti nel Work Plan -WP 2023 del Programma per l'azione dell'Unione Europea nel campo della salute per il periodo 2021-2027 - EU4Health. (https://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=6122 )
>
> 10/01/2023. Aids, trasmessa al Parlamento la Relazione anno 2021.
> Trasmessa al Parlamento il 30 dicembre 2022 la Relazione al Parlamento 2021 sullo stato di attuazione delle strategie attivate per fronteggiare l'infezione da HIV illustra le attività svolte dal Ministero della Salute con riferimento ai settori dell'informazione, della prevenzione, della diagnosi, della terapia, dell'assistenza e dell'attuazione di progetti di ricerca.
> (https://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=6125).

An example of institutional communication of the ISS:

> 07/12/2022. Nominato il Comitato Nazionale per la Bioetica, anche esperto Iss tra membri (https://www.iss.it/en/web/guest/-/nominato-il-comitato-nazionale-per-la-bioetica).

Information disclosures in the section "Transparent administration" of the PA websites are another typical example of institutional communication.

The guiding communication principles of 'parent' institutions - MoH and ISS - apply to RIPI, but can this type of communication be practised by an individual unit not having a policy-making competency? The answer is yes. Analysing the current communication practices of RIPI against the above-mentioned macro-functions of institutional communication stated in the Law 150/2000, we find examples of activities that perfectly correspond to some of these functions.

| **Public communication functions stated in the Law 150/2000** | **Related communication activities by RIPI** | **Example** |
|---|---|---|

| | | |
|---|---|---|
| (a) illustrate and promote knowledge of the regulatory provisions, with a view to facilitating their application | RIPI informs its audiences about new national and European directives of direct relevance to registries | News on the RIPI website. 04/06/2021. The European Medical Devices Regulation came into effect |
| (b) illustrate the activities of the institutions and their functioning | RIPI additionally informs its stakeholders about Registries' operations and related PA developments | News on the RIAP website (in Italian). 24/06/2022. Avvio della collaborazione con il National Joint Registry (Launching the collaboration with the National Joint Registry)<br>News on the RIPI website (in Italian). 21/06/2022. Registro Nazionale degli impianti protesici mammari: c'è il via libera della Conferenza Stato-Regioni (National Breast Implants Registry: Green light from the State-Regions Conference) |
| (f) promote the image of the administrations, as well as that of Italy, in Europe and worldwide, giving knowledge and visibility to events of local, regional, national and international importance. | | News on the RIAP website. 09/07/2019. European Commission: Italy's CND replaces GMDN for DM nomenclature (the nomenclature developed in Italy was accepted as the basis for the renewed European Database on Medical Devices nomenclature). |

*Table 1. Examples of institutional communication in RIPI practice.*

## Health communication and public health communication as research perspectives and practice

There is a number of peacefully coexisting definitions for health communication as a practice and as a research discipline: it is sometimes defined as a study and use of communication strategies to inform and influence individual and community decisions that enhance health[2], or a wide-ranging discipline that studies the communication processes and practices. A new field of study between communication and healthcare emerged in the 1970s. It is internationally referred to as health communication. In the literature, health communication is often associated with patient experience, patient's interaction with caregiver, physician or the healthcare system, mostly interpersonal. As a research area, it is rooted in psychology and nursing studies. This dissertation

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[2] https://www.thecommunityguide.org/topics/health-communication-and-health-information-technology.html

does not discuss this type of communication. So, "health communication" is used as an umbrella concept for health and healthcare-related types of communication, from interpersonal (patient – caregiver) to mass communication (awareness-raising campaigns).

### Public health communication

Kreps & Maibach characterised public health communication (PHC) as an "exciting emergent new research framework" that combines key aspects of communication and public health scholarship perspectives (Kreps & Maibach, 2008, p.1). They write about it as a mutually enriching liaison, exchange of theories and methods. Public health scholars brought in ecological social theory, and communication research introduced Weick's model of organising that describes the systemic role of information and communication for social organising. In the authors' view, communication scholars took from their public health colleagues and adapted the randomized clinical trial method, while public health began to use qualitative methods such as interviews and focus groups, as well as content analysis, more actively.

The collaborations between communication and public health enriched evaluation research methods for public health communication interventions. The evaluation research benefited from use of both communication-specific methods like audience analysis, usability analysis, and message-testing, and health statistics methods such as cost analysis and the evaluation of policy implications (Kreps & Maibach, 2008; Hornik, 2002). A factor that enhanced the PHC and collaboration between public health and communication was the growing use of health promotion campaigns as a primary strategy for public health intervention (Hornik, 2002).

The European Commission (EC) sees communication interventions of its departments and projects as a support for policies, with functions to persuade, inform, normalise, inspire or motivate, engage (EC, 2017). Normalising is a subtle, and hence underexplored concept. It means "to give people the sense that everyone else is doing the same as the activity you suggest (such as taking flu precautions), that there is a societal expectation for people to do a certain thing – or not do something (such as smoking near children)" (EC, 2017, p. 28). This kind of persuasive communication is characteristic for public health campaigns that have an end goal of behaviour change. This approach can be further found in public health-specific communication guidelines of EU bodies. ECDC identifies six key areas that have to do with the object of health communication: health literacy, health education, social marketing, risk communication, crisis communication, and health advocacy (https://www.ecdc.europa.eu/en/health-communication/facts ).

Health communication of public health authorities and institutions (Ministry, supervisory body, research institute, regional healthcare authority, etc) is centred on health issues - disease prevention, epidemic trend, healthy lifestyles, and not on the role of the institution in these issues. It can be aimed at raising awareness, education, changing opinion, attitude, or behaviour (e.g., quit smoking, get vaccinated). By default, health communication is targeted at the general population or at social groups at risk due to their condition.

Implant device registries differ in their patient relations strategy, depending on the registry mission, design, and resources. As analysed in Chapter 2, RIPI was not designed to interact directly with the potential and actual implant patients and the general public. Still, the section "For patients" on the RIAP website contains materials that are characteristic for health communication, such as infographics "Useful tips while waiting for your arthroplasty" dedicated to pain-relief exercises and techniques.

### Risk and emergency communication

In the public health setting, risk communication is a sub-type of health communication, covering a vast area of public health emergencies and disease risks.

As other notions discussed previously, risk, crisis and emergency are related concepts often used interchangeably, sometimes added by composite terms such as crisis risk communication. Anzera, after Coombs (2007), refers to this conceptualising of emergency communication as its most widespread and generally accepted definition: a process that acquires and disseminates the information needed to counter an emergency event, and notes that the extensive literature on the distinction between crisis and emergency does not always succeed in curbing definitional errors, situational overlaps or the use of terms as if they were synonyms (Anzera, 2014, in: Comunello, 2014, p.12). Glick (2007) convincingly argues that risk communication is a set of practices and relationships more generic in relation to crisis risk communication. The latter presumes an emergency / crisis is already imminent. In a situation of normality, health communication deals with contrasting risky behaviours, by means of awareness-raising campaigns and health promotion. In the scenario of a hazard, crisis risk communication not only ought to be timely and accurate, it must also reassure and give hope (Glick, 2007).

In EU project report on Covid-19 crisis governance (HERoS, 2020), risk communication is defined as the exchange of (real-time) information, advice and opinions between policy makers, experts/practitioners and people facing threats to their physical, mental, economic or social well-being.

Covello (2006) describes the main goals of risk communication, in particular in public health: to inform and educate; to gain trust and credibility; and to create informed dialogue, decision making, and behaviour. He cites Jong-wook Lee, WHO ex-Director General who recognises that communications are as critical to outbreak control as laboratory analyses or epidemiology (Covello, 2006, p. 1).

For public health communication research, the emergency communication is now more relevant than ever. Covid-19 pandemic has yielded a huge amount of literature on the subject. For example, publications on "emergency communication & public health" in WebOfScience core collection doubled in 2020 (n=454) compared to 2019 (n=204). Public agencies communicate very intensely during a public health emergency. Depending on their profile, public health registries may be involved to different degrees in emergency management. The founding law of public health registries in Italy, DPCM 3/3/2017 gives surveillance systems and registries a role in risk communication, specifically the function of a timely alert:

> "allerta rapido [sic], per lo scambio di informazioni su eventi passibili di provvedimenti urgenti per la tutela della salute pubblica a livello nazionale e internazionale, con le Autorità competenti, in conformità alla normativa europea e internazionale" (DPCM 3/3/2017, Art.1, comma 2 (h).

One of aims of implantable device registries is so formulated: "rintracciabilità tempestiva dei pazienti in caso di necessità di specifico follow-up o di eventuale espianto" (DPCM 3/3/2017, Art. 2, comma 1 (p)). So, even if RIPI's routine work does not involve risk/emergency communication, it has a function to help identify and notify implant patients in case of an implant recall. This function is in stand-by mode, but probably a crisis communication plan for such situations would be necessary.

In a situation of a nationwide emergency caused by a communicable disease, such as Covid-19 pandemic, it is not the Registry's competency to communicate as it does not produce emergency-relevant information. Still, if the registry management deems it useful for their audiences it can provide supporting information or facilitate information flows.

## Science communication

Science communication (SC) is usually understood as communication about science, bridging scientific knowledge with its specific language to the wider audiences. 'Scientific communication' is sometimes used as a synonym, but it can also describe peer-to-peer communication, academic knowledge sharing through scholarly publications and conferences within a certain discipline. Burns et al. (2003) proposed a definition of science communication as the use of appropriate skills, media, activities, and dialogue to produce one or more of the following personal responses to science: awareness, enjoyment, interest, opinions (the forming, reforming, or confirming of science-related attitudes), understanding of science. Other definitions are rather similar and share the same basic idea of SC as a practice of informing the non-specialist public about scientific knowledge. Scientists from other fields also belong to the non-specialist public in this sense. As a practice, SC involves scientists themselves, mediators (e.g. science communicators), members of the general public.

Currently, the SC scholars deal with a number of challenging societal conditions and ideas: the loss of public trust in science (which can partly be attributed to communication failures), the now-criticised deficit model perspective, the scientists' resilience to communicate with non-specialist public (Dudo, 2012). Other researchers interpret SC as a social conversation about science, in which ideas move freely across different groups and acquire new meanings: "This process does not always or only depart from and return to science, its actors and its institutions; it swirls in society, somewhat independently and with interruptions" (Bucchi & Trench, 2021).

Being both a public health and a research institution, ISS is involved in science communication. Many of its press office activities consist of transforming the research results into concise, simple yet not over-simplified messages. The ISSalute portal (www.issalute.it) is an example of SC.

RIPI is a research unit - as stated before, a research group is one of its identities. By now, the emphasis has been made primarily on scientific communication in the sense of scientific literature production and participation in scientific events, to build and maintain relationships with the world of research. As for SC meant as divulgazione, popular science publications based on RIPI data and research, it is less practised. The press release based on RIAP Report 2019 "Protesi ortopediche: nel 2019 un intervento ogni 2,4 minuti, nel 2020 in rallentamento per il Covid" is a characteristic yet rare case. The special report "The Impact of COVID-19 pandemic emergency on joint arthroplasties in seven Italian Regions" (Torre et al., 2021) included in the ISS series Rapporti ISS COVID-19 can also be called a popular science publication, suitable for a prepared, interested, but not necessarily expert reader.

Many factors now predict active development of RIPI science communication as well as of the implantable device field in general. Among these factors are an international trend on seeing stakeholder relations as collaboration and co-production, the need to promote "registries culture", and even the first steps towards establishing a new academic discipline - medical device science. Lübbeke and colleagues in a programming article name the reasons why this science is needed, including the recognition by policymakers and regulators of the importance of devices, growing public awareness of their benefits and possible harm, increasing amount of available data on medical devices, and the fact that devices are becoming more complex (Lübbeke et al., 2021).

## 1.2 Overview of contemporary approaches to communication effectiveness evaluation

### 1.2.1. What is effective communication?

Effectiveness is one of the most important and most discussed dimensions of communication activity. But what communication should be called effective? Is "effective" in this case equal to "good", or is "effectiveness" only one of the parameters of "good" communication?

Palumbo defines effectiveness as the degree to which the objectives of an intervention have been achieved or the needs that originated it have been satisfied (2001b, p. 111). This definition with little variations is commonly used. In the case of institutional communication, the referents of the effectiveness evaluation are, on the one hand, the needs of the target group and, on the other hand, the objectives of the organisation. For Muzi Falconi (2015), in social communication of PA, an effective message is the one that contributes to changing the recipient's opinion, attitude, decision and behaviour.

In practice-oriented literature on effectiveness evaluation, the OECD set of criteria for development evaluation is the one widely accepted. Effectiveness is understood as the extent to which the intervention achieved, or is expected to achieve, its objectives, and its results.
Effectiveness is one of six evaluation criteria, along with relevance (is the intervention doing the right things?), coherence (how well does the intervention fit with the principles and practices of the same institution, and with other actors' interventions in the same context?), efficiency (how well are resources being used?), impact (what difference does the intervention make?) and sustainability (will the benefits last?) (OECD, 2019). This framework was developed for evaluating international development and humanitarian interventions including policies, projects, strategies, and can also serve as a reference for communication strategies.

So, effectiveness here is placed alongside five other criteria, each of which, according to the authors, plays the role of a different lens to view the subject of the evaluation. But if effectiveness is the ratio of the results to objectives, what if we include in the objectives such target characteristics of communications as coherence, efficiency, sustainability? Then effectiveness becomes a summarising criterion. Indeed, in the OECD Report on Public Communication (OECD, 2021) bringing together practices from many national governments, the effectiveness of communication is understood in a broader sense. As emphasised by the OECD experts, the criteria depend on the purpose of evaluation and should always be contextualised.

In public health, criteria are strongly audience-oriented. WHO (2017) sees its ideal communications to and with key audiences as: accessible, actionable, credible and trusted, relevant, timely and understandable, which suggests that for WHO "effective" means "optimally perceived by the recipients". This guiding document was written from the perspective of care and health literacy, instructing the WHO communicators to aim at behaviour change towards healthier and safer behaviour.

The European Centre for Disease Prevention and Control (ECDC) relies on the following principles, which it considers to be generally accepted as attributes of effective health communication practice and message development. They can be grouped by content-related and process-related. Content-related attributes of effective communication are:

accuracy (of the content), balance (of different perspectives in the message content), consistency (of the content across contexts and over time), evidence base (scientific rigour of the content), reliability (of the source), understandability (by the specific audience).

Process-related attributes are:

availability (accessibility for target audience), cultural competence (in sending the message to different population groups), reach (largest possible), repetition (the delivery of/access to the content is continued or repeated over time), timeliness (sent when most appropriate) (ECDC).

It becomes evident that the effectiveness of communication as a continuing process is determined by effectiveness of its "pieces", i.e. communication interventions, campaigns, project activities.

### 1.2.2. Evaluation approaches

Evaluation as a discipline has formed on the crossroads of applied social sciences and is practice-oriented by nature. The concept of communication evaluation as practice is self-evident. This definition given by Palumbo is used for the purposes of this research: "the complex of coordinated activities, of a comparative nature, based on social science research and inspired by its methods, which has as its object intentional interventions and as such endowed with instrumental or substantive rationality, with the aim of producing a judgement on them in relation to their performance or their effects" (2001b, p. 61).

The object of evaluation is the results of communication activity. Results come in the form of outputs, outtakes, outcomes. Outputs can be defined as a measurement of those directly reached by the activity; outtake is the direct effect - an intermediary step toward the expected effect, and the outcomes refer to effects on the knowledge, attitudes, and behaviour within a target audience (EC, 2017).

More often than not, practice-oriented literature focuses on the evaluation of time-bound communication interventions. To apply this approach to the continuing communications that accompany the operational activity, this continuum should be broken down to time periods. In short-term projects, evaluation can be done for the whole project's life-span or can be planned once in six months. Over which period we will evaluate the effectiveness of our communications is a managerial decision. For example, we may decide to do an annual evaluation, even more so if budget planning and general objectives planning follow an annual cycle. Interim evaluation should be carried out to check the actual performance against the previously set targets and to adjust the tactics if needed.

As we have seen before, many concepts in the communication field have no clearly defined boundaries. In this case I believe that the absence of a unified definition and agreed contents of the concepts ‘evaluation’ and ‘measurement’ of public sector communication impedes the research. In the literature the concept of communication evaluation is often understood as 'measurement of results', despite the fact that these are only partially overlapping concepts as measurement leaves behind all those important elements that are not measurable with quantitative techniques. Similarly, the concept of impact is often used in a very broad sense that makes it almost to approach and to attempt any evaluation.

This happens also in industry literature and practical guides, which doesn’t necessarily preclude the practice development. In the ISS document Sistema di Misurazione e Valutazione della Performance (ISS, 2019), evaluation (valutazione) is defined as a “complementary activity to measurement that has a purpose of interpreting the results with respect to the contextual factors that may have influenced on alignment or deviation from targets” (p.6), which is debatable. One of the milestone documents in the communication evaluation practice worldwide, the Barcelona Principles uses terms ‘evaluation’ and ‘measurement’ alongside, as in “Principle 4. Communication Measurement and Evaluation Should Include Both Qualitative and Quantitative Analysis” (AMEC, 2020). In the Dictionary of Public Relations Management and Research (Stacks & Bowen, 2013) there is no dictionary entry for ‘evaluation’. ‘Evaluation Research’ is defined as a form of research that determines the relative effectiveness of a public relations campaign or program by measuring program outcomes against a predetermined set of objectives. ‘Measurement’ is defined as “a way of giving an activity a precise dimension, generally by comparison to some standard; usually done in a quantifiable or numerical manner” (p. 18). It can therefore be concluded that evaluation area includes measurement area, the boundaries are not clear and pass somewhere between the qualitative and the quantitative (=measurable).

Finardi (2010) analysing the literature on PA communication notes the numerous references to the term ‘flow’ (flusso) - something unmanaged and uncontrollable as flows are - when communication processes are being described. According to the author, the concept of flow reflected the stage of development of communication activities in many public authorities by that moment: "Fragmentation and randomness emerge from the fact that there is no particular attention paid to the various organisational phases, staff roles and tasks, selection of tools, timing, etc., and in the fact that there are no traces of evaluation" (p. 91). In addition, she claims that the PA focus almost solely on the outputs and rarely on the outcomes. This increases the risk of self-evaluation errors on the part of institutions, because the focus all too often remains on completing the task, on what 'must be done' (outputs) without due reflection on the real results (outcomes) for the target audiences (ibid, p. 91).

Notably, public authorities in Italy in their open documents rarely invoke the term ‘comunicazione’ when describing its relations with the external publics and stakeholders, and rather use ‘disseminazione’ and ‘divulgazione’. Both concepts presume a one-way information flow: one-to-many. This appears to be quite a common situation in public administrations internationally. Noar from the University of North Carolina writes that some healthcare communication campaigns still do not adhere to the principles of effective campaign design. "Many campaigns continue to be developed without any theory at all," the author argues (Noar, 2012, p. 485).

As stated in the OECD Report on Public Communications, evidence points to the lack of institutionalisation, the limited integration of evaluation within strategic planning processes and the predominant focus on outputs over impact as the main inhibiting factors (OECD, 2021). Internationally recognised standards and principles of good practice, and the codifying of successful practices would be needed.

OECD survey results among government centres in European countries showed that only just over half of respondents developed clear [communication] strategies. Notably, 82% of surveyed national Ministries of Health pointed at the lack of human and financial resources as a key challenge in this issue (OECD, 2021, p. 11).

In the last few years, however, the interest in evaluation of communication strategies and interventions has been growing, because the importance of communication is already widely recognised in the institutions. ECDC includes evaluation instructions in its communication toolkits for behaviour-change campaigns, claiming that formative research should be carried out on an ongoing basis to help refine and improve programme activities (ECDC, 2019, p.8). The recent national level case is provided by the Ministry of Health of Portugal: The Portuguese National Health Plan 2021-2030 for the first time contains a separate chapter Plan of Strategic Communication that also includes evaluation as a necessary stage. In 2020, in the Italian Ministry of Health, a new professional profile was introduced, that of the Communication Officer (funzionario della comunicazione) (Ministero della salute, 2022a). New triennial activity plans for 2022-2024 and 2023-2025 of the Ministry of Health and the ISS have moved beyond the “flow” approach and have all the objectives translated into time-bound actions, including in the communication area (more on this in Chapter 4).

### Evaluation mandates

A researcher dealing with the evaluation of institutional communication has numerous methods at disposal. The choice depends on various factors, but first and foremost on the research objective itself. In the evaluation literature, three main types of reasons for carrying out an evaluation are distinguished, the so-called evaluation mandates (Bezzi, 2001; Palumbo, 2001):

- compliance control (compliance with the norms established by the law/statutes);
- accounting, the reporting of results (monitor the level of achievement of the organisation's/department's objectives (e.g. with respect to what is set out in a Triennial activity plan (Piano Triennale di Attività, PTA);
- learning for improvement. In this case, aims are to understand the extent to which the communication meets the needs of the target audience; to refine communication strategies and tactics in the future, or, simply put, to make public communication more data-driven, more evidence-based.

Social research is by its nature primarily concerned with the third type of evaluation mandate, that of learning, and this requires diversified methods. Mauri argues for the importance of the multidisciplinary and, however difficult to achieve, interdisciplinary approach in applied social research, whatever methodological option is chosen (Mauri, 2010).

Evaluation activities are necessary during all phases of the communication planning and plan implementation. The dominant practice is that of conducting interim, final and ex-post evaluation after the communication intervention, as its effectiveness can be judged upon only subsequently. But the evaluation criteria should be obviously set up at the planning stage.

### Challenges for evaluation of public sector communication

The intangibility of communication offers a methodological and practical challenge to the evaluator: how to gather data for making an evaluative judgement, if the context is so fluid and uncertain? Another problem is that the object of study is the reality of which social scientists are a part, which varies at the very moment in which it is being observed. Mauri calls this the problem of reflexivity (2010). Another critical element is the consideration that, to evaluate communication, the only operational instrument is language, which is itself communication. Evaluation, therefore, finds itself in a situation well known to linguists: one wants to understand communication using a communicative tool. The mentioned problems can be related to the high degree of subjectivity often attributed to qualitative methods of social research.

Bezzi deepens the epistemological reasoning on the statement "Effective communication is that that has been understood by the recipient" to a sort of infinite regression: what does ‘understanding’ in fact mean? Add to this the problem of indefinite receiver of communicative messages sent by a typical public authority targeted at the general public, when the actual penetration of the message is unknown: “in very concrete terms: how many brochures will be thrown away, and how many will be used?” (Bezzi, 2001, p. 47). At this point, the methodological complexity of any attempt at evaluation may seem excessive. It can only be eliminated if a researcher circumscribes the evaluation parameters for a specified case, based on commissioning, practical limits and the purpose.

### Mixed methods approach

For Bezzi, carrying out communication evaluation in the public sector becomes "a test bed" (banco di prova) for multi-method experimentation that implies hermeneutic techniques alongside more traditional ones (2001, p. 62). Multimethod and mixed methods are very near methodological approaches and are understood as interchangeable in this dissertation (Creswell & Plano Clark, 2017).

Creswell and Plano Clark propose a non-exhaustive but nevertheless convincing list of reasons for a researcher in social sciences to adopt a mixed methods approach:

- the need to describe and compare different types of cases;
- the need to involve participants in the study;
- the need to develop, implement and evaluate a programme (Creswell & Plano Clark, 2017).

Many of these reasons are relevant in the case of RIPI communication.

Mauceri proposes a vision of mixed methods as a full complementarity between qualitative and quantitative approaches that allows various techniques to be integrated into the same research design and data analysis to be carried out in an integrated manner. Qualitative research, if appropriately combined with questionnaire surveys, can compensate for the shortcomings of the questionnaire or support the possibility of combining different levels of analysis (Mauceri, 2019). Particularly appropriate is the use of mixed methods in projects that have many components, such as multi-stage evaluation studies in which the researchers may need to link several studies to achieve an overall goal.

In addition to this predominant methodology, there are also various frameworks suitable for specific areas of evaluation research. Noar (2012) proposes an Audience-Channel-Message-Evaluation (ACME) model that organises the principles of design, implementation and evaluation of health-related campaigns. Evaluation becomes an integral part of all phases of a communication or information campaign. In the Italian context, Paoletti (2001) proposes using an ethnomethodological approach in the analysis of the conversation as part of an evaluation research.

### Marketing Approaches

In the interdisciplinary perspective, some methods and techniques developed in corporate communication evaluation studies can be used in the public sector, including web marketing tools and customer satisfaction studies.

The social marketing approaches developed by Kotler could be useful, even though developed more than 50 years ago. He described the use of marketing strategies and techniques to influence a target group to accept, modify or abandon a behaviour voluntarily in order to gain an advantage for individuals or society as a whole. Specifically, as Fattori (2005) argues, social marketing applies the concepts and techniques of marketing and other disciplines to achieve behavioural goals aimed at improving individual/collective health and to help reduce social inequalities, within the framework of community policies. Evaluation is seen as a final part in the structure of a social marketing plan.

Some practical tools developed in web marketing are perfectly usable among the quantitative methods for the evaluation of various aspects of digital communication of public bodies. These are techniques such as analysing a website user experience, tracking metrics of social media interactions, and online surveys (Comunello, 2014; Lovari, 2017). The Italian Ministry of Health, for instance, used the web marketing toolbox to measure the performance of its Facebook page during the first months of the Covid-19 emergency. The number of 'likes' increased from 61,196 on 30 January 2020 to 409,145 on 3 April 2020, with an average of 1,983 shares per post. These data make it possible to estimate the real audience of the published content (Lovari, 2020). Social media channels of ISS also saw a surge in followers during the pandemic.

### Participatory evaluation

The concept of participation has become very important in evaluation sociology (Stame, 2016). The pluralist, participatory nature of contemporary communication has implications for evaluation methods. The process of designing the research can be participatory through dialogue with stakeholders (commissioners, representatives of target groups, professionals). According to Klein-Dossou Leeuw, some indicators established in the research design are 'objective', while others should be negotiated with the commissioner of the evaluation research (Klein-Dossou Leeuw & Fava, 2001). Indeed, the commissioner’s perspective is highly relevant in the process of a communication strategy development for RIPI.

Then, the evaluation itself is participatory. Anchoring evaluation in an end user perspective is crucial for improving its relevance (OECD, 2021). Following Bezzi's reasoning, stakeholders should be involved in the evaluation process "not to adhere to a demagogic agenda of participation and democratisation, but out of a selfish need to get to the heart of that true information without which effective evaluation cannot be achieved" (Bezzi, 2001, p. 61). For example, interview respondents or focus group members are an active part of the evaluation research as they can change its course with their input. And in general, it can be argued that meeting stakeholders' communication needs should be taken into account at the stage of setting communication objectives and defining criteria for their effectiveness.

## 1.3. Final observations

Research dealing with the evaluation of communication in public health is interdisciplinary by its nature and should bring together different theoretical perspectives. In this chapter, an overview was made of principal types of communication characteristic for a research institution in public health. We’ve seen that of three traditionally identified kinds of public sector communication - institutional, social and political - the first two are relevant for a public health institution. Social communication takes the form of health communication, which in its turn can include risk communication. As a research institute, ISS is also engaged in science communication and, of course, scientific communication.

This chapter started with a question, where to place RIPI communications in the bigger picture of national public health communications. Having done the exercise of trying to apply each type of communication to RIPI, we got the same result. All of them - institutional communication, scientific and science communication, health communication, risk communication - are applicable and practicable at the level of the registry. This repetition of the functions of the whole structure (ISS) at the level of its part (RIPI) can be compared to a fractal[3], with its self-similar pattern.

In the perspective of participatory evaluation, a new question arises: what are the communicative priorities of RIPI stakeholders? Next chapter is dedicated to answering this question.

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[3] More on fractal-based management in public health: Pronovost & Marsteller (2014).

# Chapter 2. The case of RIPI (Italian Implantable Prostheses Registry)

## 2.1. Brief history of Italian Implantable Prostheses Registry (RIPI). Analytical overview.

**Key concepts**

The International Medical Device Regulation Forum defined a medical device registry as "organized system with a primary aim to increase the knowledge on medical devices contributing to improve the quality of patient care that continuously collects relevant data, evaluates meaningful outcomes and comprehensively covers the population defined by exposure to particular device(s) at a reasonably generalizable scale (e.g., international, national, regional, and health system)" (IMDRF, 2016).

Implantable medical devices form a subclass of medical devices. A national implantable prostheses registry is a systematic data collection of all the implantable device procedures for a specific prosthesis at a national level. As defined in the DPCM 3/3/2017, a milestone bylaw that established the major part of national public health registries in Italy:

> "registri di protesi impiantabili: sistema di raccolta dei dati relativi all'utilizzo di un dispositivo protesico impiantato, per consentire la valutazione clinica di efficacia e sicurezza del dispositivo dopo l'immissione sul mercato, nonché' per la rintracciabilità tempestiva dei pazienti in caso di necessità di specifico follow-up o di eventuale espianto" (Art.2, comma (p).

The Italian Implantable Prostheses Registry (Registro Italiano Protesi Impiantabili, RIPI) aims to collect and analyse data of the procedures of orthopaedic implants (hip, knee, shoulder, and ankle joints), spinal implants, implantable cardioverter defibrillators, pacemakers, and artificial heart valves performed in Italy. Its main objectives, as already mentioned in the Introduction, are twofold: to enable tracking patients in the event of a recall of their implanted prosthesis, and to perform statistical analyses on the collected data. So-called survival analysis permits to measure how long an implant remains in place before being removed; it is a powerful tool for early detection of possible problems (Torre et al., 2021).

The Italian Arthroplasty Registry (Registro Italiano ArtroProtesi, RIAP) collects data on the procedures of implantation, revision and removal of orthopaedic implantable prostheses performed in public and private clinics nationwide. It is organised as a federation of regional registries coordinated by ISS as a *super partes* institution, which means that data is first collected at the regional level and then transmitted to ISS. The registry collects combined data: those of Hospital discharge records (HDR, in italian "schede di dimissione ospedaliera, SDO") integrated by an additional Minimum data set (MDS). MDS describes procedure (operated side, previous operation, diagnosis, type of procedure, surgical access, implant fixation method) and device (CND[4] classification code, manufacturer, name, product code and lot number). A pseudonymised code is associated to each patient to ensure the respect of their privacy, in compliance with the rules of data protection. The implanted devices are identified and described using the device library - Dizionario-DM - built by RIAP in cooperation with device manufacturers.

One of the aims of data collection and analysis is to be able to calculate the implant survival rate. Comparison with survival rates, measured in other registries or available in the literature, will make it possible to assess the real performance of the individual device. Should this prove to be substandard, the data from the registry will be able to provide a benchmark for manufacturers and the regulatory authority to take the necessary action and possibly proceed with a device recall.

### Historical background

The need to have implantable device registries in public healthcare is caused by a big and growing number of implant procedures, which in turn is caused by the ageing of population and by the progress of biomedical technology. Other reasons are the elevated cost of the implants for public health expenditure and relatively high risks for patients in case of implant malfunction.

The first national arthroplasty registries were established in Scandinavian countries already in the 1970s, and later in New Zealand, Australia, UK, and Canada. Many other countries followed; research networks and international associations were formed. By the end of 1990s, the registries were already recognised as a gold standard in epidemiology and biomedical statistics that provided reliable real-world data for health researchers. Following the positive experiences of Scandinavia and precisely Sweden, since 2000, some Italian regions have independently organised

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[4] Classificazione Nazionale dei Dispositivi Medici, Italian national classification of medical devices

registries for hip, knee, and shoulder arthroplasty. In particular, in Emilia Romagna the regional registry was established in 2000 (RIPO), and Apulia conducted a number of important studies. In 2005, all the regions agreed on the necessity of establishing a national registry organised as a federation of regional registries coordinated by the ISS.

The ideation of the implantable device registries started with the most impactful categories of implants, and orthopaedic prostheses are among them. In 2002 the Health Minister Girolamo Sirchia ordered an outcome assessment of several types of surgery, including hip arthroplasty. In terms of lethality there are more risky categories of implantable devices, such as heart valves. But due to high and growing numbers of hip replacements, cumulative public expense was higher than for some more costly but more rare type of implantable device. In 2002, based on HDR data, more than 110,000 admissions were made for joint replacement and revision in Italy, 25% more than in 1999. 68.5% of them concerned hip arthroplasty (Torre et al., 2005, p.147). The economic burden of this type of surgery on public expenditure is significant. In the same year, considering only hip prosthesis operations (approximately 75,000) and knee prosthesis operations (32,000), the spending was about 800 million euros for surgical DRG[5] and about 500 million euros for post-surgical rehabilitation (Torre et al., 2005, p. 149).

Considering the relevance of this topic, in 2002 ISS launched a special research project funded by the Ministry of Health with an aim to propose a national registry model that could be applied to all Regions. Eng. Marina Torre led the operative unit. Initial name of a proposed registry was National registry of hip replacement (*Registro Nazionale degli interventi di protesi di anca*). It was designed as a network of regional registries under the coordination of the ISS. The situation in Italy is peculiar: public healthcare is managed autonomously by the Regions, so a national registry was supposed to be of support to the Regions in integrating separate data flows in the system of national healthcare service (SSN).

In May 2004, a multistakeholder meeting with broad regional representation was held to elaborate a shared proposal of the registry. Following topics were on top of discussion: ranking the medical facilities and surgeons, an idea vaguely proposed but then rejected; the mode of data publication;

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[5] DRG (acronym for Diagnosis Related Groups, or Raggruppamenti Omogenei di Diagnosi) refers to the system of remuneration of hospitals for treatment activities, introduced in Italy in 1995.

avoiding overloading the clinicians with registry work; technical issues in data transfer (for example, in those days some clinics were still sending the device labels by fax).

The project report, written in 2005 with wide participation of the Regions (Torre et al., 2005), expressed the shared agreement to have a national registry “in view of the requirements related to the evaluation of the outcome of the intervention, post-marketing surveillance and vigilance, technology assessment, and cost-effectiveness assessment” (Torre et al., 2005, p.154). The national registry was designed as a federation of regional registries, coordinated by ISS. Data would be gathered following the HDR information flow, integrated by some additional information (MDS). Further decision of the Ministry of Health (MoH) was needed.

In 2006, the General Directorate for Medicines and Medical Devices (now General Directorate for Medical Devices and Pharmaceutical Service) of the Ministry of Health decided to promote the regulation establishing registries of implantable medical devices (IMD), and to invest resources in the research in this direction. The Italian Arthroplasty Register Project (RIAP) was launched. Consequently, RIAP was included among the Special projects of the ISS and started developing in two directions: technical-scientific and regulatory. From a one-person project at its start, the team was gradually growing, new competencies allowing for further growth. IT specialists joined the team and developed registry-specific tools for data collection (RaDaR, Raccolta Dati Ricoveri), for transmitting data from regions to ISS (SOnAR, Sincronizzazione Online Automatica Ricoveri), and a webservice to find a device (RiDi, Ricerca Dispositivi). Another utility allowed operators to access directly the Dictionary - a product catalogue updated by the manufacturers. RIAP and subsequently RIPI are based on a multi-step engineering infrastructure created ad hoc. In 2018 a need for the re-engineering became clear, to standardise and amalgamate these services. Due to the lack of resources, only some improvements were implemented.

The first period of RIAP development was dedicated to creating a collaborative network, drafting and testing work protocols that could be used within the existing regional and national healthcare systems. The registry positioned itself as national but in its first years the word "national" described more the intention than the reality. As written in the Executive summary to the First RIAP Annual Report 2014, “strictly speaking, it is not yet a national registry (geographic coverage is still partial) but alea iacta est [“the die is cast”], and sooner or later data collection will reach the whole country: this publication aims to be an incentive in that direction" (Torre et al., 2014, p. XXX). Starting from 2018, the word "Project" was eliminated from the annual report titles.

Participation of the Regions in the Registry grew at an uneven pace. In 2004, all 21 Regions and Autonomous Provinces expressed their interest to establish and adhere to a national registry (Torre et al., 2005). In 2014, RIAP collected data from only nine Regions, two autonomous provinces (PA Trento and PA Bolzano), and one hospital in Liguria. Later, some Regions quit participating, others joined after years of preparation. By the moment, the list of participants includes ten Regions and two Autonomous Provinces, three clinics and two Local health authorities (ASL).

First results achieved by RIAP supported the inclusion of implanted medical devices registries among the surveillance systems considered by the National Law 17 December 2012 n. 221. However, a real milestone policy measure arrived with the Decree of the President of the Council of Ministers "Identificazione dei sistemi di sorveglianza e dei registri di mortalità, di tumori e di altre patologie" approved in March 2017 (DPCM 3/2017). It widened the range of implant types concerned and established 31 surveillance systems and 15 registries at national level, among them the Registry of implantable prostheses. Following its implementation, the Regions should assign regional reference centres that would guarantee the administrative, technical and IT management of the registry and the data treatment.

In 2018, the amendment to Law 221 made the feeding of regional and national registries a clear duty of healthcare workers. ISS in its turn was requested to lay the groundwork for setting up registries concerning additional implantable devices.

The DPCM 3/2017 did not have immediate practical implications: it still requires an adoption of the Regulation, currently in preparation, that would specify the mechanisms of feeding the databases and make the data collection effectively mandatory.

### From RIAP to RIPI

The RIAP Annual Report 2018 mentions for the first time the activities that expanded RIAP experience to other medical devices of high impact for patient safety and for public health. Since 2018, RIPI team has collaborated with the Ministry of Health in developing the National Breast

Implants Registry (RNPM) which had been introduced by Law 86/2012 but actually established only by the DPCM 3/3/2017. RNPM is directly managed by the Ministry of Health. It is not included in RIPI, but its infrastructure was designed taking RIAP as reference. The head of RIPI project M. Torre was assigned Scientific director of the RNPM pilot study, concluded in 2022 with the drafting of the Regulation (Ministero della Salute, 2022c). The registry monitors the breast implant procedures both for reconstructive and for aesthetic purposes, although the significant part of aesthetic surgeries is made in private clinics. The Regulation makes sending data to the RNPM mandatory for all the hospitals and private clinics.

The organisational model envisaged for RIPI represents a transversal coordination structure that governs registries of specific types of devices. RIPI can therefore add yet new registries, as they all can share the common IT infrastructure and logics. RIAP is a reference model for the other registries under the RIPI umbrella. By the moment, RIPI comprises:

- Italian Arthroplasty Registry (Registro Italiano ArtroProtesi, RIAP),
- Italian Spinal Implants Registry (Registro Italiano Dispositivi Impiantabili per chirurgia Spinale, RIDIS),
- Italian Implantable Cardioverter-defibrillator and Pacemaker Registry (Registro Italiano Defibrillatori e Pacemaker, RIDEP),
- Italian Heart Valves Registry (Registro Italiano Valvole Cardiache, RIVAC),
- Italian Implantable Hearing Device Registry (Registro Italiano Dispositivi Impiantabili Uditivi, RIDIU) (started in 2022),
- Italian Craniofacial Implants Registry (Registro Italiano impianti Cranio Facciali, RICRAF) (started in 2023).

From the engineering viewpoint, the data flow and RIPI infrastructure can be represented in a scheme:

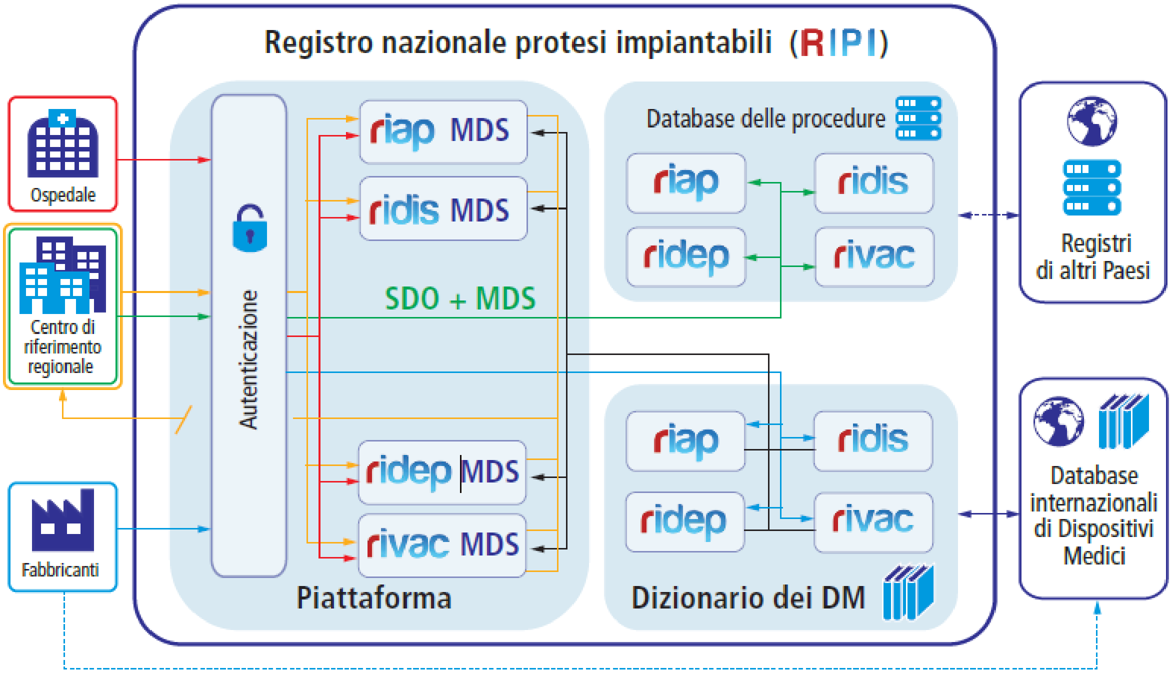

*Figure 1. RIPI infrastructure and data flow diagram. Source: RIAP Annual Report 2021*

Many metaphors have been used to describe its technical infrastructure: from a cupboard with many drawers (individual registries) to a construction site to space station to which new blocks can be attached, or simply an umbrella. The registries under the RIPI "umbrella" are all at different development stages.

**RIDIS** became a new line of research of RIPI in 2018. Its Technical committee, established in March 2020, researched the field and proposed a spinal devices taxonomy that was shared with the manufacturing companies in the sector. Design of the RIDIS data collection system should follow.

**RIDEP** was launched as a research line in 2019, and its technical committee was also established in March 2020. In this case, though, there was a pre-existing structure, RIP (Italian Pacemaker Registry) and RID (Italian Defibrillator Registry) managed by Italian Association of Arrhythmology and Cardiac Pacing (AIAC) since the late 1970s on a voluntary basis. In collaboration with ISS, in 2018 the process of their harmonisation with RIPI structure has begun. Further work of establishing RIDEP based on this legacy is made in close collaboration with AIAC, the association that brings together around 1400 cardiology specialists. Collaboration started with the analysis of temporal trends of pacemaker and implantable cardioverter-defibrillator procedures in Italy. The growing trend (in the time period 2001-2017) was identified for all device types in question, especially for the age group over 80 (Zecchin et al., 2021). The device taxonomy was proposed and the list of clinical variables to be collected was defined. The data collection has yet to start.

According to the National expenditure report in the public health service for purchasing medical devices published by the Ministry of Health in 2017, cardiac devices (category J01 of CND), turned out to be the second category of medical devices among those with the highest expenditure, with a cost of approx. 343 million euros. The third category by expenditure, with approx. 325 million euros, were artificial heart valves (category P07)[6], and this was among the reasons to launch **RIVAC**. The work on the project of this registry has started with the research of international literature and mapping of heart valve interventions nationwide. A technical committee is yet to be formed.

**RIDIU**, now at the preparatory stage, will collect data on implantable hearing devices that include cochlear implants and non-cochlear implants (or implantable hearing aids). According to the analysis of the Hospital Discharge record national database by RIPI research group, over the last 20 years the number of cochlear implant procedures in Italy more than doubled. The RIDIU technical committee has been set up and started working.

For **RICRAF,** the technical committee has been set up in January 2023.

The actual development stage of RIPI has been made possible due to the achievement of adequate level of IT infrastructure and due to constant organisational efforts of its founders. At the same time, the trajectory of its development has often been the result of the choices made by the authorities and by individuals (for example, a decision of a hospital to adhere to the registry data collection). Some development directions might have been preferred over others due to their immediate feasibility. Such factors as the logic of project funding adopted by the Ministry of Health, and internal dynamics at ISS also shaped the evolution of RIPI, as will be discussed in following chapters.

## 2.2. RIPI in the organisational context of ISS

The majority of national surveillance systems and registries established with the DPCM 3/3/2017 and coordinated by ISS were assigned to various departments in line with their field. RIPI by that

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[6] https://ripi.iss.it/ripi/it/il-progetto/rivac-registro-italiano-valvole-cardiache/

time represented a stand-alone unit, and in 2018 it was incorporated in the Scientific secretariat of the President of the ISS (*Segreteria scientifica del Presidente*). Currently, ISS coordinates 33 registries and 48 surveillance systems active in a great variety of public health topics (ISS, 2002b, p. 35). Among them, National rare disease registry (RNMR), Integrated epidemiological system of acute viral hepatitis (SEIEVA), National registry of medically assisted reproduction (RPMA), National observatory for monitoring of iodoprophylaxis (OSNAMI) and other bodies.

ISS is a public research body and technical-scientific organ of the National healthcare service that "promotes and protects public health through research, control, consultancy, regulation, training and information, prevention and surveillance activities" (ISS, 2021). The role of ISS in Italian public health is that of an expert consultancy. As the public healthcare in Italy is mostly managed at the regional level, the national system is governed by the Ministry of Health together with the Regions. ISS is funded mainly by the SSN and reports to the Ministry (e.g., its Three-year Activity Plans should be approved by the Ministry). At the same time, ISS has wide autonomy of operational activities. Given the numerous public health fields in which ISS scientific community is involved, the Institute needs to establish effective communications with multiple audiences.

There is, by the moment, no document that explicitly outlines the communication strategy of ISS. In the statute, the development and management of the Institute's information and institutional communication activities are ascribed to the Director General (ISS, 2022c, Art. 8, comma 2 (j).

Two units in the ISS are occupied with communications: the Scientific Communications service (SCS) and the Press office. SCS is part of the President's office structure. Its role is defined as follows: "develops policies for the communication and dissemination of technical-scientific information; it supervises the enhancement and dissemination of ISS activities"[7]. These communication strategies are aimed at different targets. Following stakeholders are listed in the official description: researchers, decision-makers, citizens, students. The scope of SCS responsibilities under the general goal includes curation of ISS owned scientific publications, dissemination products such as handouts for schools, reference tools, digital archives; organisation of popular science events; managing the multimedia assets (ISSalute web portal, graphic and multimedia production, video-photographic services and typography), the library and ISS Museum. ISS produces periodic scientific publications: Annali dell'Istituto Superiore di Sanità, Rapporti ISTISAN, ISTISAN Congressi, Bollettino Epidemiologico Nazionale, Notiziario

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[7] Retrieved from https://www.iss.it/presidenza on 19.12.2022

dell'Istituto Superiore di Sanità. In addition, there are ad hoc projects, such as Rapporti ISS COVID-19 - series of articles and reports active in 2020-2021. The most significant articles and volumes by ISS researchers are translated in English.

Scientific publishing of ISS-based research is curated by SCS. Recently, the respective policy and guidelines have been updated. The core idea of the Policy on the Management of Research Results (ISS, 2021) is that the research results of the ISS should be of high quality, widely visible and available to the entire scientific community, applying the open access policy. The document Promoting Research Integrity: Guidelines of the Istituto Superiore di Sanità (ISS, 2002a) dedicates a chapter to research dissemination.

Publications to be disseminated are those peer reviewed. Preprints that were well accepted during the pandemics as a way to share more information possible, now are considered the products too premature to be disseminated. The guidelines give detailed advice on approaching the "translation" from the scientific to common language with rigour and clarity combined in such a way as to guarantee the authoritativeness of the source and to counteract sensationalism and the misinformation. Facts should be distinguished from opinions in the text. In the case of the communication of innovative studies on human health, especially if they are still in the experimental phase, it is essential to be very cautious in making statements, in order to avoid raising excessive expectations.

The functions of the ISS Press office are outlined as follows: "provides daily support to ISS researchers and staff in their interactions with the media. It also has the role of facilitating journalists' access to the results of research conducted by ISS researchers. It also manages the Institute's image and disseminates the results of its public health activities" through the regularly updated website and social media channels[8].

Both communication services - SCS and the Press office - exist for many years, but it can be claimed that with the Covid-19 pandemic their workload and responsibilities increased manifold and their functions became strategic. The ISS entered the public spotlight in March 2020 when the joint Technical Scientific committee was formed by the Italian government to provide expert epidemiologic consultancy to the national crisis management force. It included ISS President Silvio Brusaferro who was often the spokesperson at daily press conferences and delivered updates on Covid trends.

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[8] Retrieved from https://www.iss.it/sala-stampa-chi-siamo on 19/12/2022

Press office manages the digital communications of ISS. From pre-pandemic January 2020 to November 2020, the number of followers of the ISS Twitter account has increased almost tenfold, from around 6.000 to 55.000. In 2022, the Press office produced 85 press releases (73 in 2021 and 63 in 2020). ISS has accounts on Facebook (37 845 followers as of 30.12.2022), Twitter (about 98 900 followers), Instagram (about 18.500 followers) and YouTube (1310 subscribers). For RIPI as an ISS unit, these resources add to other registry's communication channels analysed in the following section.

Web portal Iss.it is the Institute's "showcase", a diversified portal targeted at both specialists and lay public. Besides, ISS operates a general interest website ISSalute with topics on diffused diseases, healthy lifestyles, nutrition and environment, and fake news debunking. The Institute also coordinates a multi-centre project - portal EpiCentro, a tool for public health professionals to stay updated on developments in epidemiology. Some of these digital communication projects are carried on in collaboration with external partners.

ISS researchers are required to inform the Press office of their new scientific publications with possible media relevance. When a research unit wants to share their findings or news with the lay public or press, the news item is produced together with the press office and then published in owned digital media or distributed as a press release. Figures within the Centres and Departments who deal with communication should liaise with the press office in order to coordinate the flow of content. Another rule is that in personal profiles on social media researchers should point out that the opinions expressed are personal. The Institute's position is expressed only through official channels managed by the press office.

Other than this document, ISS does not have restrictive communication protocol for its divisions, nor a prescribed one-voice policy. However, it is considered good practice for ISS experts to keep the Press office informed when they talk at a public event or to the press. In case of sensitive and potentially controversial topics the Press office is involved directly. Individual units are not encouraged to have separate social media accounts. Some units do run their own webpages. The process of integrating them into the uniform structure of ISS web portal started in 2021 and is underway now.

## 2.3. Analysis of RIPI stakeholders

### 2.3.1. Concepts of stakeholders in management and communication theories

The concept of stakeholders originates in management studies. Different theoretical frameworks have been developed to identify who stakeholders are and how organisations interact with them. The studies on this topic proliferated in the 1970s - 1990s, driven by the fast-paced development of marketing and management applied research. Some researchers gave very broad definitions, assuming that a business or an organisation can be affected by almost anybody. Evident practical need to prioritise and balance the managerial efforts led to a narrowing of the definitions and to stakeholder groups identification. Definitions varied from "[those] who have an interest in the actions of an organisation and…the ability to influence it" (Savage et al., 1991: 61) to "persons or groups with legitimate interests in procedural and/or substantive aspects of corporate activity" (Donaldson & Preston, 1995, as cited in: Mitchell et al., 1997). The definition given by Freeman in 1980s - any group or individual that ''can affect or is affected by the achievement of an organisation's objectives'' (cited in: Fassin, 2009, p.116) has remained relatively consensual until now.

The stakeholders were divided in many ways in the management literature: broken down into external and internal, primary or secondary, actors or those acted upon. For Savage et al. (1991), the attitude is another important variable, as a stakeholder can be supportive, unsupportive or indifferent to the organisation's efforts. Mitchell and colleagues (1997) in the classical study proposed the stakeholder salience framework and a model based on three characteristics: (1) the stakeholder's power to influence the organisation, (2) the legitimacy of the stakeholder's relationship with the organisation, and (3) the urgency of the stakeholder's claim on the organisation. In their typology, a stakeholder can be in possession of one, two or all three requisites. However, the salience framework defines stakeholders' level of impact on a project only if they decide to act.

As common in applied management literature, the models were often visualised in more or less intuitive figures. The classic Freeman model had a wheel form with the firm in the centre surrounded by stakeholders bi-directionally connected to the centre (Freeman 1984, cited from Fassin 2009). Mendelow (1991) proposed another stakeholder mapping technique: the power/interest matrix, further developed by Johnson and Scholes (1999), and later by Olander

(2007) as the impact/probability of impact grid. It divides stakeholders in four categories in quadrants at the axes low->high impact (stakeholder power) and the probability that a stakeholder would really impact the organisation (interest).

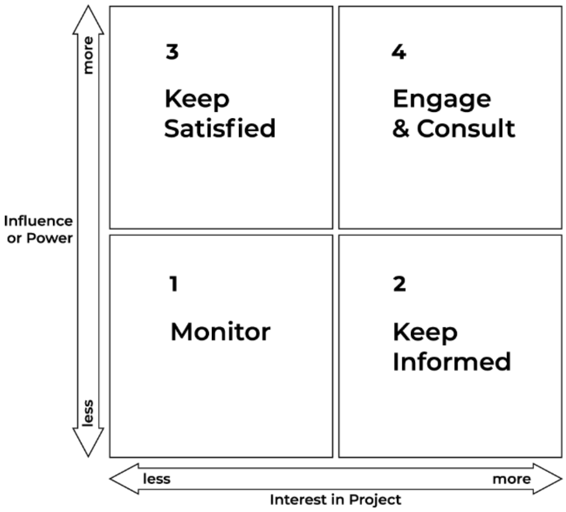

*Figure 2. Stakeholder types matrix by level of power over the project/interest in the project, or by level of possible impact/probability of impact on the project (Source: Mendelow, 1991; Olander, 2007)*

In this way, we have four stakeholder categories:

1) Low level of power (influence) and low level of interest towards the organisation/project in question. In terms of stakeholder relations, they should be monitored, kept in mind but not prioritised.

2) Low power, but highly interested/actively involved. They should be kept informed regularly about the developments of the project / organisation of relevance to them.

(3) High power, but less interested/involved. Important as they are for the functioning of organisation or project (for example, funding or surveillance bodies), they should be kept satisfied and their expectations met.

(4) High power, highly interested/actively involved. Key stakeholders without whom the organisation/project would not function; they should be actively engaged and consulted with.

Variations of this classification are extensively used in management practice. However, the stakeholders' characteristics underlying their relationship with the organisation are not steady and do not reflect the objective reality; rather, they are socially constructed, can change in time and can be perceived differently by the organisation and by the stakeholders themselves. For example, a stakeholder can be unaware of having legitimacy or potential power to push his agenda or influence decisions. In public health, this very situation resulted in a growing trend of patient empowerment. For Mitchell *et al.* (1997), the potential relationship is as important as the actual one. If a group or entity has a potential to develop interest for an organisation or influence upon it, it should be considered among its stakeholders. It can be claimed that there are not only temporal but also spacial variables: a group that is of utmost importance for some activities of the organisation can be irrelevant for some of its new projects. That is, a RIAP stakeholder is not necessarily a stakeholder for the ISS at large.

### 2.3.2. Stakeholders in public health

Stakeholder theory evolved almost exclusively in business management literature, putting a firm in the centre of all models. Are they applicable in the public sector? From the 2000s, the stakeholder theory is widely introduced in scientific debate on public sector organisations' reputation (Boon et al., 2000). It can be claimed that the models are rather universal, while their contents change. On a stakeholder map of a public sector institution, commercial players are substituted by community and political ones.

A characteristic indicator of the academic interest to stakeholders in public health is the fast-growing number of publications in the field. By the moment, the Core collection of Web of Science database contains 17,412 results on 'stakeholders in public health' which makes 9,5% of all publications containing the term 'stakeholders', growing from 504 in 2012 to 2,537 in 2022 with a peak of 2,756 publications in 2021[9].

Key stakeholders of public health agencies can be specified as follows: health care providers, community-based organisations serving vulnerable populations, the general public, the agency's internal workforce (Revere et al., 2015). In a study seeking stakeholders' ideas on health communication and related research (Synnot et al., 2018) another approach guided the list: patients, consumers, caregivers, and their advocates, health professionals, policy makers, researchers, funders, and persons interested in health communication and participation. And in a study of stakeholder engagement in patient-centred outcomes research (Concannon et al., 2012), a

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[9] Retrieved from https://www.webofscience.com/ on 8.01.2023

"7 Ps Framework" list of groups with a stake in clinical, health services, or health policy research. was proposed. It included (1) patients and the public, (2) providers, including individuals and organisations that provide care to patients and populations, (3) purchasers, responsible for underwriting the costs of health care, such as employers, (4) payers who are responsible for reimbursement of medical care, such as insurers, (5) public policy makers and policy advocates working in the non-governmental sector, (6) product makers, representing drug and device manufacturers, (7) principal investigators, or other researchers.

These three examples of stakeholder grouping illustrate the existence of 'core' stakeholders in public health, to which the specific groups are added depending on the character of an individual project.

Stakeholders of an organisation/project do not necessarily coincide with the key publics, or key audiences of its communication policy. Research in communication and public relations paid some attention, although not extensive, to distinguish between concepts 'stakeholder', 'public', and 'audience' from an organisational perspective. In the WHO's Strategic Communications Framework, "decision-makers" and "key audiences" are declared to be used interchangeably (WHO, 2017). Wakefield & Knighton (2019) call for a wider discussion of interrelated questions such as: 'If publics, audiences, and stakeholders are the same or interchangeable, as so often suggested by authors in the field, why use all three terms? (...) Would widespread acceptance of the definitions and distinctions of all three terms guide better communication practices and give the field increased credibility within organisations?' (p.1). For the authors, audiences are collections of rather passive message recipients, scattered individual actors, while publics are potentially active groups that form for some common cause. An audience "connects to a message and reacts to it", while a public "connects to an issue and presses that issue to effect change", and a stakeholder "connects to the organisation, either individually or as a group, to help sustain the organisation" (p.3). This latter claim appears reductive compared to the classic vision of a stakeholder that can be just a powerful entity that controls, or is affected by the organisation, but not necessary acts to help sustain it. However, this study based on extensive literature analysis captures well the subtle yet important difference between the concepts.

'The audience' and 'the public' are still used interchangeably in the majority of research. For example, Morsing (2006) mentions that 'external stakeholders are the target audience' (of CSR messages). The point is that the prioritising and classification of stakeholders for the organisation may vary with changing the perspective. Key players in the general institutional sense may be less prioritised as an audience/public of communicative messages produced by the organisation/project and vice versa.

### 2.3.3. Identifying RIPI stakeholders

Funded with the contribution of the Ministry of Health and managed by the ISS, RIPI is relatively autonomous in its operative decisions, although necessarily depending on policy guidelines and strategic plans of both the MoH and ISS.

RIPI has a multifaceted identity: it is a registry in the meaning of a data collection system and its outputs; it is a project in development with its project budget and timeline; it is a working and research group that analyses data and produces scientific and popular publications; it is a collaborative network at national and regional levels. These characteristics define the variety of RIPI stakeholders. RIPI is a part of a whole, belongs to a national public institution. At the same time, its activity is so particular, "niche", that its stakeholders may differ from that of the ISS.

Based on literature, participant observation of RIPI activities and interviews with some key actors, a list of the Registry's stakeholders was drafted. It includes:
European regulatory bodies, national and regional policy and decision makers, scientific societies, surgeons and other clinical staff, medical students and residents, implant manufacturers, international registries and registries associations, potential new RIPI group members, Registry's scientific committees (currently the RIAP Scientific committee) and technical boards, and, last but not the least, the media.
A brief overview of the salient characteristics of each stakeholder group follows.

**European regulatory bodies.** Those are EU bodies, first of all the European Commission, entitled to regulate, control the medical device industry and determine policies. They are crucial for the existence and development of RIPI, so they are necessarily placed among key stakeholders. At the same time, from the communications perspective, they might be seen more as an 'environmental factor' than a stakeholder as there is no direct communication or expectation from EU policy makers to be kept updated at the level of a national implantable device registry. These contacts are maintained at a higher institutional level, i.e. the Ministry of health.

A recent measure on EU level that impacted the medical device manufacturers and indirectly all other actors of the field, was The European Union Medical Device Regulation (Regulation (EU) 2017/745, or MDR) that came into effect in May 2021. It increased the requirements for clinical evidence on high-risk medical devices (including orthopaedic prostheses and heart valves) making the registries yet more valuable source of implant performance data for the manufacturers. In 2019, Italy's CND codes were used as the basis for the new European medical device database nomenclature (EMDN) to be adopted in the European medical device database (Eudamed).
EU provides funding for research projects and promotes collaborations such as CORE-MD - a cross-country project aimed at identifying the ways to enable the scientific, fair, and systematic evaluation of medical devices. It was launched in 2021, and several members of RIPI working group are among the participating experts.

**National policy and decision makers.** The Italian Ministry of Health has been the source of project financing that partially funds RIPI. The exact stakeholder is the Directorate General for Medical Devices and Pharmaceutical Service (Direzione generale dei dispositivi medici e del servizio farmaceutico). RIPI collaborates directly with its Medical Device Adverse Incident Surveillance Office (Ufficio 5 - Vigilanza sugli incidenti con dispositivi medici). The DGDMF of the Ministry supports the activities of the Registry as it considers them functional to support the institutional activities of the Ministry in turn. Probably in the future there will be, formalised by the Registries Regulation now in draft, the regular reporting and data exchange. Since 2006 to date, the Registry has been funded as a series of temporary projects of 12-24 months duration that are then prolonged or concluded and the new are being launched, permitting the RIPI to continue its development. Medical device registries are considered important by the Ministry, yet RIPI doesn't have a permanent status, due to a complex public funding regulation and other organisational reasons.

RIPI management prepares technical reports for MoH at the end of each project term. They can be called the main formalised channel, although not for communication but for unidirectional information. Other communication opportunities are work meetings, participation (not regular) of MoH representatives in the RIAP Scientific committee meetings, and direct interpersonal communication. RIPI contributes to the MoH work also due to the fact that Eng. Marina Torre is deputy member for ISS within the Health Technical National Committee section f) medical devices (Comitato Tecnico Sanitario, sez f) dispositivi medici) established at the MoH.

The ISS top management is another institutional stakeholder. Since the launch of RIPI as a research line, the ISS has had four General Directors and four Presidents. The current President Silvio Brusaferro has been in office since 2019, same for the current Director General (DG) Andrea Piccioli. Communication with them is a natural part of a working relationship, also due to the institutional assignments of M. Torre as a member of ISS Scientific Committee. Most RIAP Annual reports contain a preface signed either by the DG or by the ISS President, sometimes both. The DG being an orthopaedist opened the proceedings of two events organised by the RIAP as part of the Annual congresses of the Italian Society of Orthopaedics and Traumatology, SIOT (in 2019 and in 2022). He was also interviewed among key stakeholders for the RIPI video presentation. Finally, ISS as an organisation is a stakeholder because it provides RIPI with premises and infrastructure, and most of the RIPI group members are full-time staff of the Institute.

**Regional policy and decision makers.** Currently, the decision to establish and implement a regional implantable devices registry can be taken only by the Regions. This makes the heads or high-level employees of regional public health authorities strategically important partners. The representatives of healthcare authorities of the Regions that adhere to RIAP are represented in its Scientific committee.

**ISS researchers.** It can be claimed that this group has relatively low level of interest and power over the RIPI project and is not therefore among strategic stakeholders. Communicating with them, on the contrary, might be important for growth. The relationship with this group is based on the declared values of the ISS: knowledge sharing and collaborative approach. It is a part of wider reformist discourse on the need to abandon the traditional working style of silos, or closed departments that did not communicate, one of the declared priorities of public administration innovation in Italy. The communication between colleagues from other registries working in the ISS could be beneficial for finding the common technical solutions and exchanging best practice.

**Patients**. Patient safety and quality of health care are the main goals of RIPI. Patients are potentially key beneficiaries, their anonymised data are the core of registry dataset, and the Patient Reported Outcomes (PROMs) constitute an important dimension of RIPI research. Therefore, patients form a natural stakeholder group. In 2019, more than 200,000 joint replacement surgeries were performed in Italy, and the trend is growing. This illustrates the potential size of this group.

Of course, the question remains open for how long a person identifies themself as a patient once a "touchpoint" - the surgery - is over.

As RIPI was not designed as a citizen service, no hotline or PR service was ever planned. As an audience, as a partner in communication, patients are not among key groups for RIPI. However, already in early years of RIAP, attention was given to providing dedicated contents for orthopaedic patients. In cooperation with a publicist agency, a dedicated section was set up on the initial RIAP project website (iss.it/riap, now non-existent). The patient association APMARR contributed by verifying language clarity and effectiveness. The current RIAP website also has a section "*For patients*". (The detailed analysis is presented in Chapter 3).

APMARR (Associazione Nazionale Persone con Malattie Reumatologiche e Rare) represents orthopaedic patients in the RIAP Scientific committee. For other registries that make part of RIPI such representatives are yet to be defined. APMARR grew from a regional association founded in 1984. Now it is a well-established patient advocacy focused mainly on rheumatology, including related chronic and rare conditions. Orthopaedic patients are only a part of its vast patient community. The Association declares a vast range of statutory activities aimed at improving quality of patient life, empowerment, advocacy, awareness-raising, health literacy work. It can also represent its members in court. RIAP is one of two institutional entities with which APMARR officially collaborates, the second being the National Centre of Rare Diseases of the ISS. Among scientific societies, APMARR's closest collaboration is with SIR (Società Italiana di Reumatologia), not with SIOT which is the RIAP's longstanding partner.

Is the established relationship with a patient advocacy, such as APMARR, enough to reassure sufficient communication between RIAP and the patients? The stance of an association might not be representative of the orthopaedic patient population, considering the above-mentioned situation: implant patients remain such for a relatively short preoperative and postoperative period. After the rehabilitation period is over, they are supposed to return to normal life and rarely maintain the same level of interest in the topic of implants if the prosthesis doesn't cause problems. This audience is heterogeneous and fluid, and, unlike the chronic patients, does not have a common agenda to advocate.

**Scientific societies.** Uniting the surgeons, researchers and other medical practitioners, scientific societies still represent a distinct stakeholder group if seen as structures with their managerial and organisational resources. The scientific societies have been initiators and founding partners of the registries under RIPI umbrella.

Italian Society of Orthopaedics and Traumatology was participating in RIAP development from the early days of the project. SIOT counts about 5,000 members[10]. For several consecutive years SIOT includes events dedicated to the registries in the scientific program of its annual congresses. In collaboration, thematic sessions are organised.

In 2020, the representatives of SIFO (Società Italiana di Farmacia Ospedaliera e dei Servizi Farmaceutici delle Aziende Sanitarie) were included in the RIAP Scientific committee. Hospital pharmacists are important partners for RIPI because the implantable device procurement passes through in-hospital pharmacies. This is also an example of how good stakeholder relationships can lead to new collaborations. In the beginning of 2023, on SIFO initiative, RIPI researchers held a lecture on traceability systems and national prostheses registries in a master's program Clinical Governance of Medical and Diagnostic Devices, organised by Università Cattolica (Rome).

Italian Association of Arrhythmology and Cardiac Pacing, AIAC is now the structural partner in the construction of the pacemaker & defibrillator registry (RIDEP) based fully on the Association's legacy. The Italian Society of Neurosurgery (SINch, Società Italiana Neurochirurgia) and the Italian Society of Otolaryngology and Head and Neck Surgery (SIOeChCF, Società Italiana di Otorinolaringoiatria e Chirurgia Cervico-Facciale) entered the technical committees of RIDIS and RIDIU, respectively. From January 2023, these two societies together with the Italian Society of Maxillofacial Surgery (SICMF, Società Italiana di Chirurgia Maxillo-Facciale) are partnering with RIPI in the launch of the newest registry under the 'umbrella' - the registry of craniofacial surgery implants.

**Surgeons.** Potentially, surgeons are among the key beneficiaries of the big data collected and analysed by public health registries. They can rely on registries as sources of data on implant performance to improve their clinical practice, as international experience shows (Graves, 2010; Malchau et al., 2015). Surgeons can influence their hospital's decision to adhere to the registry.

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[10] *https://siot.it/la-storia/*

RIAP closely collaborates with surgeons from the very beginning. Many publications have been written in co-authorship with surgeons. A non-formalised group of surgeons enthusiasts of registries promote participation in RIAP among their colleagues nationwide, at scientific events and in their research contributions. A publication entitled "Perché il Registro Italiano Artroprotesi merita un po' del nostro tempo"[Why the Italian Arthroplasty Registry deserves some of our time] (Tarantino et al., 2020a) illustrates well the status quo. In terms of data completeness and coverage, RIAP should still arrive to the point that it could really make a change in the quality of surgical decisions; but it isn't possible to arrive there without surgeons' participation (feeding data to the RIPI database, advocating for the "registries culture") and consulting. Surgeons are represented in the technical committees of all RIPI registries. A formal structure that often partners with RIAP and RIDIS is GLOBE (Gruppo di Lavoro Ortopedia Basata sulle prove di Efficacia), the scientific group of Italian orthopaedic surgeons promoting evidence-based medicine.

**Clinical staff feeding data** (currently, only relevant for RIAP). The task of providing the data to the RIAP database after each joint implant surgery is assigned in different hospitals to different professionals: surgeons themselves, nurses, residents, clinical assistants. The time required for filling in the registry forms was for years reported by the members of the CS among the reasons for reluctance to participate in RIAP. Efforts were made to change this belief: an ad hoc study showed that only about two minutes are needed for the compilation of a single case of primary total hip and knee surgery, and four minutes for shoulder and revision surgery. "L'aggravio di lavoro per l'ortopedico non sembra giustificare la riluttanza nella raccolta dati osservata in questi anni di esperienza del RIAP" ["The burden of work for the orthopaedic surgeon does not seem to justify the reluctance in data collection observed in these years of RIAP experience"] (Tarantino et al., 2020b). These persons are crucial for the operations, for the data quality and the growth of RIAP completeness, so the most important part of the relationship with this group is training. When the RaDaR platform was launched, M. Torre and E. Carrani (head of IT function at RIPI group) organised a series of mini training courses in the participating Regions on how to use the platform. From the communication perspective, clinical staff hasn't been considered key audiences.

**Manufacturers.** The industry association Confindustria-Dispositivi Medici (Confindustria-DM) counts 456 members - mainly medical device manufacturers, national and international, active on the Italian market[11], including implantable device manufacturers. Their interest in public health data derives from their need to be compliant with the requirements of post-marketing surveillance of their products, yet more so with the new European regulation, MDR. The companies would also be highly interested in the device survival rate at national level, that the RIPI does not provide at the moment. In its turn, RIPI's interest is that the manufacturers fill in their product codes and information to the Dictionary database, and, in case with orthopaedic devices, the common Library of NJR under the collaboration agreements. To avoid any possible conflict of interest, the manufacturers are represented in the RIAP Scientific committee by Confindustria-DM. For other RIPI registries not yet operational, the industry representatives collaborate on devices taxonomy development.

**International registries and registries associations.** This group consists of colleagues, it is a reference group for best practice and scientific and practical collaborations. International Society of Arthroplasty Registries, ISAR, is the principal association of orthopaedic registries worldwide. Since 2005, it unites the registries with the aim "to improve the outcomes for individuals receiving joint replacement surgery worldwide" yet recognising that all registries are different (ISAR, 2022). For the RIPI research group, ISAR annual congresses have always been major occasions for scientific exchange. Themes discussed at these congresses mainly fall into the areas of biomedical statistics, epidemiology, and infrastructure engineering. RIPI researchers and PhD students contribute each time with presentations, posters, and publications. In 2022, the group presented eight posters. In 2022, M. Torre entered the ISAR Scientific committee as a Member at large.
At European level, M. Torre is the advisory board member of Network of Orthopaedic Registries of Europe (NORE) established as a committee of the European Federation of National Associations of Orthopaedics and Traumatology (EFORT), and so RIAP takes part in some of its activities.

National Joint Registry (NJR, United Kingdom), which is among the most advanced orthopaedic registries internationally, collaborated with the German registry Endoprotesenregister Deutschland (EPRD) in developing a common implant database. RIAP plugged into this project and signed a collaboration agreement with NJR to access this database and feed it for devices that were not already there. In this collaboration, NJR has an expert role; the management shares their know-hows regarding the industry relations and the virtuous use of big data.

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[11] Retrieved from https://www.confindustriadm.it on 15.02.2023

**Medical students/orthopaedic residents.** Young surgeons, specialising in orthopaedics and working as residents in the clinics and hospital, are also stakeholders as they are future partners. It is essential for RIPI that they get acquainted with the culture of registries - the idea that providing data for the registry is a standard practice, necessary and beneficial. In 2022, a collaboration with the Italian Association of Orthopaedics and Traumatology Residents (Associazione Italiana Specializzandi in Ortopedia e Traumatologia, A.I.S.O.T.) started with co-organising a dedicated seminar "A note to the registry" at SIOT Annual congress. Before the event, AISOT surveyed its members to find out the level of awareness of young orthopaedic surgeons about the registries and RIAP in particular. Out of 101 respondents, 40.6% have only heard about RIAP but didn't know anything in particular about it, while 24.8% didn't know RIAP at all. This situation can be regarded as a baseline for change. AISOT is now represented in the RIAP Scientific committee.

**Potential newcomers.** I suggest identifying this stakeholder group as well, although with a relatively low engagement level in terms of communications. This group is heterogeneous and not numerous, but is crucial for the quality and the velocity of RIPI development. In the situation of lack of human resources, RIPI aims at engaging PhD students to do their registry-related research at the ISS, and welcomes ISS colleagues interested in studying and contributing to the development of the implant registries. Currently the RIPI group consists of 15 people, 5 of them are PhD students. There is an evident need for permanent researchers, without whom it would be impossible to advance the registry's activities. Towards this group RIPI should have an attractive image as a place of work and research, something that in the private sector is called "employer brand" or "HR brand".

**RIAP Scientific Committee** (Comitato Scientifico, SC RIAP*)* was established in 2008. Currently it includes 30 members (plus substitutes and collaborating members) representing the ISS, the Ministry of health, the Regions, the scientific societies, manufacturers and patients. The Committee meets twice a year. Formally its terms of reference and functions have not been described in any statute. Despite the name "steering" in many English versions of RIPI documents and the decision-making function assigned (Torre et al., 2014), it does not have the classic governing mechanisms as for example majority vote. It participates in the operative choices of the project and all strategic decisions are discussed with the Committee. The establishment of the RIPI Technical-scientific committee is foreseen in the RIPI Regulation, now in draft.

SC RIAP members are informed of key developments on a priority basis, and directly or indirectly participate in the registry activities in first person. In communication perspective, the Committee has a double role - it is a stakeholder itself, and a channel to the external world.

**Media.** This group includes editorial media and professional “influencers” - high-rated bloggers, science communicators, celebrity doctors and other mediatised persons. Communication researchers interpret the mass media as an audience or a channel to reach the audience, or sometimes both. The claims for its dual role are convincing. In stakeholder studies, the media are ‘increasingly recognised as powerful influences on the politico-administrative system’ (Boon et al., 2020) and placed among key stakeholders (Fassin, 2009). There is ample evidence in the literature of the ability of national and international media to influence health-related behaviour, both in the general population and in healthcare professionals (Gianfredi, 2018). However, this group is highly diversified. In this dissertation, when the media is intended as a stakeholder, both general interest media and specialised press are included, while scientific journals do not make part of this group.
What kinds of information does the press seek from RIPI? To date, about 60 media publications concerning RIPI and RIAP monitored by RIPI working group and ISS press office are collected in dedicated sections Rassegna stampa [Press clipping] of RIPI and RIAP websites. The topics that attracted the most interest were the publication of "talking" data on the increase in implantation rates in Italy or in individual regions, the new governance of medical devices (including in relation to the foundation of the breast implants registry), advice to patients while waiting for surgery. The specialist press has written about new technologies and surgeons' attitudes towards registries.

A “black swan” event happened in 2019 when the International consortium of investigative journalists collaborating in Italy with L'Espresso magazine and investigative team of Report TV show (Rai3) published a major cross-country investigation named Implant files. It exposed flaws in the regulation of implantable devices, especially of poor-quality breast implants that had led to serious complications in some patients. In Italy, as the authors of the investigation claimed, the investigation led to the launch of breast implant and prosthetic registries. As RIAP was founded much earlier, the information was not consistent in this part. But the promptness of the founding of the RNPM was indeed affected by the investigation. M. Marletta, who was at that time Director General for medical devices at the Ministry of Health, told a journalist from “The Report”: “The registry has now been rolled out, thanks to you” (English transcript of The Report: Update “A rough legacy". Rai 3, 25/3/2019). Since one of the key themes of the investigation was that governments were failing to monitor the CE certification and trace the implants, journalists demanded registries. That is, registries were the only positive thing in this narrative, they were positioned as a long-awaited solution.

As this study does not consider RIPI management separately from the RIPI working/research group, the RIPI staff is not included among stakeholders. However, the role of internal communication in RIPI group is big and interlinked with organisational culture (see Section 3.6). Employees are messengers: everybody who ever worked for or with RIPI influences other people's ideas on what it is and why it is important.

"General public" is not among stakeholders as it can be claimed that the general public does not exist as a group, given that contemporary society is highly fragmented. According to European Commission experts, "the public" is not a target audience in professional communication terms. "The public" means 'everyone', so by choosing it you have failed actually to target anyone" (EC, 2017, p. 29). When we think about RIPI stakeholders, "general public" cannot be characterised with more precision than "anyone else" or "all the rest" that do not make part of any stakeholder group. The group that has most porous borders with general public are orthopaedic patients and their families, but when one is not yet - or no more - in the role of patient to be implanted a prosthesis, he or she can belong to any socio-demographic profile and remains non-targetable for communication planning. However, this is a complex question for public health that by its mission should address the issues of the general population nationwide.

If we try to apply the impact/probability of impact matrix to RIPI stakeholders, it can look as follows. As discussed above, the level of impact or influence of a stakeholder as well as the probability of their active involvement in the registry changes when we look from a communications perspective: some groups change their position in the quadrants or simply aren't there. For example, European regulation bodies are a key influencer for RIPI development but are not meant to be involved in direct dialogue. Clinical staff in charge of filling in the forms is crucial for RIPI functioning but the relationship of RIPI as a group with them are mostly indirect and rarely imply the use of communication tools. Similarly, the patients are the endpoint and key beneficiaries of any public health registry but in the actual RIPI design they are not direct communication partners.

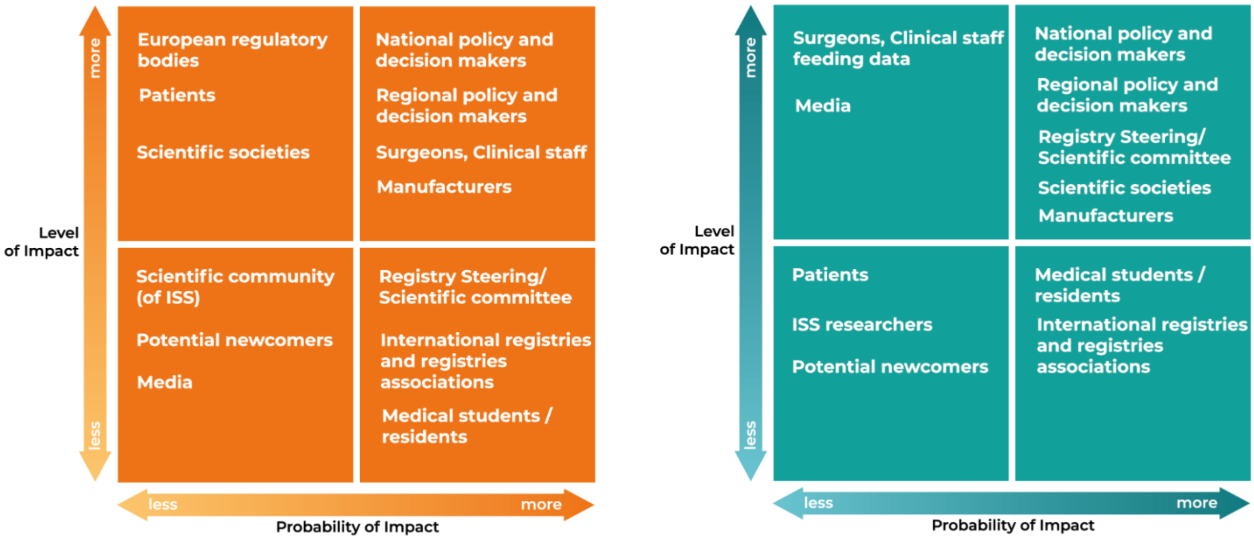

*Figure 3. RIPI stakeholders in general (left figure) vs Audiences of RIPI communication activities (right)*

Worth mentioning is the presence of close collaborations in each of these groups that form an inner circle that is much closer to RIPI than other members of the same group. Thus, the inner circle itself forms a group. For RIAP, it partially coincides with the Scientific committee. An important characteristic is that this inner circle is not formalised. Its members all know each other by names, some for many years, united by joint projects, collaborations, co-authorship of publications. It can be assumed that the communication with the inner circle is much less formal.

## 2.4. Summary

The need to have implantable device registries in public health is caused by a big and growing number of implant procedures. A national implantable prostheses registry is a systematic data collection of all the implantable device procedures for a specific prosthesis at a national level. The Italian Implantable Prostheses Registry, RIPI, collects and analyses data of the procedures of most high-risk, diffused and costly implantable devices. Its main objectives are to enable tracking patients in the event of a recall of their implanted prosthesis, and to perform statistical analyses on the collected data. Its data can also help to improve the surgery outcomes, in particular by identifying the implant survival rate.

The Italian Arthroplasty Registry project was launched in 2006, funded by MoH and based at ISS. The decree DPCM 3/3/2017 was a milestone policy measure in public health in Italy as it established and made mandatory 31 surveillance systems and 15 registries at national level, among them the Registry of implantable prostheses.

ISS is a public research body and technical-scientific organ of the National healthcare service that "promotes and protects public health through research, control, consultancy, regulation, training and information, prevention and surveillance activities" (ISS, 2021). The Institute entered the public spotlight when the joint Technical-Scientific committee was formed in March 2020 to counter the Covid-19 diffusion in Italy, with the functions of an epidemiologic consultancy to the national task force.

There is, by the moment, no detailed document that explicitly outlines the communication strategy of ISS. A brief outline of ISS communication facilities – the Scientific communication service and the Press office – is given in section 2.2.

RIPI has a multifaceted identity: it is at the same time a data collection system, a project in development, a working and research group, and a collaborative network at national and regional levels. Therefore, its stakeholders belong to various categories: institutions; scientific societies; medical practitioners; implant manufacturers; international registries and registries associations; potential new RIPI group members; medical students and residents; the technical / scientific committees; the media.

RIPI stakeholders are discussed, defined as groups or individuals that can affect or are affected by the achievement of the project objectives. General stakeholder groups have been identified, the majority of them are stakeholders also in the communication perspective as communication partners or audiences. Mendelow’s power/interest matrix, further developed by Olander as the impact/probability of impact grid, is applied as a basis for future analysis and research for optimal communication approaches.

Two claims are made: 1. RIAP stakeholder is not necessarily a stakeholder for the ISS at large. 2. Stakeholders in the general institutional sense may be prioritised differently when seen as an audience/public of communicative messages.

# Chapter 3. Analysis of RIPI communication from the viewpoint of the audiences

The effectiveness of communication, as stated earlier, can be briefly defined as the ratio between the achieved and expected results of communication. As the communication has dialogic or polylogic nature, all the participants of this process have their objectives and agendas that should be harmonised. In an open, non-manipulative communication between an organisation and its stakeholder, maximum effectiveness can only be reached when both parties reach their communicative goals.

We can support Grunig's affirmation, as cited by Muzi Falconi (2015) that every organisation, to be successful, must integrate harmoniously into the surrounding environment and to do this effectively it must know and interpret the values and expectations of its influential audiences even before defining the specific goals of the organisation, so as to select effectively achievable objectives.

In a public authorities (PA) setting, another dimension of communication is essential, that of duties of a public body towards citizens and interest groups. The "contract" between public administration and citizens entails their right to be informed and the obligation of PA to be transparent and accountable. Mancini (2008) writes about the right of citizens to be informed by PA, right for simplification (diritto alla semplificazione) which means a right to be informed in a concise and clear manner, to be informed about the real-life opportunities in one's environment, enabling everyone to participate fully and with equal opportunities. This framework shapes the PA communications even before the needs-objectives paradigm. ISS has its duties as "Ammistrazione trasparente" and certain documents have to be published on the website in the homonymous section. RIPI as a single unit doesn't have any specific obligations to publish, yet the common principles apply: code of conduct, research ethics and integrity. Besides, following the ISS policy of making the data available, RIPI group is now working to prepare and publish the spreadsheets from RIAP Annual reports in editable format (XLS, XLSX) and not only as a part of the whole PDF file.

To identify an ideal picture of effective communication, understood as communication that meets both the predefined objectives and stakeholder needs, these two aspects should have been analysed. As stated in the Introduction, RIPI communication objectives were not available as a prerequisite for this research but were yet to be formulated. Methodologically, it was decided to start from revealing the stakeholders' positions and consider them in the process of setting the communication objectives.

This chapter reports the research of RIPI stakeholders' positions, preferences and needs in terms of communication with the registry. Associated with this discourse is the concept of consumer/user satisfaction (CSat). Born to be used in marketing practice, it easily entered the public sector in its efforts to adopt the logic of better possible service. In Italy, The Office for Innovation of Public administration approves of CSat measurement implementation in PA and claims in a dedicated memo: "Rilevare la customer satisfaction consente alle amministrazioni di uscire dalla propria autoreferenzialità"[12]. CSat measurements help to identify the gaps between what a citizen needs and what the PA can really do, or between the perceived quality and expected quality. CSat is a subjective perception.

There doesn't seem to be a universal agreement if CSat fits for evaluating public sector communication (PSC). As legends say, in ancient times, a messenger who brought bad news was killed. If the administration has to communicate something unpleasant, such as an environmental risk, or an incident with an implantable device, should citizens be able to distinguish between the contents of the message (that does not depend on the messenger) and the clarity and timeliness of the message (that makes it effective)? This perspective should be approached with a grain of salt.

## 3.1. Mixed methods and instruments

Methods and techniques that were used to explore the communication between RIPI and its stakeholders and audiences are briefly reported in Table 2. There were multiple tasks: to compare the practices and objectives of RIPI to other registries, to understand the underlying priorities of key stakeholders, as well as their attitudes towards RIPI, and to test available tools for communication effectiveness measurement. This "mix" of aims defined the choice for mix methods approach outlined in the Introduction and in Chapter 1, as it was considered the best fit for the object of study (Creswell & Plano Clark, 2017; Mauceri, 2019; Reid, 1979).

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[12] http://qualitapa.gov.it/sitoarcheologico/relazioni-con-i-cittadini/conoscere-processi-di-lavoro/customer-satisfaction/index.html

The choice of a particular method for analysing different stakeholders was dictated by several factors: the degree of importance of a particular group (both in terms of the stakeholder map presented in Chapter 2 and in perspective), the accessibility of the methods, and the relevance of the method. For example, expert interviews were chosen for stakeholders whose agenda could not be sufficiently understood through participant observation, analysis of decisions and documents. In contrast, a questionnaire was used for the RIAP Scientific committee because the group is not homogeneous, and an interview would not convey a collective voice. For the media, no separate expert interview was conducted with journalists, but the issue of the relationship of ISS and registries with the press was raised in other interviews. Digital methods (web survey, web analytics) were used as a source of user insights; unlike participant observation and interviews, their use was not complicated by Covid constraints.

By accessibility of methods, I mean that primarily those already available were used. Conducting, for example, a representative sociological survey or a focus group to find out attitudes towards public health registries among important, but presumably under-informed groups (ISS staff, family members of patients, journalists) would have been time consuming and required funding, which was not envisaged in this project. The accessibility of interviewees played a role, too.

The analysis was mostly made on RIAP, but also applies for RIPI as a whole and the registries within it.

| **Stakeholder group** | **Methods and techniques used** |
|---|---|
| National policy and decision makers | Document analysis, participant observation (PO) |
| Regional policy and decision makers | RIAP Scientific committee survey, PO |
| Registry steering/scientific committee | RIAP Scientific committee survey, PO |
| Surgeons and clinical staff | RIAP Scientific committee survey, PO (incl. in scientific collaborations), website survey |
| Scientific societies | PO (incl. scientific events), document analysis |
| Manufacturers | Expert interviews, PO (incl. RIAP - industry meetings) |
| Media | Document analysis (publications and press clippings), expert interview |
| Medical students and medical residents | PO, document analysis (survey of AISOT members) |

| | |
|---|---|
| ISS researchers | PO, expert interviews |
| Potential newcomers | PO |
| Patients | Expert interview, document analysis |
| International registries and registries associations | Expert interviews / Benchmarking, PO (incl. scientific conferences) |

*Table 2. Methods and techniques used to explore the communication between RIAP / RIPI and its stakeholders.*

The whole picture is more complex than shown in Table 1, as some methods were used for several purposes. Implementation of some methods in a rigorous and complete manner was limited by the absence of points of reference, and comparison was not always possible where there was no established baseline.

**Participant observation (PO)** on RIPI communication practices and resources was a method "by default" in this research: it started in November 2019 and finished in January 2023. Due to its practical nature, the research work was carried out through full participation in working group activities and special projects. It allowed for clearer understanding of the commissioner's perspective and for gaining first-hand experience of delivering communication products for the registry. Also, PO was used to study several stakeholder groups, as indicated in Table 2.

PO belongs to classic qualitative methods of data collection and provides rich descriptive information. A researcher enters a social group and observes people and processes in the given environment to better understand the dynamics behind the observed reality. As seen by many authors, such research can involve a range of other methods. Kawulich (2005) claims that PO also includes natural conversations, interviews of various sorts, checklists, questionnaires, and unobtrusive methods (such as document analysis). The levels of participation vary from a detached observer to full participant. My stance while collaborating with the RIPI working group was that some authors name "active participant", others "participant as observer": the researcher is a member of the group being studied, fully embraces skills and customs, and the group is aware of the research activity.

I was completely embedded in the RIAP / RIPI working group, but a certain detachment still existed which allowed for an "external" perspective.

Well-known limitations of PO are inevitable bias of interpretation of observed facts and a risk of "going native". It happened to me as well, after a relatively short time I began to identify with the RIPI group and use “we”, “us”, “our” when referring to it. Then, the very presence of a researcher as a new player changes the original situation, even if there is no Hawthorne effect (a type of reactivity in which individuals modify an aspect of their behaviour in response to their awareness of being observed). Finally, PO research raises ethical questions on how much should the group members be aware to be observed and sociologically studied, especially in non-public situations. Should informed consent be signed? Opinions differ and depend on a specific context. Cellini (2008) leaves the choice to inform or not the group to the professionalism of the researcher but admits that a researcher that has good relationships with the group will feel in conflict “between the need to use certain information and the wish to respect the right to privacy and not to harm the people under study” (p.110). However, the persons observed, even if they know the aims of the research, do not necessarily interpret them in the same way as the researcher. Sometimes to fully inform means to ruin the authenticity, as in an imaginary situation when in the middle of highly important informal talk one announces: “And now I’m going to take notes”. A trade-off here is to preserve the anonymity of the participants in the final write-up to prevent their identification.

In this research, RIPI group members were fully aware from the beginning that I was doing a hands-on PhD research on communication strategy for RIPI but might not be aware that I was observing the working routines for the future research. The observations were intended only for aggregated use, all anonymised, therefore I decided to not emphasise the participant observation to not create tension and ruin authenticity.

Nine **expert interviews** (interviste ai testimoni privilegiati) were conducted with four different types of interviewees with four different goals, respectively:

- 3 RIPI stakeholder representatives, to explore their communication agenda;
- 2 International registries representatives, to inform the comparative analysis of other registries’ communication strategies;
- 3 ISS communication professionals, both from the stakeholder perspective and to add to the understanding of ISS-RIPI interactions;
- RIPI Scientific director, to obtain the commissioner’s perspective.

All interviews were semi-structured, based on brief thematic interview guides, and conducted either in person or via video conference. They were audio-recorded, with notes taken in the course

of the interview. Some of them were only used to inform the strategy proposals, and were not intended to be published, also for confidentiality reasons. In other cases, findings are reported in the following sections illustrated with verbatim quotations of the interviewed experts.
Raw thematic analysis was used for data analysis. Mostly the interviews were used simply for primary data collection grouped on macro-themes (see Appendix 3).

**Questionnaire-based survey** of a RIAP Scientific committee. The aim was to explore modes of Committee members' communication with RIAP and about RIAP, and their level of satisfaction. The method was chosen over semi-structured interviews as more suitable for this ‘inner circle' but heterogenous group. No one Committee member can be considered representative for the whole Committee's views. At the same time, this questionnaire didn't intend to be a survey and no statistical inferences were expected. A detailed questionnaire was designed, containing many open questions.

**Online survey of website users**. A 13-item questionnaire was designed, and a survey placed on the RIAP website (riap.iss.it) in May - November 2021 (see Annex 2). RIAP website was chosen over RIPI website as it is much more frequented, regularly updated and informative due to the fact the data collection through the website is active. This reflects overall RIAP development level against other RIPI registries. Aim was to get the insights on user experience. Most RIAP site users were clinicians using the Restricted Area (Area Riservata) for feeding data to the Registry. They were invited to participate via direct mailing, the invitation was sent also to the Scientific Committee with a request to invite their colleagues to fill in the survey. 60 users responded to the survey.

**Web analytics.** Metrics describing user activity of the RIAP website were analysed with Google Analytics tool. The method served to support some claims that derived from other methods. The examples of data retrieved are average monthly use rate, sources of traffic, most popular contents.

**Document analysis** included analysis on several types of documents:

- RIPI and RIAP internal and open documents,
- national Laws and bylaws,
- RIAP annual reports,
- scientific publications on implantable prosthesis registries,

- ISS press clippings, and other.

**Benchmarking** was made with two foreign orthopaedic registries - National Joint Registry, NJR (United Kingdom) and the National Registry of Orthopaedic Interventions, LROI (Netherlands). They were chosen as a benchmark for RIAP, while for RIPI it was not possible to identify a comparable structure.

Benchmarking as a methodology permits comparison of processes, approaches and best practices between two or more organisations or units. Its core idea consists of learning from others in similar conditions. As a practice benchmarking was developed in the private sector to improve efficiency and quality and used widely in environments from manufacturing to printed media. It fully applies to the public sector. As argued by Balagué & Saarti (2020), benchmarking is a learning process that is effective when the parties provide similar services, share common cultural environments and face the same typical challenges. It can be applied to the whole system or institution as well as to its individual areas or processes.

In addition, the elements of qualitative comparative analysis (QCA) were used. QCA is considered particularly suited for understanding the complexity of individual cases (Pattyn et al., 2019) while comparing them in terms of preconditions and outcomes. Within benchmarking as a basic approach, semi-structured expert interviews, document analysis and participant observation were used for data collection.

As evident from Table 2, the amount of research resources was not equally distributed among stakeholder groups. Some were studied more intensely to gather first-hand evidence, for others only one technique was used, or only secondary data were analysed. Correlation here is not with the "weight" of a mapped stakeholder in general or as a communication partner. Rather, those with more challenging or developing relationships with RIPI were considered worthy of in-depth study. For example, communication with the national policy and decision makers, such as the Ministry of Health, important as it is, is rather strictly aligned and follows certain institutionalised formats. At the same time, patient communication is not a priority now for the registries in Italy, but public health regulatory bodies, both international and national, see patient engagement as one of the priorities, so probably patients are the key audience of tomorrow.

It is not the aim of this dissertation to report all the results of methods and techniques used. This would not only be an impossible task in the limited space and timeframe of the dissertation, but also an inefficient detailing. Sections that follow report most relevant and salient results for the most important or less structured directions of stakeholder relations in the case of RIPI. There was no common criterion applied to subdivision of the chapter: some sections are dedicated to specific stakeholders while other to the findings of a specific project within the PhD research.

## 3.2. Inner circle expectations. Questionnaire-based survey of the Scientific Committee of RIAP

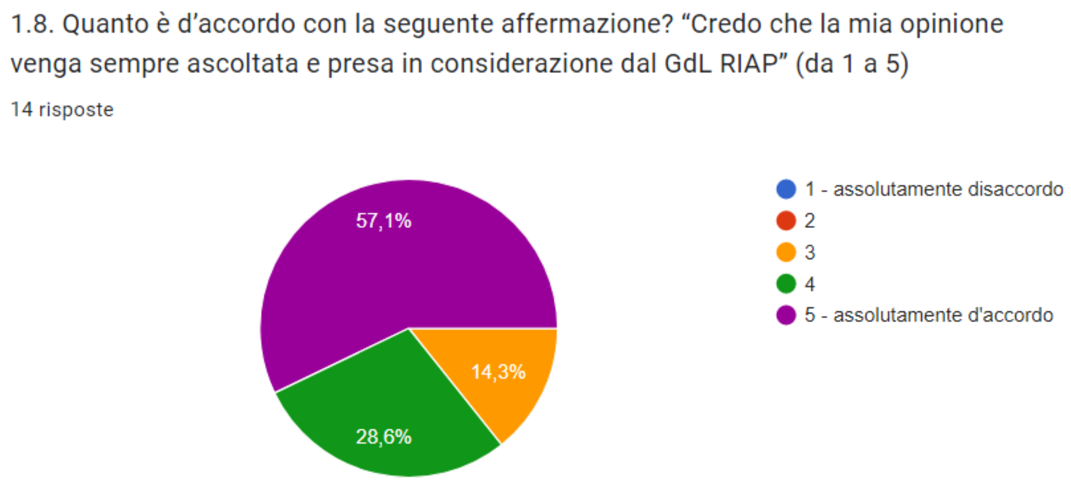
The questionnaire was sent by email to the RIAP Scientific committee (SC RIAP) in January 2021. Google Forms was used as a surveying platform. Out of 55 email addresses, 14 respondents filled in the questionnaire (13 responded in January 2021 and one in June 2022), among them SC RIAP effective members, deputy members and constant collaborators, excluding ISS staff.

The response rate and the quality of answers (absence of response sets, many meaningful answers to open questions) allowed for this survey to be considered valid even without any statistical inferences. Given the commitment and time that the questionnaire required, 14 participants were a legitimate number of respondents: this is more than 25% of Committee and, besides, respondents represented all types of members (surgeons, regional authorities, etc). To add to this, of 55 invited to participate 19 were the deputies and probably did not respond if the corresponding effective SC RIAP members did. Internally, the survey findings were perceived as meaningful and worth discussing at a SC RIAP meeting (one every 6 months).

The questionnaire (see Annex 1) consisted of 26 questions, divided into four thematic sections: individual experience of communicating with RIAP (13 questions), the website user experience (6 questions), SC RIAP communications *about* RIAP with other audiences (4 questions), and technical/profiling information (3 questions). The third series of questions was due to the dual role of SC, that of 'inner circle' stakeholder and that of the advocacy for RIAP in scientific, clinical and institutional environments.

A premise was made in the instructions: “Please remember that there are no right or wrong answers. We can only improve RIAP communications based on a true picture of the situation”. For privacy, the form was anonymous and didn’t automatically gather email addresses. Follows a brief report of survey findings.

- The average of the points given to “To what extent do you feel informed by the RIAP working group?” on a scale from 1="Poorly" to 5="I am informed about everything I want to know" was 4.64, and all but one outlier response were 4 and 5.
- Three properties of information periodically delivered by the RIAP working group (on a scale of 1="not adequate" to 5="exceeds expectations / extremely adequate") were given the averages of 4.07 for timeliness, 4.21 for data quality, and 4.28 for completeness. The cumulative average was 4.19.
- Quantity and frequency of the information shared with SC was esteemed as “adequate” by 13 respondents of 14. The selection of information topics, from the point of view of one's professional interest, was esteemed as “absolutely adequate” by 11 of 14.
- The experience of interaction with the RIAP working group, including by email, calls, and periodic meetings, was evaluated by all respondents as “satisfying” (n=11) and “moderately satisfying”.
- Whom do SC RIAP members contact when they have a RIAP-related question? 11 out of 14 directly contact the RIAP Scientific director M. Torre. These options were given only 1 response each: “Consult the RIAP website”, “Contact the scientific secretariat/ RIAP working group”, “Write to riap@iss.it”. No one chose the option “Consult the materials I have already received as a member of the SC RIAP”.
- In the communication between the Scientific committee members and RIAP, Timeliness of response was given an average of 4.57 on the scale from 1 to 5, Ease of retrieval of data 4.29, and Information quality 4.57 (or 4.77 without one outlier response).
- There was no unanimous consensus on SC RIAP members’ participation in communication. “How much do you agree with the following statement? "I believe that my opinion is always listened to and taken into consideration by the RIAP working group" (on the scale from 1=”absolutely disagree” to 5=”absolutely agree”). Opinions were divided.



1.8. Quanto è d'accordo con la seguente affermazione? "Credo che la mia opinione venga sempre ascoltata e presa in considerazione dal GdL RIAP" (da 1 a 5)

14 risposte

*Figure 4. How much do you agree with the following statement? "I believe that my opinion is always listened to and taken into account by the RIAP working group" (from 1=absolutely disagree to 5=fully agree)*

- Only two respondents answered the optional open question "If you believe that some topics are missing or that there are shortcomings in the methods of information, could you indicate which ones?". Both of them proposed the topics: "Survival analysis / Outcomes per region", "Activities of prosthetic centres, new materials". In the similar question but about the formats of information products, again only two suggestions were made: "Information sheets with key indicators for clinical governance" and "links to industry" (this one was ambiguous).
- For what other audiences should RIAP develop communication products? Regional decision-makers, medical directors, surgeons and medical students. Suggestions on communication materials lacking for these audiences: regular data reports to be sent to regional decision-makers and the directors of orthopaedic departments to raise awareness of data collection; position papers, testimonials; survivorship rates; FAQ dedicated to privacy; social media accounts (Facebook, Instagram, Twitter...).
- A series of questions regarded the use of the website Riap.iss.it as a communication tool (i.e. besides its use for data input that some surgeons - SC RIAP members might do regularly). Only 50% responded they had accessed the RIAP website within the previous month. Others used it rarely. Those who indicated the reason for visiting the website sought technical information like patient privacy regulation, annual reports, or just looked for news/ updates.
- Nobody claimed to be unsatisfied with their last experience of the website. The averages given to the statements about their user experience in general, on the scale from 1="absolutely disagree" to 5="absolutely agree":

  "The site is structured in a clear way": 4.21

“I like the graphic layout of the site”: 4

“Usually, I quickly find what I'm looking for”: 3.71

“The information published on the site is useful for my work”: 4

“The information published on the site is useful for external users (doctors, healthcare professionals, patients and others)”: 3.43

- The Scientific committee becomes a communication channel when its members share information about RIAP with other audiences, e.g., disseminate RIAP analytics and data on professional occasions. Respondents indicated they shared data in following modes: presentations at scientific conferences (n=10), in interviews or other forms of interaction with the press (n=5), in publications (n=6), and 2 of 14 didn’t share RIAP data. On which occasions and how often? In a multiple-choice grid, these occasions were indicated as frequently used: “In a colloquial exchange between colleagues” (9 responded “often” and 1 “every time I get news from RIAP”) and “In my work as presentations at internal meetings, reports, presentations, lectures to students, etc.” (12 responded “often”). Meanwhile, sharing on social media was non popular. SC RIAP members “never” or “rarely” shared RIAP information on their own social media accounts (n=13) or on their institution’s digital channels (n=11).
- Only one person during the last year shared RIAP data in English. It was with the Addendum to the Annual report 2019.

Findings show a high level of satisfaction. No one of the proposed parameters of communication between the RIAP working group and Scientific committee was rated lower than 4 on a scale of 1 to 5. In most cases, one outlier response (the same person in all cases) lowered the average.

However, a high level of satisfaction does not mean the current practices shouldn’t change. Regarding the communication needs, the majority prefers to just contact Eng. Torre directly, often by a phone call. This is an illustration of the presumption made in Chapter 2 (1): the inner circle sees the RIPI-related communication as interpersonal. The quality of information received in this way was rated so high (4.57, or 4.77 without one outlier response) that this stakeholder group would not even appreciate the introduction of any intermediary tool, no matter how effective. This is perceived as a problem by the research commissioner as well.

Many proposals made by SC members on new communication formats and products can be studied and put in practice. However, in some cases the information required is not, or not yet, available. For example, survivorship rates are a long-awaited data that would be appreciated by many stakeholders, but their inaccessibility goes beyond communication tasks. This feedback was given to SC RIAP during the survey findings presentation at the committee's regular meeting.

Some questions arise when analysing the findings of RIAP data sharing practices by SC RIAP members. In general, sharing is relatively active. However, there is scarce sharing in social media. This can be due to a general low rate of social media use by individuals in their socio-demographic groups, and by regional institutions. Another possible reason is that RIAP, not having its own social media accounts, does not provide anything directly shareable by repost. The question about sharing English-language content raises another issue. Communication products such as Addendum (slightly reduced English version of RIAP Annual reports), and numerous website materials translated in English require extensive resources, and if it is of little use even for the active and knowledgeable "inner circle", efficiency and effectiveness of their production should be revised.

## 3.3. Manufacturers: collaborative pragmatism in the light of new EU Regulation

To better understand the manufacturers' agenda and communications needs, two expert interviews were conducted: with Dario Pirovano, Senior Regulatory Advisor - External Consultant for MedTech Europe (a European trade association for the medical technology industry that represents many multinational manufacturers), and Fernanda Gellona, Director General of Confindustria-Dispositivi Medici. The results were compared to the findings of participant observation at the scientific meetings and the RIAP-industry meetings.

The configuration of the relationship between RIPI and implant manufacturers is shaped by the presence of an association in the role of a single counterpart that "guarantees impartiality", according to F. Gellona (FG), as it "does not promote the business [preferences] of one brand over another". For RIAP, indeed, it helps to avoid an eventual conflict of interests. Confindustria-DM represents over 450 manufacturers and distributors of medical devices. Most key players are multinational. Of this number, near 30 companies produce or sell orthopaedic implants. All key players in this field in Italy are members of Confindustria-DM, while only a few cardiological and breast implants manufacturers are represented by this association. Therefore, for other registries making part of RIPI the future contact points with the spinal, cardiovascular, cochlear implants manufacturers might be different from Confindustria-DM.

FG describes the current situation of communication between RIPI and the industry as near to ideal: "there is very good dialogue by way of the website, meetings, [contact with] Marina Torre, speeches at congresses". She immediately adds: "What interests us even more is being able to have access to a range of data. New regulation [MDR] requires the collection of post-marketing data, and the registry seems to us the ideal tool". This theme is central for the manufacturers and was emphasised by Confindustria-DM on many occasions. FG doesn't yet have any precise requirement as to which exact data the industry needs. The general demand is for safety and performance data, such as number and character of incidents with a given implant, implant revision rates. She feels that "that's a part that is still missing from the registry, it is a sensitive issue".

Currently, MDR obliging manufacturers to provide the clinical evidence on safety and performance of their products is widely discussed internationally. The registries are seen as being the best tool for providing this evidence.  At the ISAR Annual congress 2021, a session was dedicated to how MDR completely changed the rules for manufacturers. Already since 1993 when the CE mark was introduced for medical devices in Europe, clinical evidence [of the device safety and performance] was mandatory when bringing a new device to the market. It was common, though, to reference the clinical data of an "equivalent" device, similar enough and already available for several years. It was even acceptable to use the clinical evidence for a device produced by a competitor. From 2021, the MDR requires clinical data on the actual implant, and one has to demonstrate safety and performance for the entire lifetime of the device. Registries are so helpful for the manufacturers because they have multiple data split out, they are continuous, and are viewed by regulators as a reliable source of safety data.

FG suggested in the interview that given that companies can collect the clinical evidence in any country they operate in, they invest in collaborating with foreign registries, and "the risk is that Italy will be put a little bit on the margins of this type of activity". Currently, RIAP does not publish data reports by brand.

ISS, and therefore RIPI, cannot provide this type of service for business as there is no regulation of reference for that, no procedure. M. Torre, in regard to the issue, mentioned at the working meeting with Confindustria-DM in May 2022 that the RIAP group was working on it and studied the international experience (of the German arthroplasty registry, EPRD, in particular). RIPI was established by the DPCM 3/3/2017 that required the approval of a detailed Regulation to become mandatory and fully operational. The first version of this decree has been drafted by a dedicated working group within the RIPI research group and is waiting to be examined by the MoH to start the process for its formal approval. M. Torre invited the companies to wait until the Regulation is adopted: "It is better to work having the text that has been approved and operational".

Finding a solution beneficial for both parties is beyond the scope of communications discourse, rather it would need strategic decisions at the level of national policy makers. I dwell on it because this issue shapes the entire character of RIPI-industry relations.

Back to the effective ways of communication, one format was discussed in detail in the course of the interview with FG: industry meetings with RIAP, organised by Confindustria-DM for its members. Recently, such meetings were held in May and November 2022 at the initiative of the industry, the former set up as a videoconference, the latter held in presence during the SIOT Annual congress, with NJR management sharing best practices. For FG, the success criteria for such events are the companies' presence and their positive feedback (both criteria applied without any exact measurement), as well as the very fact of "talking about these issues [of manufacturers' need for detailed data] in the public context not just behind the scenes". Participant observation showed that major manufacturers participate at meetings with RIPI. The discussion, though, is not particularly active. In both meetings, only 1-2 questions were asked.

FG would wish to involve the orthopaedic surgeons more, to "find the occasions to get them to know RIAP activity, I mean to *many* surgeons". The same topic was brought up by one of the big manufacturers: the surgeons are essential as they should endorse the use of registries. Here a new topic opens up, that of interrelations of RIPI stakeholders. Manufacturers, medical practitioners and medical scientific societies in Italy collaborate and cooperate in multiple ways, balancing to avoid conflicts of interests.

The choice to interview D. Pirovano (DP), MedTech Europe, was partly a choice “of convenience”, due to his personal acquaintance with M. Torre and a long history of collaboration. He is also an expert in Italian public health system, the demands of industry, the registries and the MDR regulation (the interview was conducted on May 21, 2021, five days before its coming into force). Hence, the interview was focused on registries in general. It was a videoconference, and four people participated in the conversation: D. Pirovano was accompanied by a colleague, and M. Torre took the leading part.

The findings confirmed a pragmatic approach of industry that sees registries as tools, instruments that could help them meet the requirements of the new regulation. RIAP and many other national registries in Europe do not publish the data split out by brand. Another issue mentioned was that the registries are still “scattered”, not coordinated nor harmonised among them in terms of types of data collected, methods of analysis and results reporting. “From an economic point of view, for manufacturers to have to follow 27 different registries with different enquiry types is too much resource consumption”, DP argued. In his view, the eventual unification of international registries’ information would be very beneficial.

This topic is in line with the aims of the agreement between RIAP and NJR that allows RIAP to access and manufacturers to feed a unique medical device library already shared between NJR and EPRD. RIAP researchers update the industry on various occasions on this project development, using detailed presentations. This is well accepted: as FG puts it, “what frightens is to have to feed many different databases”.

In addition, I asked DP to share the RIAP Annual Report and its English version, Addendum, with colleagues from a working group representing the implant manufacturers and ask their feedback on its usefulness (including, what data are lacking) and clarity (if the report is easy to read and navigate). Three managers of multinational companies responded. The feedback on clarity was positive: “well-written, easy to understand, well structured”, “nicely done, clear layout, informative”. Regarding the information, all three were unanimous in saying, without prompting, that the manufacturers need additional data: specific implant usage, number of revisions, and survivorship rates. NJR and AOANJRR (Australian national orthopaedic registry) were cited as examples for providing such data. Given the increasing requests from authorities of clinical evidence, clinical data and Patient reported outcome measures (PROMs) are also essential for manufacturers. As one of managers puts it, now the information presented in RIAP reports "limits us as a manufacturer to only being able to use the information for discussing the state-of-the-art in hip or knee arthroplasty".

Several themes emerged from both industry expert interviews and participant observation: an urgent need for data on implant performance; registries that are seen as "tools" that help manufacturers to be compliant with European regulations; positive perception of communication modes of RIAP.

Relationship between the medical device industry and the registries like RIPI is doomed to develop, because manufacturers need the data that national level registries collect and produce, and registries need the first-hand product information to be introduced in the database. Given the multinational profile of the industry and the supranational character of the key market regulation (MDR), stakes in this stakeholder relationship are high. Based on findings, it can be assumed that the current situation is perceived by the industry as asymmetrical. The high requirements of regulatory bodies and unavailability of required data create tension. The proof is the fact that manufacturers have kept asking RIPI to produce and share the data on performance of their products for several years now. Key objective of industry-RIPI communication becomes clear: to ease this tension by communication means.

## 3.4. What do patients want from a registry?

Based on the real-world evidence, patients' requests for a public health institution can arguably be of very practical character, such as: what are patients' rights guaranteed by the public health service in a particular situation, what clinic/surgeon to choose for a specific procedure, what is the best way to treat one's condition that the public healthcare service can offer, what to do in a major emergency such as Covid-19 pandemic.

RIPI is not supposed to consult patients, it is not its purpose. Besides, the types of registry data do not allow for producing specific information upon request that could address the needs of individual patients. The scope of RIPI and RIAP activities is clearly outlined, and its description is available for public knowledge, on the RIAP website and on the RIPI website. More detailed RIAP

FAQ in Italian highlights (physically, in bold) that "the purpose of setting up a national registry is to protect patient safety by trying to reduce the failure rate as much as possible". To the question "How can the registry be useful for me?" a general answer is given: "The Italian Arthroplasty Registry can therefore directly affect patients' lives in a positive way: by improving awareness of the outcomes of hip, knee and shoulder prosthetic replacements; by finding out how long the different types of implants last; by helping to identify - if necessary - individual patients who have been implanted with a device for which the Ministry of Health has issued a safety alert". There's no hotline number indicated, no invitation to give feedback or to ask a question, in order to not encourage what cannot be guaranteed. Nevertheless, there is a contact form and email riap@iss.it indicated on the website, and the questions from patients and their family members arrive occasionally, on average once a year.

The questions received to this mailbox in previous years were: how to obtain a compensation of damage after a metallic implant incident of some years before; how hospitals acquire implantable devices; what is the centre most specialised in particular procedure or working at best with a particular type of implant; who is the surgeon with the greatest number of successful operations to his credit. As one citizen wrote in 2015: "Being particularly confused by the too much information available, which is often contradictory, I thought to ask the ISS joint implant registry because it is an independent and reliable body for the type of data in question". All emails were responded to by the RIPI Scientific director upon consulting the surgeons or other experts, on her own initiative and goodwill. A typical response would emphasise that this kind of information is not in the competence of the Registry, provide some background data that the Registry has and provide as much advice as possible, always trying to redirect the patient to a competent authority or to an expert.

Attention was again drawn to patients in March 2020, when the RIPI group discussed how the registry's expertise could contribute to alleviating the general stress. It was decided to compile and publish generic self-help advice, and subsequently a printable infographic, for patients awaiting arthroplasty. The content was provided by surgeons. This initiative turned out very appreciated by different audiences (see Section 3.5).

Recently, it was discussed in RIPI group to add here the generalised answers to real patients' questions sent to riap@iss.it and suggested by the patient association. Resources of time lack to do this extra work.

In the RIAP Scientific committee, the patient voice is represented by National Association of People with Rheumatological and Rare Diseases (APMARR). In its Statute, the association declares the objective of "collaborating with Associations, Bodies, Societies, non-profit and profit organisations and others, operating in Italy, Europe or other countries" (Art. 7 (f). For RIAP and RIPI, AMPARR represented by its president Antonella Celano is currently the main direct contact line with patients. To understand the Association's position on registry-patient communication, an expert interview with her was conducted in December 2020. Key findings follow.

A. Celano (AC) dwells upon what is of interest for the patients contacting APMARR: whether an implant can be long-lasting or not, how safe the implants are, who is the best specialist in hand or knee surgery in Italy. APMARR doesn't make rankings of any kind, but can provide patients with practical info when possible, or put the patient in contact with the doctors for an expert opinion, or put a patient in touch with those who have already had this surgery and can share their experience. Networking and community liaisons are strong in APMARR: "We do a lot of communication; patients write to us through various channels... we only miss a messenger pigeon"[13].

"Unfortunately, even today not all patients are aware of the existence and importance of registries, let alone know the RIAP or what a "SDO" is. These are technicalities and it is not this information that patients ask us for". But what is needed is the idea of the Registry, the awareness of its existence. "The idea that there is a specific tool that collects data on orthopaedic implant surgery is very reassuring. Because it shows there is attention to the problem". AC sees APMARR as a bidirectional channel, an intermediary between the patients who do not need technical information and a registry that is and should remain a high-level instrument for the scientific community that produces evidence based on real-world data: "It is not necessary for everyone to be able to read the RIAP data. The registry also opens up to the outside world through the association".

That's why she finds the inclusion of APMARR in the RIAP Scientific committee as an added value. "Managing the registry is not only up to the doctors and the SDO, but there is also a view of the patient that can be totally different, there is a real experience, there is an important point of view to be heard". For APMARR, collaboration with the RIAP is also "being able to provide information that we would not otherwise have".

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[13] This and other quotes in this subsection are by A. Celano, if not indicated otherwise.

According to AC, orthopaedic patients contact APMARR both in pre- and post-operative period, and those who have to undergo a first operation represent the largest number. Many patients keep addressing the APMARR for surgery-related or implant-related advice, but they are not the same, always new, and in case of a successful surgery after a relatively short time they might not any longer identify as patients. Being an orthopaedic patient is often a temporary role. It is like with wedding magazines that interact with a constantly rotating audience of brides. NJR Associate Director Deirdra Taylor in another interview elaborates on it: "We use 'patient', but what about before and afterwards? we should use 'people who are seeking, having or have had a joint replacement' ".

When asked if there is anything that RIPI should change to improve patient communication, AC says that it would be better to have more time to reflect upon it, but that external visibility should be increased to "give people a chance to at least know of the existence of the registry".

APMARR often shares RIAP news on its website; they have moderate visibility. In a collaborative research on patients' lived experience launched by RIAP in 2021, the participant recruitment campaign "What do 'suspended' patients experience? Participate in research on prolonged waiting for surgery" using many APMARR digital resources brought only one participant.

Now the patient communication can be considered equilibrated: the registry does what it was designed for and counts on APMARR to monitor patient needs. However, what now depends on a personal goodwill to go an extra mile trying to respond to patient requests, can become a standard of registry-patient communication in the near future. On the part of the RIPI team, the main difficulty in developing patient communication directly or through associations might consist in limited time resources.

While chronic patients stick to their advocacy associations and are aware of who are institutional stakeholders on their topic (be it AIFA that approves new medicine, or the Ministry to release/update *piano di cronicità*), short-term patients are not always willing or have time to engage with the stakeholders. And this should be considered in patient communication strategy.

## 3.5. Website users. Online survey of user experience and web analytics

*Overview*

All stakeholders can potentially communicate with RIPI on the web, be it in their institutional role or just as common citizens. Seen in their entirety, the websites of RIPI and RIAP should be not only relevant for healthcare professionals but also accessible for the wide audience.

As Simonetti puts on, the specific property of "an interactive 'two-way' channel" makes the web resources "particularly suited to an administration attentive to the needs of users and in constant dialogue with citizens" (Simonetti 2005, p.40).

The "ancestor" of the RIAP website, a page within the ISS website, was launched in 2008 (see Figure 5) when the name was still *Registro nazionale degli interventi di protesi d'anca*. It took years before the website gradually evolved to its present design model, determined by its two functions: be the Registry's showcase and a point of data collection for the regions.

**Registro Nazionale Protesi d'Anca**

**Responsabile:** Marina Torre

**Chi Siamo**

Il Registro Nazionale Protesi d'Anca è una federazione di Registri Regionali che realizza la continua e completa raccolta, registrazione, conservazione ed elaborazione di dati relativi alle sostituzioni protesiche dell'anca.

**Pazienti**

In questa sezione è presente un approfondimento sul tema degli interventi di sostituzioni protesiche dell'anca e sui dispositivi medici.

**Operatori sanitari**

In questa sezione sono presenti una descrizione delle attività svolte e i dati utili al Registro Nazionale Protesi d'Anca per ogni Regione, nonché un riepilogo dei dati nazionali.

**Appuntamenti**

**Gennaio 19** **Riunione Comitato Scientifico**
"Studio per l'implementazione di un nuovo flusso informativo su base multiregionale in tema di impianti di protesi di anca". Istituto Superiore di Sanità. Roma, 19 Gennaio 2009

**Giugno 25** **Riunione Comitato Scientifico**
"Studio per l'implementazione di un nuovo flusso informativo su base multiregionale in tema di impianti di protesi di anca". Istituto Superiore di Sanità. Roma, 25 giugno 2008

**Pubblicazioni**

In questa sezione è possibile consultare le pubblicazioni prodotte dai dati del Registro.

- Consulta Dspace

**Area Riservata**

Accesso riservato agli utenti autorizzati.

**Link**

- Ministero della Salute
- EAR
- Public Health DG SANCO
- ROLP
- RIPO ®
- SIOT
- GLOBE

**[M]appa del Sito**

[A] Chi Siamo :: [B] Pazienti :: [C] Operatori sanitari
[F] Appuntamenti :: [G] Pubblicazioni
[I]Informazioni :: [R] Cerca :: [K] Contattaci :: [W] Link
[H] Home :: [S] Torna a ISS Home :: [V] Accessibilità

[J] Italiano :: [Y] Inglese

CSS: caratteri medi :: CARATTERI GRANDI :: Versione stampabile di questa pagina

RSS: Sottoscrivi l'RSS di questo sito per essere informato sugli aggiornamenti

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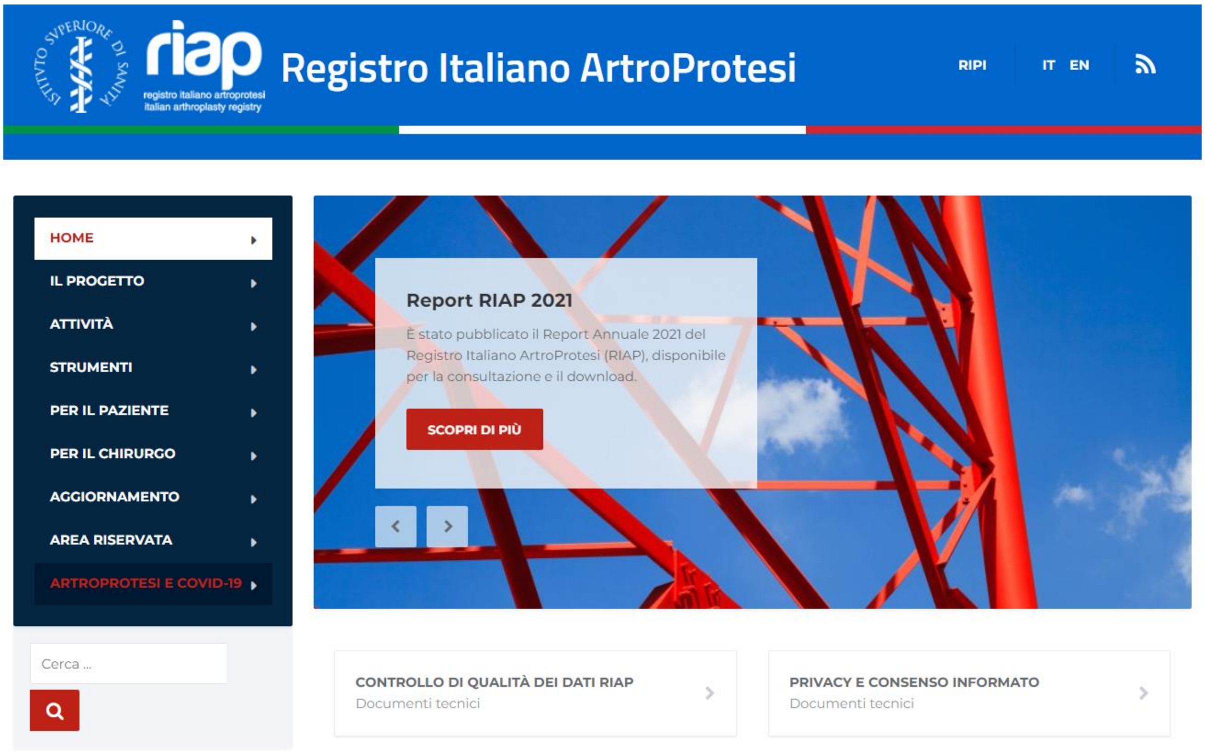

Report RIAP 2021

È stato pubblicato il Report Annuale 2021 del Registro Italiano ArtroProtesi (RIAP), disponibile per la consultazione e il download.

*Figure 5. The first RIAP webpage on the ISS portal (above) in 2008, and the current website homepage.*

The communicative function of the website has been always emphasised. It was described as "RIAP promotion" (promozione del RIAP) (Torre et al., 2014, p. 22), and "dissemination of results" (divulgazione e disseminazione dei risultati) (Torre et al., 2021).

In December 2019, the Registry's new website riap.iss.it went online. It was completely redeveloped from a graphic and structural point of view. All the legacy content was transferred to the new site. In the same period, RIPI website was conceptualised with the aim to give visibility to all RIPI's activities. It is a "container" that hosts the vertical sites dedicated to RIPI's areas of interest, including the RIAP website. The development and further management of both websites was commissioned to an external agency. Follows a descriptive analysis of RIAP and RIPI websites.

The contents of the websites are managed by RIPI group and updated by the external agency. All the decisions about design and structure changes are discussed with the RIPI group.

Technically, these are stand-alone websites, but they also make part of the ISS portal. They are ISS-branded, have "iss" in the URL and are linked from the ISS portal section "Registries and surveillance systems". Importantly, they follow the AgID guidelines for institutional websites. In line with ISS requirements, RIAP and RIPI websites have extensive English versions. Two sites share the same design and writing style. Interestingly, a figurative approach was chosen for the illustrations: one will not find any implantable device in the graphics on either site, but the minimalist photos of objects associated with the registries.

RIAP website is subdivided into sections in a mixed logic: that of topics and of audiences (an approach characteristic for many institutional websites). Menu on the homepage consists of the sections Project, Activity, Tools, For patients, For surgeons, Updates, Restricted Area, and, since 2020, Arthroplasty and Covid-19. There is a search box on all pages.

As we see, of all the stakeholders, only two audiences are specifically highlighted: patients and surgeons. Surgeons have a duty to report incidents with medical devices to the Ministry of Health. RIAP publishes the incident report form and explains the procedure, thus acting as a public service structure helping surgeons to fulfil their legal obligations. To date, this item is the only content of the "For surgeons" section.

For patients, especially those new to the topic, the website is the only direct access point to RIAP. There was a need to gather all contents explicitly dedicated to the patients under one section, as all the rest of the contents is rather of specialist interest. In the previous RIAP websites, APMARR association collaborated and verified that the communicative language adopted was effective. Since then, there was no external analysis made ad hoc. For specific terminology, the Glossario (only in Italian) was developed with 44 entries.

The section "For patients" contains five pages: "Covid-19" (the leaflet on self-help during anti-Covid measures that lead to surgery postponement), "Tools", "FAQ", "Informed consent", "APMARR Association", "Useful links". Under "Tools", to date, there is a facsimile of a certificate for a metallic prosthesis wearer to be compiled by the physician as a reference, for example, at the airport security control.

FAQs are "Why are you asking for my consent to join RIAP?", "How can RIAP help me?", "Which data are collected?", "Are my personal data safe?".

RIPI website is a showcase, with much smaller number of sections than RIAP website and no data input or other functions that could require a "Restricted area". It contains a catalogue of descriptive pages about each registry among RIDIS, RIVAC, RIDEP and RIDIU, link to the RIAP site and to the RNPM site (it is hosted on MoH platform). The scope of News and Publications sections is to cover overarching themes, developments common for all registries or for one except RIAP. The FAQ page explains briefly in plain language RIPI purpose and mechanisms. An email address is indicated as an only contact.

On both websites, technical information in specific formats (e.g., the templates in XSD format) is published to support the local data collection according to the RIPI standards. It is important for registries' core activities.

**Web analytics**

Website analytics and online surveys are the most common tools for website evaluation (EC, 2017). Both instruments were implemented for a status-quo analysis of the RIAP website to see the dynamics since the launch and to inform the baseline for future goals setting. The user survey was undertaken in 2021, more than a year before this dissertation was written. To balance this with obtaining the latest data possible, a brief analysis with Google Analytics was made for the period September-December 2022. The variables collected with analytics were informed by literature and European guidelines. For the RIPI website, such analysis would not yet be relevant, as its average traffic is only about 80-90 users per month.

Average monthly user rate grew from 918 in the first year (1.12.2019 - 30.11.2020) to 1123 in the third year (1.12.2021 - 30.11.2022). Counting separately the period 1.09.2022 - 31.12.2022, one can see that it was particularly active, with an average of 1370 users per month[14], which is 10% more that in the same period of 2021.

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[14] User rate for January and February 2023 was not counted to avoid bias due to heavy internal use.

1.09.2022 - 31.12.2022 is the reference period for all the following data.

What do website users look for? Biggest traffic is due to data input. The Restricted area (18% of visits) and the homepage (17%) with predictably big traffic share lead the top-10 pages by a wide margin, but RIAP Annual reports and Glossary entries are also among the most visited. Rated in the top-10 are also pages dedicated to participating regions and, probably, of region-specific interest, such as the lists of directors of orthopaedic units in Campania and Puglia. Relatively high traffic on Campania page was registered also in January 2023, caused by a recently published update. It was a reminder by the Campania Region public health authority to the orthopaedic surgical units that feeding the RIAP database is mandatory and the remuneration from the Region would only be provided for procedures registered in RIAP.

Where do users come from? The overwhelming majority arrive via organic search (87,5%), looking for RIAP in Google and other search engines. For many cases analytics on keywords is not provided; for the known cases, search keywords were "riap", "riap accedi", "REGISTRO ITALIANO ARTROPROTESI". It means the name and abbreviation are easily remembered to be used for search. It also means that these users knew well what they were looking for.
Around 10% of users come to the site via direct traffic, i.e., typing or pasting in the URL or clicking at a saved link not monitored by Google Analytics. Referrals from other websites and social media give a very scarce flow of users, but these are highly interested and spend much more time than average on the site. Such parameters as number of sessions per user and time on page remained stable over time. The majority of users have Italian as their set language preference, and English language is set by only approx. 6%. The English version of the website therefore has more of an image function.

During the Covid pandemic, not much changed in terms of user behaviour, except for an explosive growth of visits on 24-26.03.2020. This peak was due to the publishing of the new page "Arthroplasty and Covid-19" and in particular the self-help advice for patients. It was widely shared, including the website and social media of the Ministry of Health and national media, both specialised (QuotidianoSanità) and of general interest (La Repubblica), which caused intense direct and referral traffic. To date, such peaks were never reached again.

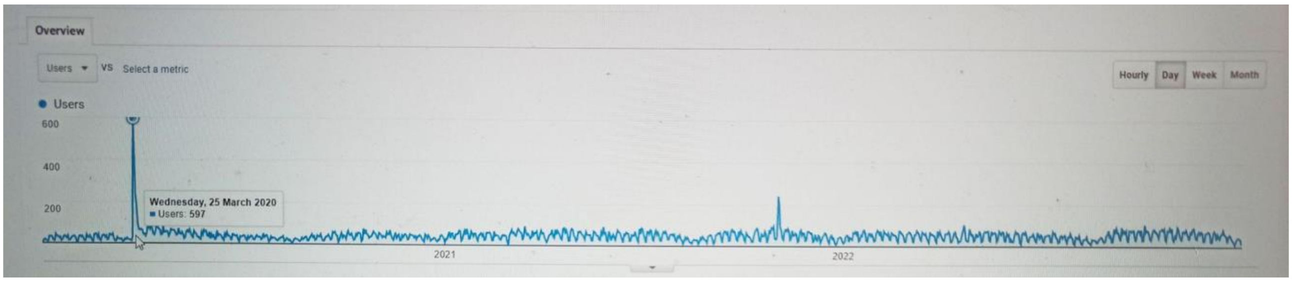

*Figure 6. Peak of website traffic in March 2020 due to Covid-19 related content: 597 users/day.*

Evidently, this analysis doesn't allow for the same kind of inferences as for a commercial website. For RIPI which is a public health entity, the understanding of website performance and effectiveness is different. Even the most rarely visited pages are necessary in the light of public service duty of data transparency. The mere presence of information and its completeness is also a valid criterion.

### Web survey

A web survey has been developed to study the level of user satisfaction. The survey was online from 25 May to 1 of November 2021, and in the last months users were prompted to take the survey with a pop-up window. Only 60 filled-in questionnaires were received from more than 5700 users that visited the site in this timeframe. The page has been viewed 200 times.

The 13-item questionnaire contained 9 substantive and 4 profiling questions. For satisfaction evaluation questions, a qualitative scale was chosen "not at all" - "scarcely" - "fairly" - "much" - "very much"[15].

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[15] In Italian "per niente" - "poco" - "abbastanza" - "molto" - "moltissimo". In this text, the English translation will be used for convenience. Sometimes the English equivalent does not fit the way the question was formulated in Italian but still conveys the sense.

The purpose of accessing the website ("What kind of information do you usually look for on the RIAP website?", multiple choice) for half of the respondents (31) is to access the Restricted Area for data input. Of them, only 6 *also* look for other information - medical and technical data, information on the organisation of the Registry, updates on scientific events of interest and useful tips for patients. Overall, the second purpose indicated was seeking medical and technical data.

The general level of satisfaction was assessed positively by 50 of 60 respondents ("In general, to what extent does the RIAP site meet your needs?" - "Fairly"=25, "much"=22, "very much"=3). In 10 cases, the website met the respondents' needs "scarcely" (7) and "not at all" (3).

The website was assessed rather high for easy navigation, graphic layout and content clarity. However, 13 responded that it was difficult to find what they were looking for, with no correlation to the fact of visiting the website for the first time. 52 respondents approved of the website's graphic layout. For the majority (55) the content was clear, and useful, which could indicate that the website talks its audience language. That the information is useful for website visitors doesn't mean it is sufficient. In the question "What other content would you like to see on the RIAP website?", only 7 respondents ticked the option "Nothing is lacking". Three most popular choices were: surgery statistics (39), information on hospitals (24), scientific articles, including international (22).

2/3 of the respondents were orthopaedic surgeons. The distribution of the answers within this group was not particularly different from others who were public health service employees, patients or their representatives, medical students. But the surgeons were particularly active in proposing improvements when asked for suggestions for the RIAP website. 11 proposals were made in the final open question, all of very different nature.

Technical issues were mentioned, such as a need to make the access and data input easier, enable data input via barcode reader, but also "change graphics" (without any further explanation) and "make the website faster". Other proposals were related to new kinds of content that the users, mostly surgeons, would like to have: more detailed statistics on implant failures, a ranking of surgeons based on how many successes/failures they report, guidelines on orthopaedic implantology based on recorded data. Looking from the RIAP side, it is clear that at the current stage and with resources at disposal these contents cannot be provided or are outside the scope of the registry. Other requests such as more detailed tables are more realistic as new data may arrive with RIAP further development.

The most populated age groups among survey respondents were 55-64 years (25) and 45-54 years (14). 5 respondents were over 65. As the survey did not have an aim of statistical representativity, it can't be determined if this profile might be extrapolated to the entirety of RIAP website users. Based on real life experience, it looks very probable, though. If so, we can say that a typical RIAP website user is an orthopaedic surgeon, male, over 45. This hypothesis might be useful to construct user personas[16] for further analysis and website content development.

In coming years, the age distribution can slightly change due to more active engagement of medical students/residents - future surgeons. In fact, the collaborative educational campaign on the website of the Association of Orthopaedics and Traumatology Residents (AISOT) and a co-organised seminar raised awareness of RIAP in orthopaedic residents nationwide.

The websites are tools with great communicative potential. In 2022, a concept of a comprehensive institutional web portal of implantable medical devices (IMD) was proposed by RIPI researchers and presented in the scientific context (Urakcheeva et al., 2022). It would bring together the national registries of all types of IMD, meeting the needs of various stakeholders, from patients to surgeons to decision-makers. Its architecture and content structure might be developed in collaboration between national and regional public health authorities by a multidisciplinary team. The portal would also have the function of data input to feed the registries in a standardised way. Software for data input and data flow schemes are ready. The module-based architecture of the web portal would allow for progressive growth, as new modules can be added using the same pattern. By now this is a first concept. In the nearest future, yet new registries will be established in Italy for other types of IMDs.

The idea of a common portal can be taken as a vision, given the beneficial impact of a single access point on a topic on the stakeholder communication.

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[16] Archetypical users whose goals and characteristics represent the needs of a larger group of users.

## 3.6. Getting into the flow: Participant observation and document analysis of RIPI current communication practices

Main purpose of the participant observation (PO) was to understand the real situation related to Research Question 1: How can the technical and scientific results of the implantable medical device monitoring activity be made available to the stakeholder groups? PO was aimed at describing the current reality of how RIPI communication activities are organised in day-by-day work. Observational focus was on: who interacts with whom in the RIPI group to produce information for external audiences, how much attention is dedicated to these activities, what is important for group members in communicative tasks. The events of stakeholder communication (such as SC RIAP meetings, scientific conferences) were also an object of observation. PO provided the context for further interviews.

The research duration from November 2019 to January 2023 might have given an opportunity to thoroughly explore the communication practices in the ISS. But a long period of COVID emergency meant that in March 2020 all interactions turned digital. Smart working ("lavoro agile") was promptly mandated by the ISS, and for more than a year usual teamwork in the Institute premises was interrupted. Besides, the development of new communication guidelines planned by the ISS communication departments was postponed in view of a public health emergency that required crisis communication.

The hands-on work as part of PO included many types of activities:

- drafting reports and scientific articles in co-authorship with RIPI researchers,
- press releases, content preparation for ISS social media accounts,
- conceptualising and co-production of new dissemination materials intended for patients (infographics on self-help), for those practically interested (Compendio - a brief Italian executive summary and key findings from the report; a periodic newsletter with updates from RIAP and RIPI websites), for broader specialist audience (video-presentations of RIAP and RIPI involving key stakeholders as speakers),
- participating in RIPI-coorganised events and related scientific conferences.

Some of these activities are classical duties of a communications specialist. Almost all of them involved collaboration. A major part of collaboration was with RIPI Scientific director M. Torre, but also with other colleagues and external contractors.

As mentioned in method description (Section 3.1), participant observation implies an a priori biased instrument - a human. The researcher's personal background and experience define the references for comparison. I was new to the context of Italian public administration, which could be beneficial for objectivity. At the same time, the corporate communications practitioner background defined my pre-set ideas of what effective communication is and what is feasible. That's why the interpretation of the observations was adjusted by discussing them with RIPI group members to compare perspectives.

For reasons of space and ethical considerations, the sheer amount of observations and inferences resulting from PO could not be entirely reported in this dissertation. Key observations that lead to proposing solutions for the RIPI communication strategy are grouped by theme and reported below.

While doing the research, I noticed some factors of organisational nature that could limit the development of RIPI and in particular its communication effectiveness. To draw valid conclusions on these factors, one should do research in public sector management studies rather than communications. Therefore, without claiming to be scientific in proposition, my inferences have the value of three years of observation. Possibly if some of the practices described could be changed, the situation could be improved, and communications could be made more effective. Other observations regard directly communication activities, and the inferences made in this context contribute to build the basis for a strategy proposal in the next Chapter.

- COMMUNICATION MANAGEMENT

  Even if the need of effective communication is recognised as essential by RIPI working group, the specific word "comunicazione" is not embraced in the routine activities. Words and phrases frequently used by group members to describe communications are "divulgazione", "disseminazione", "visibilità / dare v.", "informare", "rendicontare", the same in the Reports and other documents. No one in the group is directly responsible for communication activities.

An external agency updates the RIAP and RIPI websites under guidance/upon request of a group member responsible for the websites. All communicative materials are published on these websites, and the only printed product is the RIAP Annual report. Much attention is given to SC RIAP meetings which are held twice a year. In the period of PO, all external communication activities were performed only with the involvement and approval of the RIPI Scientific director.

The analysis of what works and what doesn’t is informal, applying common sense, as there are no established time-bound indicators to perform any evaluation. At the co-organised educational events, for example seminars and presentations at the SIOT congresses, immediate feedback from partners and the presence itself seems to be sufficient to establish the successful outcome of the event. Since 2020, Google Analytics has been used to monitor the websites.

External communications activities of the RIPI group seem to confirm what Finardi (2010) described as characteristic for public authorities: perception of a “flow”, process-orientation more than result-orientation. In fact, in the RIPI group tasks that have clear deadlines are almost always given priority, especially if this deadline is set by external subjects, i.e., cannot be shifted. In the absence of time-bound targets or other settled references, this can lead to a constant prioritisation of the urgent over the strategic. And urgent tasks come in all the time and overlap. Communication activities therefore do not seem to follow any system and just accompany salient events or developments (for example, there is a routine practice to publish news and to send an update to the RIAP Scientific committee once the Annual report is published or there is a publication in an international scientific journal by RIPI authors). Aside from the Scientific director, it did not happen to me to notice any proactive interest in the group regarding how many people have really read the news.

Internal communication in RIPI group takes forms of informal conversations, calls, email exchange. The instrument for “official” group interactions is an ISS-owned cloud solution for teamwork. The group meetings are held on this platform, usually every two weeks, for 1,5 - 2 hours, always by leader’s initiative. During the meetings everybody updates colleagues on activities, which are often unknown to the rest of the group. Usually there are few questions.

- COLLABORATION WITH ISS COMMUNICATION DEPARTMENTS.

Relations with the ISS Press office are sporadic, only by initiative of RIPI when some findings are considered worthy of publishing (e.g. "Protesi ortopediche: nel 2019 un intervento ogni 2,4 minuti, nel 2020 in rallentamento per il Covid"). In 2021, for the first time, several posts were prepared for the social media accounts of the ISS. A post on Twitter using RIAP data was illustrated by the external agency collaborating on ISS social media accounts with a photo of a person with an ortho-prosthesis (artificial leg). This situation suggests there is a lack of understanding of what RIAP field actually is. As a practical measure, set up a photobank with RIPI-related images could be suggested.

Relations with the ISS Scientific Communications Service (SCS) are collaborative based upon the occasions of RIPI contributions to ISS journals, including the peer-reviewed "Annali dell'Istituto superiore di sanità". The initiative for such publications comes mostly from RIPI, even though sometimes proposals and internal calls for papers arrive from SCS.

- IMPACT OF COVID ON COMMUNICATION ACTIVITIES

For the RIPI group, as for the whole ISS, Covid-related restrictions and introduction of smart working meant working mostly from home and communicating in videoconference. As the RIPI research doesn't involve laboratory methods, it was feasible and didn't affect the work much, if not for some technical questions regarding the necessity to maintain remote access to the office-held documents needed for work.

The RIPI presentation workshop that was roughly planned for 2020 had to be postponed, and then was shelved. The group focused on online communications and products aimed at different types of stakeholders, focusing in particular on patients. The section 'Arthroplasty and Covid-19' was added to RIAP website, bringing together all the materials produced on the topic including a leaflet with self-help advice for patients whose arthroplasty had been suspended due to the Covid-related clinical practice reorganisation in March 2020.

For some reason, possibly of a socio-psychological nature, there has been a burst of working and creative activity in the first weeks of pandemic alert and national lockdown. A collaborative group was formed, that included RIPI researchers, surgeons, and regional public health authorities, that analysed the consequences of pandemic on arthroplasty in Italy. A 44-

page report written by 19 co-authors called “Impact of COVID-19 pandemic emergency on joint arthroplasties in seven Italian Regions” was the result of these efforts.

To date, since the Covid restrictions have been lifted, no full RIPI group gatherings have taken place.

- ANNUAL REPORTS

  In 2014, the first RIAP annual report was published, and it became the showcase of RIAP results, a detailed public accounting of the registry’s activities. From the beginning it was conceived as a dissemination tool: “we wanted it to be available to anyone, downloadable from the RIAP website and organised to spark general interest about orthopaedic surgeons, patients and administrators. Last but not least easy to read, because of its streamlined structure inspired by the first report of the National Joint Registry of England, Wales and Northern Ireland” (Torre et al., 2014).

  Annual reports contain a descriptive part and a comprehensive set of tables and figures with the data collected during the previous year and analysed by RIAP researchers: number of procedures by joint, diagnosis, provider, procedure type, gender, age, and other variables, as well as implant characteristics. In 2018 the Report has been condensed, slimming down the number of pages. The reports also include the analysis of hospital discharge records (SDO) provided by the Ministry of Health.

  The reports are inevitably retrospective: the Annual Report 2021 is published in 2022 and covers the activities of 2021 including the analysis of data of 2020.

  Notably, the authors of the reports describe dissemination activities in a dedicated section, also including Registry’s network-building and knowledge-building activities: seminars, working meetings and site visits to other Registries abroad.

  The annual reports are written internally by the members of RIAP research group, while an external provider is in charge of the layout and publishing the paper version and the electronic version. From 2015, the English version - Addendum with all tables and figures is published as a separate file. Since the very beginning, an executive summary of 7-8 pages has been published as a separate file. Since 2019 it has been renamed Compendio and has been reorganised to make it more effective, not repeating the structure of Executive summary.

The RIAP Annual report has an awareness-raising function, but then has to be disseminated in its turn.

Besides ad hoc products such as leaflets, RIAP Annual report is the only printed material currently produced by RIPI group. The first Report was distributed at the national Congress of the Italian Society of Orthopaedics and Traumatology in November 2014 and at the National Conference on Medical Devices in December 2014. Also, the following reports were distributed at big scientific conferences. The number of prints has been reduced over the years, from 3000 to 800-1000 copies. It may be suggested to evaluate the experience of progressive registries in other countries that have fully or almost fully switched to online-only reports. It would also permit RIPI to adhere to the global paper reduction trend.

| | **Annual report title** | n. of printed copies | n. of downloads from riap.iss.it |
|---|---|---|---|
| 2014 | Progetto Registro Italiano Artroprotesi. Idea, sviluppo e avvio. Primo Report | 3000 | 878 |
| 2015 | Progetto Registro Italiano Artroprotesi. Verso l'operatività. Secondo Report | 1500 | 744 |
| 2016 | Progetto Registro Italiano Artroprotesi. Controllo e qualità dei dati. Terzo Report 2016 | 1000 | 850 |
| 2017 | Registro Italiano Artroprotesi. Potenziare la qualità dei dati per migliorare la sicurezza dei pazienti. Quarto Report 2017 | 800 | 1296 |
| 2018 | Registro Italiano Artroprotesi. Report Annuale 2018 | 800 | 5041 |
| 2019 | Registro Italiano Artroprotesi. Report Annuale 2019 | 800 | 3820 |
| 2020 | Registro Italiano Artroprotesi. Report Annuale 2020 | 800 | 2520 |
| 2021 | Registro Italiano Artroprotesi. Report Annuale 2021 | 1000 | 527 |

*Table 3. Number of printed copies and downloaded PDF-versions of RIAP Annual reports as of 13.02.2023.*

All RIAP reports are published on the website. The limit of the reported data is that the document is published as a PDF. This renders data editing by researchers willing to use the data for further analysis difficult. Ultimately, the objective is to start publishing them in 2023 as XLS/XLSX files, in line with the open data policy of the ISS.

Drafting of the Annual report and the related docs (Addendum, Compendio) is a time-consuming work, to the point that three or four most involved team members have to postpone other planned tasks to work on it.

The Reports follow a common structure each year, even if the content is written “from scratch”. The whole work process could probably be optimised by using ready-made text blocks and approved text formulas.

- INTERNATIONAL PERSPECTIVE

  In line with ISS requirements and objectives of giving international visibility to the Institute’s research, RIPI group produces many scientific publications in English. Both RIAP and RIPI websites have English-language versions (not based on automated translations) that mirror Italian versions to a great extent.

  Writing/translating articles in English is resource consuming. It is always made by the RIPI working group members with strong linguistic competences. Texts are not proofread by an English mother tongue.

  Sometimes, the same concepts are translated by different RIPI authors in different way, which leads to inconsistencies between documents, e.g., “centri di riferimento regionali” can be translated as “regional centers of reference” in one article or poster, and “regional reference centres” in the other. Best practices that could help are a shared list of agreed translations, and the cross-checking of drafts among colleagues. In general, the terminology unification with international registries literature might allow RIPI publications to be more easily findable and citable.

- VISUAL IDENTITY ELEMENTS

  RIPI is stationed in four rooms in a big separate Institute building outside the headquarters area. The RIAP identity is visible thanks to logos put into the office doors signs. In the “main” room (the biggest, in which the Scientific director and three staff members work) there are posters on the walls from early RIAP years, printed on paper that have gone yellow and slightly time worn. Any new person who enters the room will not see any visuals that deliver a message of a future-focused project. The space could be filled with RIAP-produced posters from recent international conferences or with ad-hoc infographics explaining RIPI structure and purpose. Similarly, the corridor connecting RIPI offices: empty spaces or outdated health statistic posters could be replaced by at least one or two RIPI posters.

Branded merchandise produced by RIPI are pens, pencils, rubbers, notebooks, post-its, and cloth bags with RIPI logo. It might be beneficial to reason, also in the entire group, on the type and quality of merchandise that would reflect RIPI values and profile in a more straightforward way.

As far as possible, observations were made without taking into account that I was included in the group and tried to contribute in terms of communication expertise. This is another limit of PO as a method: a researcher mentally splits the picture to be, in turns, participant and observer that ignores the impact of this participant on the observed environment. In practice, in those areas where there was room for improvement by changing existing practices, some changes have been proposed and tested, such as:

- starting to use Google Analytics for monitoring websites user growth,
- starting to send out newsletters,
- publishing RIAP news in ISS social media pages,
- launching Compendio for fast reading after it became clear that even Scientific committee members do not always read the annual report immediately and in full,
- streamlining the dissemination of Annual reports by introducing a Channel/Audience template (see Chapter 4).

## 3.7. What are international colleagues doing? Communication benchmarking

Following the mixed methods approach, benchmarking was performed with the use of expert interviews, participant observation (the NJR presentations during scientific events in Rome), and document analysis of multiple secondary data (performance and strategic plans, websites, social media accounts of NJR and LROI). Expert interviews alone would not be sufficient, as some information could be omitted or interpreted differently by the interviewees that would not permit the comparison with RIAP and between NJR and LROI.

The brief outline of how the method of benchmarking was applied in this research (Section 3.1) supports the methodological distinction between strict benchmarking and its extended interpretation. The strict version identifies practices that contribute to high levels of performance and uses them as a standard of comparison. It is often difficult to apply. Benchmarking in a wider sense enables comparison between a given activity and activities which in some respects are similar and in other respects are different, with a focus more on learning than on comparison (EC, 2017).

Two registries were chosen for benchmarking: National Joint Registry (NJR) and the Netherlands' National Registry of Orthopaedic Interventions (Landelijke Registratie Orthopedische Interventies, LROI). With RIAP they share common values, purposes, endpoints, and work approaches. They belong to the same "clubs", so to say, such as participation in international research networks and associations (ISAR, NORE, EFORT). There are more similarities than differences. The differences are known, they have been identified and considered while performing the comparative analysis.
Benchmarking focused on the following thematic areas:

- Presence of a dedicated communication strategy and perception of its importance for the registry's activity
- Key objectives and postulates of the communication strategy, if any
- Stakeholders: who they are and how the registry communicates with them
- Communication evaluation, measurement metrics

As stated in Chapter 2, of all foreign registries, NJR is a closest partner of RIAP. The collaboration goes in two directions: developing a common implant database, "Global library" on the basis of NJR Library and sharing of best practices from the NJR side with RIAP and Italian orthopaedic community. NJR was founded in April 2002 and started collecting data in April 2003. The registry is well aware of being "described as a global exemplar of an implantable medical device registry" and claims to be the largest registry globally with around 3.7 million procedure records[17]. Technologically and organisationally advanced as it is, NJR has always been perceived by RIAP as an elder brother. It can't be taken entirely as a model to follow, for the different preconditions: organisational model, difference in public health systems in UK and Italy, and resource amount for

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[17] Retrieved from https://www.njrcentre.org.uk/about-us/ on 10.01.2023

project development. NJR management team staff comprises around 15 people and through NJR committees and NJR contractors (NEC for collection of data and The University of Bristol for data analysis), there is collaborative, expertise-based approach to delivery of the NJR's work of around a further 70 or so people. The entire RIPI/RIAP working group counts 13 (including 4 PhD students collaborating on a project basis). NJR has a continuous funding scheme, while RIPI doesn't, and a budget several times higher. NJR does not directly depend on the public health authorities. It is not government-funded but subscription-paid (by NHS trusts, independent hospitals, industry), has by design close liaisons with individual hospitals, and is much more patient-oriented.

To obtain a more comprehensive picture of the NJR communication approach, an interview was conducted in January 2023 with Deirdra Taylor (DT), NJR Associate Director of Communication and Stakeholder Engagement. The choice of time was due to the fact that in that period NJR management was discussing a possible renewal of communication approaches to raise external awareness of the registry.

The NJR does not have a communication strategy as a document per se, but it makes part of strategic and operational plans. "We have operational plans encompassing many individual areas of activity for NJR stakeholder engagement. Our plans for each element of our operational activity are very structured and collaboratively created with input also from our operational staff. At the same time, as we will go more 'externally facing' to raise awareness more generally, we will definitely develop a communication strategy", DT says[18]. But already now communication is seen as a strategic activity. Three out of six Themes supporting the ongoing development of the NJR are communication-oriented: Patient involvement, Key partnerships and international collaboration, and Stakeholder engagement and communication (NJR, 2022). The latter is formulated this way: "Ensure that the activities, benefits and outcomes of the work of the NJR are communicated effectively to a wide range of relevant stakeholders" (NJR, 2022, p. 6). To do this, and to ensure the stakeholders are informed of the benefits the NJR brings to the orthopaedic sector, DT informed that the existing instruments such as annual report, website, and social media, are constantly enhanced and new initiatives will be developed. By the moment of the interview, the communication plan 2023-2024 was in preparation. Currently, at the operational level, several

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[18] This and other quotes in this subsection are from D. Taylor interview if not indicated otherwise.

individual communication plans are drafted for individual workstreams. A new approach to communication, actively discussed in winter 2022/2023, can be described as "to become much more external-facing", and also enhancing patient engagement to the level of "co-production" of NJR patient tools, raising awareness of the registry's benefits, also in view of its 20th anniversary in 2023/24. The stakeholder list in the NJR Strategic Plan 2022-2025 includes 25 organisations among public health governmental bodies, regulators, scientific societies and patient associations. DT mentions patients, surgeons and hospital staff (both in NHS and independent hospitals) and implant manufacturers as the NJR's key stakeholder groups. The media is seen as a communication channel, not as a stakeholder.

In Taylor's view, awareness-raising among the patients in the hospitals about what NJR has been very important. There is no problem with patient consent to their data be sent to the orthopaedic registry, the compliance rate is annually around 97%. DT thinks that communicating the NJR importance for public health, for example with the help of patient leaflets in the hospitals, is important: "Data is more valuable now commercially, so people are more protective [than say ten years ago], most people don't know what registry value is, "*I am not sure what I am signing it for*", but then they see a leaflet and think "*Oh, I'll definitely sign up for it, great thing!*". So, it shares understanding and raises the profile. It makes a big difference if people understand the value". The change, in her mind, is needed because now the NJR mainly communicates to those who already know the registry. To reach out to the potential joint replacement patients, mostly likely to be of older age groups, the key to awareness-raising is establishing collaborations with those who are already engaging with these groups, like AgeUK charity or through Saga magazine. "We want to become more of a household name, if a registry can be".

With the changing strategy, the evaluation methods will also change. By now, as briefly described by DT, the measures mostly follow the reporting metrics of the CRM system and website analytics that are used for stakeholder communication; as well as occasional surgeon surveys to gauge effectiveness of messaging and their views on the ease of navigability of the NJR's reporting systems. DT added that the NJR also has a strong and effective structure of member-led committees: these include those for regionally-based surgeons, for data quality, for supported research, for orthopaedic specialist societies, public regulators – all mostly with both implant manufacturer and patient representation - where many elements of orthopaedic operational activity are discussed and thereafter relevant outcomes are shared through NJR stakeholder communication channels.

The Netherlands' National Registry of Orthopaedic Interventions (Landelijke Registratie Orthopedische Interventies, LROI) is one of the most developed registries in the EU, with its almost 100% completeness nationwide and the volume of 1 mln registered surgeries (the millionth prosthesis was registered on December 30, 2022). The LROI was set up in 2007 by the Dutch Orthopedic Association (NOV), with no direct government's participation. Both LROI and RIAP are members of the Network of Orthopaedic Registries of Europe (NORE).

On March 26, 2021, an 1-hour video conference interview was held with Geke Denissen, LROI Director. The findings were completed by document analysis of the publications on LROI website (lroi.nl). As NJR, LROI doesn't have a documented communication strategy, but in practice pays big attention to stakeholder relations and communications. The Stakeholder council is being set up, in addition to existing governance, to optimise contact with the stakeholders. The key stakeholders for LROI are the patients. The contact is maintained with patient associations.

Another important group are the orthopaedic surgeons. "It's important to feel what surgeons need. We receive feedback from specific persons from the working group Hip [of the NOV] (...) I think it's important to show what the benefit [for them] is, that they not only fill it out but can also use [the data]"[19].

Manufacturers are among stakeholders as well, and - somehow unexpectedly - medical insurance companies are, too. The relationship with the latter is based on providing LROI data requested by insurances. "Our registry was originally set up to provide internal benchmarking, but we know that this data is useful for external groups. If we do not provide information, then they will go to every single hospital by themselves to request outcomes, and that costs a lot of time and work. It is better to arrange what comes naturally, because we do have the information and we analyse it. So, hospitals don't need to do it themselves and we are the only point of communication".

Researchers are another important audience for LROI. The Registry monitors and supports the research that uses LROI data and funds the research groups with grants. As in NJR case, the government was not named spontaneously as a stakeholder, because the communication is not very intense: the government used LROI data until recently, until the statal traceability registry L.I.R. was established, mandatory for the entire class of implants and aimed at tracing implant

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[19] This and other quotes in this subsection are from G. Denissen interview if not indicated otherwise.

holders if necessary. LROI issued an information and FAQ to explain the difference between the two registries.

From the interview, the role of the media was not perceived as very important. The articles mentioning LROI are listed on the website, and by now the page “In the press” contains only seven articles, all in specialised outlets. Still, much attention is given to render the LROI data and analytics easily understandable, also for non-specialists. Therefore, the reports and materials for patients contain infographics.

LROI applies digital communication tools such as the website, annual ‘LROI magazine’ on Registry's developments, Annual report (online version only). all with regard to different audiences: dashboards and detailed data on implant survivorship for specialists, easy to read materials for patients. For posting its news, the registry uses the orthopaedic association’s social media, as the same communication specialist works both for NOV and LROI.

The evaluation practices put in place by LROI include benchmarking across the international registries - without any particular method, just updating on what others are doing - and ad hoc projects. For example, before updating the LROI website, a big evaluation was put in place of what should be on the website. With Google Analytics, LROI analyses how people reach the website, who they are, and which search words are used. To the Annual report website “nobody came via Google, as all graphs and tables were images'', not indexed by search engines and therefore unfindable. Now all possible elements were converted into identifiable text.

## 3.8. The complexities of communication with key audiences

Analysis presented in this chapter applied multiple methods and considered the perspectives of many audiences. It can be claimed that the diversity of viewpoints and methods combination while knowing their limits, allowed for high reliability of findings. Still, they cannot provide a full picture given the dynamism of stakeholder’s role and the inner heterogeneity of some groups (e.g., the patients might share common needs but are not identical in their communication modes), as well as the changing environment.

Expert interviews and participant observation have revealed the presence of inter-stakeholder relations. Each RIPI stakeholder is in some way in relation with others in the logic of a collaborative network, or sometimes of interdependability. For example, RIPI-industry relationships also involve surgeons, given the large interest of the MD industry towards medical practitioners' opinions. It makes stakeholder communication strategy a complex construct in which the aims of all involved groups should be taken into account.

In the course of expert interviews, it became clear that not always the audiences are conscious of their communicative needs in relation to RIPI. If they were never asked about it before, there might have been no reason to form an articulate view on it. Each interview was exploratory, many questions did not have ready answers. The conversation became a co-creation of sense.

A challenging aspect is that some stakeholder needs expressed or observed in this research have their solutions outside of the communication as such. Some stakeholders would like to obtain specific types of content that are not yet produced by RIPI or out of the scope of its competence. This can not be resolved by means of communication. But what effective communication can do is explain 'why not' and inspire further collaboration for development.

# Chapter 4. Development of the communication strategy and communication instruments of RIPI

In this Chapter, a new strategy of external communications for the Italian Implantable Prostheses Registry is proposed. It uses the theoretical frameworks described in Chapter 1, situation analysis and stakeholder mapping proposed in Chapter 2, and the multi-method research on audience perspectives presented in Chapter 3.

Section 4.1 proposes the analysis of general objectives of ISS and of RIPI as reflected in the documents. The external factors influencing the goal-setting in public health in Italy are also addressed. This allows us to place the communications in a cohesive context of "cascading" objectives: Environment (Context) → General objectives of the organisation → General objectives of the project → Communicative objectives of the project.

Sections 4.2 and 4.3 contain the strategy model with its key elements: objectives in relation to each stakeholder group, broken down into concrete time-bound actions and distributed by stakeholder groups, and the approaches and tools of effectiveness evaluation.

## 4.1. The context for objective setting

All approaches to communication planning agree that goal-setting is the first element in developing a communication strategy. Communication objectives derive from the overarching mission and objectives of the organisation and of the project/entity in question. It goes without saying that RIPI's own objectives are linked to the objectives of ISS and anchored in them. The development of a communication strategy for the registry is therefore not an alternative to adhering to the common ISS strategy - it would be counterproductive - but a strategy of how to effectively achieve the common goals at the single unit level. Specific goals add up, given the presence of specific stakeholders, but there is still a shared framework.

The most recent published document that illustrates ISS objectives is the Integrated plan of activities and organisation (ISS, 2022a). This format introduced for the public authorities in Italy several years ago unites different types of plans under one roof, including Triennial activity plan

(PTA), Performance plan and other management documents like the Three-year plan for transparency and prevention of corruption.
The Institute declares that its main objective consists in creating public value by supporting the country in responding to new global health challenges, by providing expertise and infrastructure. The Institute's mission is to promote and protect national and international public health through the production and dissemination of knowledge and scientific evidence, implementing what stated in the Statuto. So, expertise and research take a central part.

In its part dedicated to objectives setting, the PIAO ISS 2022-2024 takes a stakeholder-oriented perspective. The Ministry of Health (MoH), Regional authorities, national and international institutions, and young researchers are viewed as key stakeholders. The strengthening of regulatory, evaluation and control activities in specific sectors to protect public health, also through the timely handling of all stakeholder requests is declared among the priorities. In the PIAO, effectiveness and efficiency are the principal dimensions of the template for objective-setting. It gives a sense of a modern institution that abandons the self-referential and process-oriented approach historically considered typical of the public authorities in Italy (Joris & Coletti, 2012; Simonetti, 2015).

After the Covid-19 pandemic, ISS declared its intention to enhance the surveillance systems needed to monitor first of all infectious diseases, but also non-communicable diseases that currently account for up to 80% of healthcare expenditure in the EU. The ISS considers the implementation and development of surveillance systems and registries among the most impactful objectives. The aim is to provide key stakeholders with data and results useful for considering prompt public health interventions. With the PIAO 2022-2024, for the first time in the history of ISS, surveillance systems and registries are given such priority and specific annual objectives. The intention is to provide key institutions with accurate and timely monitoring of health data collection and analysis, by making aggregated and processed data available and making technical reports available on the institutional website. RIPI is compliant with these objectives.

Among the objectives set in PIAO ISS 2022-2024 that might be applied to RIPI there is also appropriate training for health workers and all stakeholders in order to increase the quality of professionalism of those involved in health protection.

In the Information category, the general objective is "strengthening the capacity to provide direct services to citizens, national and international institutions and in general to all stakeholders in order to share current information on the Institute's activities" (ISS, 2022a, p. 26). The means for that are the institutional website, scientific and technical reports/protocols, and all the variety of ISS-owned dissemination tools (see Chapter 2).  Another objective is the development of services for citizens, such as the hotlines, and recently enhanced telephone counselling.

Approaches and objectives documented in the PIAO are taken as references for RIPI programming. The stakeholder-oriented approach is shared. The expertise and research are central for the ISS, and so they are for RIPI. The declared emphasis on surveillance systems and registries instrumental in prompt decision making influences RIPI positioning.

Also, the Ministry of Health sets the series of communication-related objectives. Under the Policy priority "Development of institutional communication policies", a three-year specific objective is set out: strengthen health protection by means of communication in key healthcare areas, with the numeric targets in terms of implemented initiatives and users reached (Ministero della salute, 2011; 2022b). The Ministry's priority related to the medical devices is the development of the National breast implants registry (RNPM) directly managed by the DG of medical devices and pharmaceutical service of the MoH. The RIPI group supported the development of the pilot phase with the design of the registry and the implementation of a first version of the data collection platform.

The legal framework (Law 150/2000), guidelines for digital communication in public sector issued by AgID, the wider regulatory and development context (PNRR - National Recovery and Resilience Plan; NextGenerationEU recovery plan), large research-sustaining programs such as Horizon Europe, and the Sustainable development goals (SDGs) of the United Nations agenda are currently the external factors that affect RIPI's general and communication objectives. The ISS claims that the Institute's activities are instrumental to the achievement of at least 7 of 17 SDGs (ISS 2021, p. 5). The standards of communication in public health are further shaped by the guidelines issued by international bodies such as WHO or ECDC (WHO, 2017; ECDC). Besides the regulatory, the elements that inherently affect the communication activities and the choice of key messages are the reputation of an institution, its working culture, hierarchy and traditions.

RIPI defines its mission as developing standard systems, measuring performance and monitoring safety of implantable prostheses. As stated in the Introduction, RIPI's overarching objectives are to enable tracking patients in case of a recall of the prosthesis they have been implanted with, and to perform and enable statistical analyses on the collected data, including the implant survival analysis. In its series of research projects, or better, as a series of research projects, RIPI is aimed at creating a platform that integrates the information flows of different registries according to a shared standard. This implied specific objectives: standardisation of the flow model; definition of the technical characteristics of the platform; implementation of the platform; dissemination of results. Promoting national and international collaborations is also indicated, as it "adds value to RIPI's activities", and training related to the development and use of the integrated platform.

At the beginning of 2020, one of the first activities performed to design my research project was to break down the well-known RIPI objectives to the goals that would be specific, achievable and measurable, according to main objectives of ISS. Two macro-directions were defined: to develop RIPI from a scientific and technical viewpoint, and to bring it to the level of European best practices. The category of communication goals was articulated in this way:

> Increase the visibility of RIPI at national and international level.
> Target 1 for 2020: Organise RIPI Inaugural Conference to present the registry to Regions.
> Target 2 for 2020: Promote awareness of RIPI and RIAP in interventions at technical meetings and scientific conferences.
> Target 3 for 2020: Produce scientific and dissemination publications and contribute to external publications by providing necessary data and supportive information. Publish the RIAP 2019 Report and 2 dissemination products: the Summary in Italian and the Addendum in English.
> Target 4 for 2020: Keep the RIAP and RIPI websites updated in Italian and English and increase traffic on websites".

Because of Covid-related restrictions, the RIPI inauguration event did not take place (see Section 3.6). All other targets have been met. Looking at these goals now, they appear output-oriented ("produce N publications") and process-oriented ("promote awareness"). In the present strategy they will be revisited from the result- and stakeholder-oriented perspective.

## 4.2. RIPI communication strategy: effectiveness-based objectives and measurable goals

Table 4 contains a proposal for RIPI communication objectives that support RIPI general development goals and, more broadly, derive from the ISS plans and the context of SSN. The Objectives (left column) aren't strictly time-bound: they are valid until relevant, but to be achieved as soon as possible. They are subdivided into Actions developed on "SMART" goal-setting principle to be reached in approximately one year period. Some Actions are listed more than once, this is because they correspond to more than one Objective. An attempt was made to set the objectives and goals with the effectiveness in mind.

Although, as said, the objectives are not time-bound, the n. 1 and n. 2 in the Table cover preparatory work that chronologically should come first. In fact, it is about defining the identity and streamlining the communication work in the team. The objectives n. 3 and n. 4 are general: awareness-raising is a universal goal but it will take different forms and channels for different audiences. Indeed, one of the first actions would be to organise a discussion on what the formats could be, in addition or in change for some actions planned for specific stakeholder groups. Objectives 1-4 are called "General" in contrast with "Stakeholder-specific objectives".

This plan is a model, focused on the meaning of objectives based on the idea of maximum effectiveness. After its drafting, it has been discussed with RIPI Scientific director M. Torre, and the concepts have been agreed upon. Its feasibility should then pass the reality test. It was developed with a realistic view on the resources at disposition (due to three years of participant observation) but without taking the existing limits as preconditions. The standpoint adopted can be described as "how can we begin to move in the chosen direction" rather than "why this is impossible". These proposals are possible when there is a communication specialist working in/for the RIPI group, or the communication work is distributed among the group members. In the second case, the cooperation with the ISS Press office and Scientific communication service would need to be strengthened, and training on specific skills might be needed.

| **RIPI COMMUNICATION OBJECTIVES** | | |
|---|---|---|
| **GENERAL COMMUNICATION OBJECTIVES** | | **ACTIONS FOR THE YEAR 2023** |
| 1 | Enhancing the expert positioning of RIPI | Internal work. By April 2023:<br>● Compose (for internal use) key messages and positioning description<br>● Revise and integrate the elements of RIPI identity kit (naming and terms used, unified style of presentations, email signatures, scientific posters)<br>● Compose a one-page RIPI fact sheet to use as reference<br>● Update visual identity elements: create photo bank on RIPI and IMDs to support dissemination publications, produce posters to put in RIPI spaces<br>External work. Throughout the year:<br>● Use public speaking opportunities (scientific congresses, university lectures, other)<br>● Use key messages in presentations and publications to convey that feeding RIPI is mandatory, easy, useful and in line with EU requirements |
| 2 | Integration of communication activities as a constant element in the workflow of the RIPI group | ● Map the roles of RIPI group members in communication activities (March-April 2023)<br>● Develop a crisis communications protocol (who does what) for most probable risks (e.g., an implant recall) (March 2023)<br>● Introduce standards for communication materials, such as emails ending with invitation to subscribe to the newsletter (April 2023)<br>● Routinely plan and implement a dissemination campaign for every significant occasion (such as RIAP Annual report 2022 issued, publications in high impact journals, new strategic collaborations)<br>● Introduce RIPI Newsletter highlighting all the updates on the websites as a regular practice (1 a month), appoint a person in charge (March 2023) |
| 3 | Awareness-raising across all audiences about the purpose of RIPI and benefits it can bring to the society | ● Plan and manage an event (online or in person) to present RIPI and new Registries Regulation required by the DPCM 3/03/2017, (time depends on the date when the Regulation comes into force; plan 2.5 months for event preparation)<br>● Promote the existing email channels riap@iss.it and ripi@iss.it for all inquiries (highlight it on the websites, declare a standard for response time) (April 2023)<br>● Organise an internal/external brainstorming on how to raise awareness across different audiences using international best practice (preparation - March, brainstorming session - April 2023) |
| 4 | Dissemination of RIPI results through scientific publications | ● Examine in the co-authors' group the demand for and feasibility of issuing the second part of the Report on |

| | | |
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| | | Covid-19 emergency on joint arthroplasties in Italian Regions, with newly available data (June 2023: at the SC RIAP meeting)<br>● Plan submitting 3 publications for 2023 and involve the ISS Scientific communication department for consultancy and other services with the aim to publish in high rated journals (already in progress)<br>● Publish dissertations of RIPI-based PhD students on the website (June 2023) |
| **STAKEHOLDER-SPECIFIC COMMUNICATION OBJECTIVES** | | **ACTIONS FOR THE YEAR 2023** |
| **National policy and decision makers** | | |
| 5 | Convey to the MoH the idea of importance of RIPI further development as an "umbrella" for yet new registries and better surveillance, in line with Ministry's objectives | ● Compose a project final report in appealing style, concise and illustrated (October 2023) |
| 6 | In communications with ISS management, position RIPI as the centre of expertise in the ISS on IMD statistics and on registry platforms engineering | ● Propose a seminar on compliance with the Registries Regulation, when it comes in force, in collaboration with ISS President's Office (time depends on the date when the Regulation comes into force; reserve 3 months for event preparation) |
| **Regional decision makers** | | |
| 7 | Promote, by means of communication, the joining of remaining Regions to the RIAP | ● Develop a RIPI Quality mark (inspired by NJR practice) for participating regions and structures (discuss with SC RIAP in June 2023)<br>● Invite regional public health authorities of all Regions to the Registries Regulation presentation event<br>● Make a case of the Campania Regional Council's memo (Nota, 05.01.2023) to all the surgery units of the Region reiterating that sending data to RIAP is mandatory (April 2023: discuss at the internal brainstorming session; June 2023: discuss concrete actions at the SC RIAP meeting) |
| **RIAP Scientific committee (SC RIAP)** | | |
| 8 | Intensifying and streamlining the communication with SC RIAP between the biannual meetings | ● Introduce and test a dedicated communication space for the Scientific committee (a group on MS Teams or similar, with chat and file exchange options) managed by RIPI group, where the immediate questions can be resolved and news can be discussed (April 2023) |
| 9 | Convincing the committee that promoting the registry is a common task; enhancing SC | ● Discuss with SC RIAP members what information/format they would need to present RIPI within their institutions/organisations (e.g. to the Regional healthcare |

| | | |
|---|---|---|
| | members' role as RIPI ambassadors | authorities directors) (April-June 2023)<br>● If new materials/formats are requested, prepare the materials if possible and make them easily accessible (on the website/ in a shared folder) (July 2023) |
| **Surgeons, Clinical staff feeding registry** | | |
| 10 | Provide surgeons involved in scientific research with high-quality data | ● In collaboration with SIOT, inform surgeons on the start of RIAP open data publication (tables in XLS format) (April 2023)<br>● Share with surgeons new reports of partnering international registries (throughout the year, including them in the newsletter) |
| 11 | Promote the use of RIPI registries to the largest possible number of surgeons working with IMDs, and make them ambassadors for the registry use in their hospitals | ● Examine channels to reach out to surgeons and clinical staff population (e.g., FAD course on registries, in collaboration with ISS Training service / with medical scientific societies) (June 2023) |
| **Scientific societies** | | |
| 12 | Establishing channels of regular communication with scientific societies represented in RIPI registries' technical boards | ● Cross-post the relevant news of the partnering scientific societies (post their news on the RIPI website and send RIPI-generated news to publish in their digital channels) (throughout the year, monitor the news of partners each 1st day of the month) |
| **Manufacturers** | | |
| 13 | Maintaining active dialogue and remaining a reliable source of information on regulation novelties and MD Global library | ● Introduce a regular format (e.g., once a month) of video conferences with interested manufacturers, in collaboration with industry associations (schedule to settle together with the industry association(s)) |
| 14 | Support by communication means for the elaboration of RIPI data acquisition mechanism for manufacturers, guiding the dialogue | ● Involve manufacturers in the dialogue with institutions on defining the structure of data reports for manufacturers (throughout the year, when relevant) |
| **Media** | | |
| 15 | Establishing working contacts with key media outlets to bridge the gaps in understanding and to become top-of-mind source of expert information on IMDs monitoring in Italy | ● Develop a 6 months calendar/topical plan of RIPI-related news and discuss it with ISS press office (March 2023)<br>● Identify media outlets and journalists who publish news on implantable prostheses in Italy, and analyse registries-related agenda of possible interest to them (April 2023) |

| | | |
|---|---|---|
| 16 | Enhancing health literacy and awareness-raising regarding implantable medical devices and their monitoring by the public health registries, at every relevant media opportunity | ● In collaboration with the MoH, prepare the background information (press kit) on IMD monitoring in Italy, with special attention to "success stories" about how registries in Italy already helped to solve public health issues<br>● Deliver an awareness-raising campaign on World arthritis day (12 Oct. 2023), in collaboration with ISS press office (start planning: 1 June 2023, reserve 1.5 months for campaign development) |
| **Medical students, orthopaedic residents (& residents from other disciplines)** | | |
| 17 | Active dialogue and collaborations with AISOT and student/resident associations in other disciplines, in order to promote the "culture of registries" (persuade that adhering to RIAP is necessary, useful and simple) | ● Propose to AISOT to repeat its survey made in 2022 on awareness and use of registries among orthopaedic residents (plan for October 2023)<br>● Invite AISOT to make a presentation on the association, and on their expectations from RIAP and limits they observe, on the occasion of their first participation in SC RIAP meeting (June 2023)<br>● In collaboration with medical scientific societies, get in contact with associations for spinal, cardiological, otorhinolaryngologic, and craniofacial surgeons-residents interested in respective registries (September 2023) |
| **ISS researchers** | | |
| 18 | Knowledge exchange between colleagues from other ISS-based national registries and surveillance systems | ● In collaboration with the President's Office, develop a concept of an internal round table of registries and surveillance systems, to discuss limits and solutions (May 2023) |
| **Patients and caregivers** | | |
| 19 | Understanding patients' perspective with the help of patient associations | ● Establish working contacts with patient associations for RIDIS, RIVAC, RIDEP, RIDIU and RICRAF (craniofacial implants registry) (starting from March 2023)<br>● In collaboration with APMARR and other associations, prepare a FAQs list - answers to real patients' questions. Publish an update on RIAP and RIPI websites (May 2023) |
| 20 | Enabling disintermediate dialogue with patients, caregivers and interested citizens | ● Publicise the option to contact RIPI via email (throughout the year, control in June 2023)<br>● Examine the possibility to adopt NJR's Patient Decision Support Tool for Italian orthopaedic patients (June 2023: SC RIAP meeting) |
| **International registries and registries associations** | | |
| 21 | Maintaining a high level of | ● Establish working contacts with similar/comparable |

| | | |
|---|---|---|
| | collaboration to adopt best communicative practices and to co-produce new knowledge | registries in other countries for each of the registries among RIDIS, RIDEP, RIVAC, RIDIU and RICRAF (September-October 2023) |

*Table 4. Proposal for RIPI communication objectives (left column) and respective time-bound actions*

**Positioning and identity**

Positioning which traditionally has been a part of marketing efforts may apply in general to a variety of organisations, including in public health (Rodriguez et al., 2018). It can be understood in a broad sense as recognising one's identity and communicating it externally. The most appropriate positioning for RIPI would be that of an expert unit and a knowledge centre, responsible nationwide for a mandatory process, collecting and providing exclusive data crucial for public health. Naming is an important identity element, and with this in mind, in the RIPI group much attention has always been dedicated to giving new registries names in Italian and English and to how their acronyms look and sound. In 2021 "RIPI working group" was changed to "RIPI research group" in the context of scientific publications. These names are however not mutually exclusive and should coexist depending on the context. Due to its multifaceted nature, it's not easy to find a more general word for RIPI than a "registry". A word that has been often used to briefly refer to RIPI is a "project" (it is also used in this dissertation, only for convenience), with its connotations of something temporary, experimental. To date, RIPI has been partially funded on a project basis, but it would be far more correct to see it as an evolving entity that has been established by law and has a perpetual function within the public health system. The confirmations that RIPI is seen as a reputable entity, a source of expertise, arrive from stakeholders. In 2023, RIPI Scientific director was invited to deliver lectures on national implant registries at two master's programs, one organised by the Ministry of Health, the other, as mentioned earlier, by Università Cattolica mostly for hospital pharmacists. It is perceived by RIPI as an important landmark and a proof that an institutional activity still 'under construction' becomes a protagonist of training in the field. In Italy, Master courses are mainly practically oriented, so this is an external validation of the real importance of registries for health workers.

Formal and visual identity elements are important both for self-identification of the RIPI group and for external image transmitting. Even the small things participate in communication. Definition of job titles and of uniform email signatures in Italian and in English can convey a message of solid and expert structure. To add to this is a unified and recognisable style of presentations, posters, and technical reports. Establishing a calendar date of RIPI's 'birthday' - the date of its documented founding might become an element of cohesion that permits to have milestones (e.g., "today is an anniversary: RIPI was founded exactly 10 years ago"). To ensure correct understanding of what RIPI is doing, a photographic repository should be set up: a collection of IMD-related photos to properly illustrate eventual news stories for external audiences. These are considerations for an internal group discussion to be agreed upon.

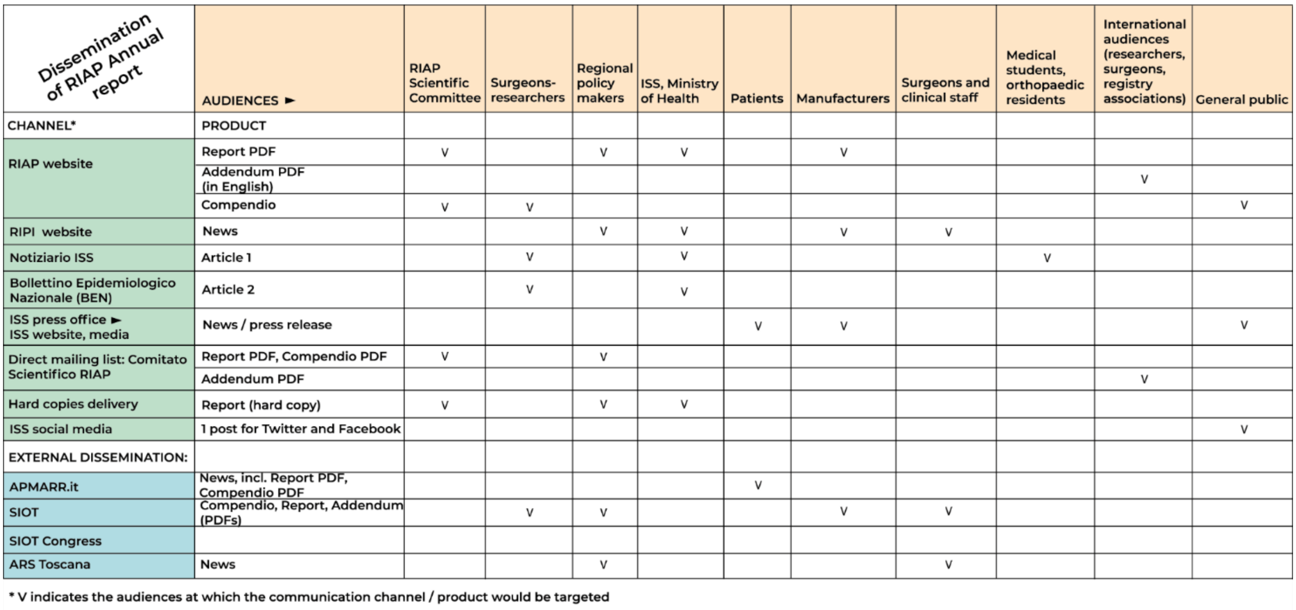
The proposals for spaces have been mentioned in Section 3.6. Gianfredi et al. (2018) argue the importance of the "physical supports" - places, facilities, equipment, as the efficient communication tools of a healthcare public service, especially if managed in a conscious and planned manner. This implicit communication represents a real identity of the organisation, that's why the visual aspect should be coherent with deliberately communicated messages (Pilkington, 2021).

### The stakeholder perspective

As was argued in Chapter 3, to adopt a stakeholder perspective means to try to see the configuration of the situation with other's eyes. Seen from the outside, many facts change their significance. Patients who are interested mainly in their personal health condition would have a "different lens" in relation to implants registries. The media is another example, as there is known to be a dramatic difference of perspectives and language between expert world and world of media (Nichols, 2017). In case of a misunderstanding between parties, the first aim of communication would be to correct (e.g. the misinterpretation of facts, terminology, cause-and-effect linkage). In other cases, communicating parties just have different focus of interest. With this in mind, the communication materials can become more concise and targeted.

If one takes a stakeholder perspective it becomes clear that information being shared does not always arrive, and that the dissemination materials must be not only produced but thoughtfully disseminated in turn. When a communication product such as an annual report or a presentation video is released, a plan should be made on how to make the audience aware of it.

One of the practical activities in this research was to develop a template for the dissemination plan of RIAP Annual Report and to introduce this approach in the workflow. The target audiences were defined, the available channels listed, and the communicative products were proposed that fit different audiences. In this case, the Annual report itself was the end product, together with its brief versions in Italian (Compendio) and in English (Addendum). A press release with statistical facts of general interest was drafted based on the report, which allowed it to reach wider audiences, directly and through significant press coverage.



| Dissemination of RIAP Annual report | AUDIENCES ► | RIAP Scientific Committee | Surgeons-researchers | Regional policy makers | ISS, Ministry of Health | Patients | Manufacturers | Surgeons and clinical staff | Medical students, orthopaedic residents | International audiences (researchers, surgeons, registry associations) | General public |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CHANNEL* | PRODUCT | | | | | | | | | | |
| RIAP website | Report PDF | V | | V | V | | V | | | | |
| | Addendum PDF (in English) | | | | | | | | | V | |
| | Compendio | V | V | | | | | | | | V |
| RIPI website | News | | | V | V | | V | V | | | |
| Notiziario ISS | Article 1 | | V | | V | | | | V | | |
| Bollettino Epidemiologico Nazionale (BEN) | Article 2 | | V | | V | | | | | | |
| ISS press office ► ISS website, media | News / press release | | | | | V | V | | | | V |
| Direct mailing list: Comitato Scientifico RIAP | Report PDF, Compendio PDF | V | | V | | | | | | | |
| | Addendum PDF | | | | | | | | | V | |
| Hard copies delivery | Report (hard copy) | V | | V | V | | | | | | |
| ISS social media | 1 post for Twitter and Facebook | | | | | | | | | | V |
| EXTERNAL DISSEMINATION: | | | | | | | | | | | |
| APMARR.it | News, incl. Report PDF, Compendio PDF | | | | | V | | | | | |
| SIOT | Compendio, Report, Addendum (PDFs) | | V | V | | | V | V | | | |
| SIOT Congress | | | | | | | | | | | |
| ARS Toscana | News | | | V | | | | V | | | |

* V indicates the audiences at which the communication channel / product would be targeted

*Table 5. A Channel-Product-Audience template adopted for dissemination of RIPI publications, using the example of an annual report.*

The question on effectiveness arises also when the materials are published on owned websites: how does the audience get to know about this content? Technical aspect - search engine optimisation (SEO) - is important, but only for those who know exactly what they are looking for. If the website traffic is scarce (like in the case of RIPI website that still has to gain its user base), what is published there can hardly be considered effectively disseminated for the very fact of publishing. Paths need to be paved to bring the readers to this digital "base station". Social media are traditional amplifiers for the information published on websites. The use of the ISS social media accounts for RIPI communication is beneficial but restricted for two obvious reasons. First, as ISS accounts on Facebook, Twitter and Instagram are aimed at the general population, their content may only be of general non-specialist interest. This makes them a good channel for health literacy campaigns but less so for communication aimed at experts. Second, the channel has limited capacity, as the topics are numerous across ISS, but the 'gatekeepers' (the press office) are few and the posting frequency cannot be excessive. Therefore, creating partnerships becomes crucial for amplifying RIPI messages. As evidenced in the analysis of stakeholder groups (see Sections 2.3.3 and 3.2), same stakeholder can be both an audience and a channel, providing the third-party validation to RIPI messages. According to a known psychological principle, there is more trust to what others say about an organisation rather than to what the organisation has to say about itself.

## 4.3. Approach to evaluation and measurement

As demonstrated in Chapter 1, effectiveness is a complex characteristic of communication success. It is defined by a degree to which the objectives of the communicative intervention have been achieved or the needs that originated it have been satisfied. Effectiveness is sometimes listed among other criteria of good communication (OECD, 2019), but this dissertation assumes that communication effectiveness is a general criterion that accommodates other ones (such as relevance, coherence, timeliness, or sustainability). It is important to envisage these characteristics in the formulation of the objectives, explicitly or implicitly.

The development of the RIPI communication strategy went from identifying stakeholders and their needs to analysing both situation and general objectives and then to setting specific objectives, taking into account the interests of the Registry and of its stakeholders. This way, effectiveness becomes a precondition, a perspective with which the stakeholder-related goals are formulated. However, only when the strategy is implemented, the presumed effectiveness will actually pass the reality test.

The argument of evaluation, theorised in Chapter 1, now can be approached in practical terms. To the pragmatic methods that assess the result against the objective, the persistent attributes should be added that characterise communication in public health.

To compile a list of such attributes, communication criteria identified by ECDC (see Section 1.2.1) appear to be suitable as they are specific and relevant for the public health sector. It is worth recalling that these criteria relate to content (accuracy, balance, consistency, evidence base, reliability, understandability) and form (availability, cultural competence, reach, repetition, timeliness) of communication, both in general and for each single activity. However, these attributes have been elaborated in the context of disease control, where the prevalent types of communications are health and risk communications. Criteria recommended in WHO and OECD guidelines should also be considered. Adding to these what ISS described as the ideal communication of a public authority: "responsible, coherent, complete, and in the interest of citizens" (ISS, 2017), a comprehensive list of attributes is proposed.

Is our communication objective / activity / product

responsible
complete
relevant
coherent
efficient
sustainable
accessible, available
actionable
credible and trusted,
reliable
timely
understandable
accurate
balanced
consistent
evidence based
culturally competent
in the interest of citizens

?

*Figure 7. The 17 necessary attributes of communication (elaborated from WHO, 2017; ECDC; OECD, 2019; ISS, 2017)*

When planning and implementing communication activities, these criteria might be used by RIPI group as a "check list" for optimal content development and for channel choice. They are also suitable for evaluation purposes.

Results of communication activities come in the form of outputs, outtakes, outcomes and contribute to impact. Outputs are direct measurable deliverables or sometimes just numeric descriptions of a communication activity, i.e., the number of Report copies distributed, number and type of participants to an event, or the readership of a post. Outtake is the first direct effect, expected or actual, on the target audience. According to some authors, outtakes may refer to awareness, or new knowledge. However, the definitions of this term are many and its distinction from outputs and outcomes can be confusing. The outcomes refer to effects on the knowledge, attitudes, and behaviour within a target audience (Pilkington 2021). Morosini & Perraro (2001) in a dictionary of terms related to the quality in healthcare translate output as 'prodotto', product, and the outcome as 'esito'. As there is some ambiguity in defining the boundaries between these three types of results, a consensus division is suggested, based on the literature and the results of this research. The outputs are "products" of a communication activity, the outtakes are first effects, the outcomes are the main effects and represent the most important result.

In RIPI's communication strategy, the function of evaluation is twofold: to assess the outtakes and outcomes against a predetermined set of objectives, and to gather the real-word evidence for effectiveness analysis. The latter function means that we capture results that were not fully predictable because they don't depend on the communicator. It wouldn't be methodologically correct to base a target on "externally dependent" variables that are beyond our control (e.g., achieve N media publications, get N positive comments for our news on Facebook) but these results should be monitored ex post.

A multi-method approach is proposed for the evaluation of communication effectiveness: three groups of methods to be used at different stages. The first group, or toolbox, applies to the outputs and outtakes of time-bound communication interventions. These are mostly quantitative tools and metrics that deal with the immediate. For separate activities such as running a seminar, sending a newsletter, issuing a news release, the first measure of output will be binary: Done / Not done. The measurement of outputs doesn't tell anything about effectiveness but provides data for further analysis of resource consumption. At the stage of outtakes, first assessment of effectiveness can be made. The second toolbox is used to evaluate the objective parameters of the outcomes. It applies to the Objective as a whole, not to specific Actions within it. Qualitative and quantitative methods are used, but the prevalent questions to answer at this stage are qualitative. The third toolbox is also used to evaluate the outcomes, but in terms of perceived quality, perceived effectiveness of communication. It deals with subjective levels of satisfaction. Are we satisfied with how the relationship is developing? Are the stakeholders satisfied? At this point the list of good communication attributes is again useful. It serves as a checklist for ex post communication evaluation.

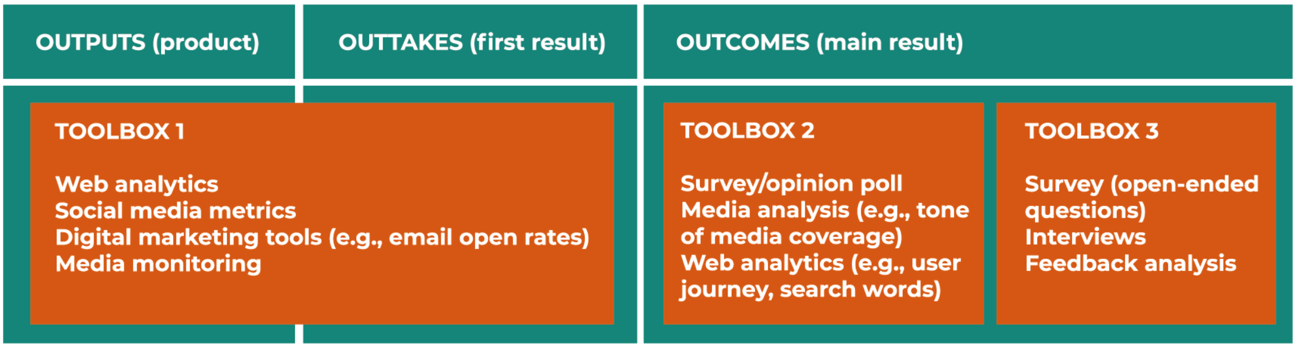


*Figure 8. Three "toolboxes" - groups of methods and tools for communication evaluation at different levels*

For each communication objective, some methods will be more appropriate than others. Each "toolbox" includes frequently used tools but the lists are not exhaustive nor mutually exclusive.

There isn't a universal answer on what is more important: perceived quality or measured results. An approach well-known in corporate assessment is attributing percentual share, or "weight" to each Action. If you accomplished only two Actions of five, but these two "weigh" 70% of the Objective, then numbers are in harmony with the perception. But the attribution of "weight" often is also judgemental. There is a space for interpretation even when deciding if a goal has been achieved. If from five Actions planned for 2023 for a given Objective only two were accomplished, but there is an overall perception of progress, of important achievements, are we dealing with a groundless illusion or a legitimate interpretation? In any case, the criteria and acceptable level of Objective accomplishment should be defined at the goal-setting stage.

Below is an example of setting the indicators and choosing the evaluation methods for a specific action.

**Objective**: Enhancing health literacy and awareness-raising regarding implantable medical devices and their monitoring by the public health registries

**Action**: Deliver an awareness-raising campaign on World Arthritis Day 12 October 2023, in collaboration with ISS Press office.

(As osteoarthritis is the main indication for hip and knee elective implant surgeries, this date can be used for awareness-raising of the outcomes of joint implants and the purpose of RIAP).

**Preparatory work for ensuring communication effectiveness:**

Analysis of the context: scientific societies, patient associations and manufacturers may also launch their campaigns on World Arthritis Day, in Italy or internationally.

Verification if the planned campaign messages and channels meet 17 communication attributes.

**Expected outputs:** Target audiences (patients, caregivers, media) are identified and key messages for each audience are prepared. A press-release on arthritis and prostheses in Italy is sent out to the media and speakers are identified for possible interviews. A dissemination piece (infographic with less known facts about joint implants) is published on ISS social media. Thematic content is highlighted on the homepage of RIAP website and shared according to the channel-product-audience grid, including direct mailing to RIAP stakeholders. Awareness-raising printed leaflets for patients are produced in collaboration with APMARR (patients association) and distributed in orthopaedic units, in collaboration with hospitals.

**Indicators for outputs**: Press-release received by N recipients, N leaflets produced and distributed in N hospitals, etc.

**Measurement tools:** Email open rate, number of printed copies, benchmarking for quality of dissemination materials across ISS units and international registries.

**Expected outtake:** Increased interest in awareness campaign themes among target audiences.

**Indicators for outtakes**: Number and characteristics of user interactions with the campaign content in social media (were there questions? positive/negative comments?), growth of subscribers to the RIPI newsletter.

**Measurement tools**: web analytic tools, social media listening, media monitoring, comparative analysis in collaboration with partners (e.g., were there more questions for surgeons about the registry? Were there more emails to riap@iss.it or new RIPI newsletter subscribers?)

**Expected outcome:** Growth of awareness and positive attitude in the target audiences of the implant registries' purpose. (Outcome should be evaluated for the entire Objective as a result of all actions implemented in the period, e.g., current year).
**Indicators for outcomes**: Traffic growth to RIAP and RIPI websites, media enquiries, mentioning this topic in public discussion.
**Evaluation methods**: Pre/post survey, individual interviews (patient associations, clinical staff), media analysis (qualitative).

## 4.4. Final considerations

Setting the evaluation criteria and indicators for each objective and action is a highly important practical task to do after the action plan is accepted. Criteria should be contextualised, and the evaluation should consider different perspectives. According to Klein-Dossou Leeuw & Fava (2001), some indicators are 'objective', while others should be negotiated with the commissioner of the evaluation research. Indeed, the commissioner's perspective is highly relevant in the process of a communication strategy development for RIPI. Besides, anchoring evaluation in an end user perspective is crucial for improving its relevance (OECD, 2021). This reverses the evaluation question from "how effective was the communication for us?" to "how effective was our communication for *them*?" (for the stakeholders) and makes qualitative methods such as observation, surveys, and interviews very relevant.

The evaluation of impact understood as a major positive change is out of the scope of our model as it should be made at a larger scale - of the whole organisation or of the entire phenomenon. Communication contributes to the impact alongside other efforts and factors. If we consider stakeholder relationships, they are influenced by effective communication, but also by behaviour and decisions taken by the parties. If some decision is unfavourable or perceived as unfavourable by a stakeholder, it can be well-communicated, with all the criteria met, but it still won't be perceived well, and vice versa. And this is where communication ceases to be a science and becomes an art. Sometimes it is important to grasp that in this moment a certain intervention just should be done. The idea of an infographic with self-help advice for orthopaedic patients appeared spontaneously in March 2020 without any plan, given that the patients were not a focus of RIPI communications. It was downloaded by a lot of users, so with great probability it turned out useful for patients; it was reprinted at the website of the Ministry of Health and mentioned in the leading media. There is also a symbolic dimension in stakeholder communication. As M. Torre comments, “Leaflets for patients were an important signal: we have not forgotten you”. Similarly, declaring that RIPI guarantees a response to your email in 24 hours might transmit a message of reliability appreciated in the society frustrated by never-responding public authorities.

Striving to embrace stakeholder perspective and to avoid self-referentiality, the proposed strategy still reflects a protagonist position: “we include you in our communication plan, we have a message for you”. However, it should be noted that stakeholders have their own goals and may develop their own communication strategies involving relationships with RIPI. These communication actions are obviously beyond RIPI’s control. More than control, a climate of open dialog is needed between the parties involved. A collaborative approach could even lead to a communication policy shared by the parties involved, which everyone applies in accordance with shared principles, including ethical norms.

# Conclusion

This study posed three research questions:

- How can the technical and scientific results of the implantable medical device monitoring activity be effectively communicated to the stakeholder groups?
- What should be the criteria of communication effectiveness in the case of RIPI?
- Is it possible to build a model of effective communication strategy for a public health registry?

These questions were put in a non-occasional logical sequence: how to do the communication? how to know if we are doing it well? Finally, is it possible to develop a replicable strategy model? This sequence guided my research. In the previous chapters, the results have been outlined. The answers to these three questions can be briefly summarised as follows.

RIPI's technical and scientific results can be communicated effectively - through establishing an open dialogue with stakeholders and by mindfully targeting the messages and channel choice for each group. The audiences have been identified, each with different expectations from RIPI and with different communication priorities. Considering this, and on the basis of pre-existing general objectives of RIPI and ISS, 21 strategic communication objectives have been identified. It has been argued that "communicate effectively" in the Research question means to maintain a balance between the stakeholders' interests and the project's own interest. Being a public health entity, the Registry has the public value as its main purpose. Therefore, responding to the interests of stakeholders becomes its natural objective.

Starting from a thorough analysis of the literature, 17 relevant attributes of high standard institutional and public health communication were selected. They are proposed to be "hardwired" into each RIPI communication objective from the outset. Examples of key performance indicators (KPIs) are provided for several actions planned in the RIPI communication strategy. In these examples, the tools for measuring the effectiveness of outtakes and outcomes are also known and some of them were experimented during this research. A model of effective communication strategy for a registry in public health is proposed. Its principles are:

- research-informed understanding of stakeholder priorities and own objectives and vision,

- stakeholder-oriented objective setting,
- communication effectiveness evaluation at different stages,
- orientation on outcomes and outtakes more than on outputs.

The latter means application of an impact-oriented mindset: by this activity, how do we contribute to a real change (in awareness, knowledge, interest, behaviour)?

Although it might generally seem that strategies are relevant only when defined by an organisation's top management, this study showed that the adoption of a strategic approach, like that developed for RIPI, might result as fully appropriate for the specific individual project, just on a smaller scale, provided that general objectives are clearly set in the project.

The present communication strategy might be applied to other similar projects in public health, first of all to the registries and surveillance system but also to research units with technological and regulatory components. Within the shared framework, though, the priorities in stakeholder relationships will vary - for example and as demonstrated, some orthopaedic registries have a strong patient-centred focus.

As for RIPI, the fact that communication activities were led without any theoretical model before doesn't mean they were not functioning. But they were largely dependent on interpersonal communication and big individual efforts. When the first annual report RIAP was published in 2015, it had an epigraph: "It's the time that you spent on your rose that makes your rose so important" (Antoine de Saint-Exupéry, *The Little Prince*). The willingness of RIPI project founders to invest all the time it takes pays off, but it can't become a universal rule and can't be replicated or included into a model.

On the other hand, what can be partly adopted and included into the model, is a focus on building collaborative networks chosen in RIPI group from the outset. In public health, the dimension of collaboration is important, and I tried to incorporate this into communicative objective setting. Among the 10 government trends reshaping the post-pandemic world revealed by Deloitte, there is "New era of global public health partnerships: Collaborating for better health preparedness" (Eggers et al., 2022). International collaboratives are growing, to help prepare the world for eventual health disruptions similar to Covid-19 that was too global to be managed in autonomy.

Grunig (2000) claimed that public relations gain its maximum value to the society "if it views collaboration as the core of its philosophy" (p. 25). Likewise for ISS, operating by 'networks' is a basic choice in recent experiences and lines of work are characterised by operating in a network, starting with collaborations with all the central and peripheral articulations of the SSN.

Applied research, such as this, contributes to enrich both theory and practice. For the researcher, being immersed in the work environment of a public health technical-scientific institution allows for hands-on experimental/control research. For the research commissioner, it can help adopt better strategies informed by theory and evidence. Method-based strategies can make the organisations more resilient and stable. It works in the opposite direction too: as van de Fliert puts it, we can only develop theory by reflecting on the practice (Thomas & Fliert, 2014).

At unit level in a complex institution, if there is no reporting linked to communication results, a strategic approach to communications may seem like a luxury that does not bring tangible benefits. In the case of RIPI, communication can help bring about the necessary change through better awareness, stronger image, and new collaborations. In practice, the main obstacle to implementing the strategy is a lack of resources: human, organisational, and financial. Financial resources should be allocated to make any "extra" activities, organising events is costly, as is evaluation (a professionally made survey or user satisfaction study). From the point of view of human resources, an ideal structure for implementing the strategy should be having a staff communication specialist on full- or part-time basis and a possibility to hire external providers for the activities that require particular skills. This together with mapping the roles across the working group and sharing routine communication work would allow the project to make full use of the potential offered by effective communication.

Despite recognising its importance, communication is often treated in organisations as a supporting function. Pilkington (2021) describes the role of communication as a strategic function, that is evidence based, planned thoroughly and evaluated. However, a vicious circle is not uncommon. To be deemed strategic, communication must rely on research and make a convincing case for effectiveness in addressing the organisation's objectives. But in order to conduct research and implement effective communication activities, resources are needed. Resources are not allocated because the function is not considered strategic.

This is changing now. Communication gradually gets recognition as a core component of policymaking and as a profession in itself (OECD, 2021). The regulatory framework of public sector communication (PSC) in Italy is also changing. In 2020, a dedicated working group proposed a reform of the Law 150/2000. The twenty-year old Law was declared "largely inadequate for the new transparent and digital PA of today". The proposal formulated in 10 points focused largely on professionalisation and restructuring of communication function in the public authorities and institutions and on overcoming the precariousness of professional roles operating in PSC. The document calls for communication and information activities to be recognised as strategic "as they are aimed at ensuring good performance and impartiality of administrative action (...) as well as the full exercise of citizenship and individual freedoms by citizens"[20].

In public health, the growing recognition of the strategic role of communication is also due to an external factor, the COVID-19 pandemic emergency. In a way, this has been a new starting point for public healthcare communication, as well as science communication: many established communication processes need to be rethought and updated (Lovari, 2020). In the Special edition of Eurobarometer 2021 respondents had a mostly positive view of scientists, but 39% saw them as "bad at communicating" (EC, 2021).

When Covid restrictions had just been lifted, Paola De Castro, Head of Scientific communication service in ISS, said in the interview for this research: "We are living in a moment of great transformation, in the world of research one speaks to the patient and expects his feedback, one speaks to the citizen. The Covid experience brings old problems into focus, makes us see them through a magnifying glass: the citizen who wants to know, misinformation or contradictory information, fake news circulating mainly through social networks, institutions that do not coordinate in institutional communication". Nevertheless, as pointed out in Chapter 2, during the pandemic, the level of popularity and authority of ISS increased and remains high today. Any institutional project, including surveillance systems and registries, while communicating with its audiences contributes to the formation of the common image of science and public health expertise and can help increase trust.

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[20]. "Le attività di comunicazione e informazione e la trasparenza, intesa in senso ampio e generale, delle pubbliche amministrazioni vanno considerate strategiche, in quanto finalizzate a garantire il buon andamento e l'imparzialità dell'azione amministrativa sancite dall'articolo 97 della Costituzione, nonché il pieno esercizio della cittadinanza e delle libertà individuali da parte dei cittadini". Retrieved from https://www.funzionepubblica.gov.it/articolo/dipartimento/15-06-2020/riforma-della-comunicazione-pubblica-proposte-operative-10-punti on 10.01.2023.

When this dissertation was in its final stage, another registry was founded under the RIPI umbrella: the registry for craniofacial implants (RICRAF). Its technical committee was set up in January 2023, and this new development was mostly due to the initiative of scientific societies. As evidenced, ISS and the Ministry of Health emphasise the importance of medical devices monitoring, surveillance and data analysis. Meanwhile, the academic community moves towards more extensive registries-based research. Lübbeke et al. (2021) argue that now time has come for a new academic discipline: medical device science. An argument is made that there is increasing recognition by policymakers and regulators of the importance of devices in terms of health outcomes, risk management, and economic influence. This new science would be of interdisciplinary nature, and among the disciplines that make it up there is a place for communication: "Better risk management strategies should include efforts in knowledge implementation among all stakeholders" (p. 162).

The interest in communication research on the part of registries was further confirmed when an abstract presenting a model strategy outlined in this dissertation was approved for a podium presentation at the ISAR Congress 2023 - the largest global meeting of orthopaedic registries.

The further development of this applied research would evidently be the implementation of the proposed strategy, ideally by the researchers and practitioners working together. This would allow to test the assumptions about the effectiveness and the methods for evaluating it. For the RIPI group, this would be training in a more informed and controllable approach to stakeholder relations. In a situation of resource scarcity, which is typical of small teams such as the RIPI group, a particularly valuable feature of this model is that it delivers, even if only part of what is planned is realised. "How" and "why" is more important here than "how much". However, the approach underpinning the proposed strategy is universal, as it is based on the idea of exploring and taking into account the interests of all parties. This approach seems particularly relevant for public health institutions, whose primary mission is creating public value.

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# Appendices

Appendix 1. Examples of interview guides for expert interviews

Appendix 2. Survey of user experience conducted on the RIAP website

Appendix 3. Questionnaire of the survey of the RIAP Scientific committee

# Appendix 1. Expert interviews: examples of interview guides

**Fernanda Gellona, Confindustria-DM**
1. Come descriverebbe l'identità del RIPI?
2. Cosa significa per voi la collaborazione con il RIAP?
3. Per voi, qual è il modello ideale di comunicazione con RIPI? (nei termini di tipologia, modalità, frequenza con la quale volete ricevere aggiornamenti)
4. Quando spesso Lei utilizza i siti web del RIAP e del RIPI e per quale motivo?
5. Una Newsletter periodica da parte del RIPI vi sarebbe utile?
6. Come valuta gli incontri periodici del Comitato scientifico? è utile per voi, visto che non siete sempre presenti agli incontri?
7. Poco fa avete organizzato un'evento - incontro delle aziende con la Responsabile scientifica del RIAP. Il feedback stato positivo, ma cosa significa? Per voi è stato un successo?
8. Come possiamo misurare l'efficacia?
9. Se un'impresa, qualcuno di vostri soci, vuole mettersi in contatto con il RIAP, come procede? fate da tramite?
10. La comunicazione è bidirezionale. Secondo Lei, informazione di che tipo da Confindustria-DM potrebbe essere utile per i registri?

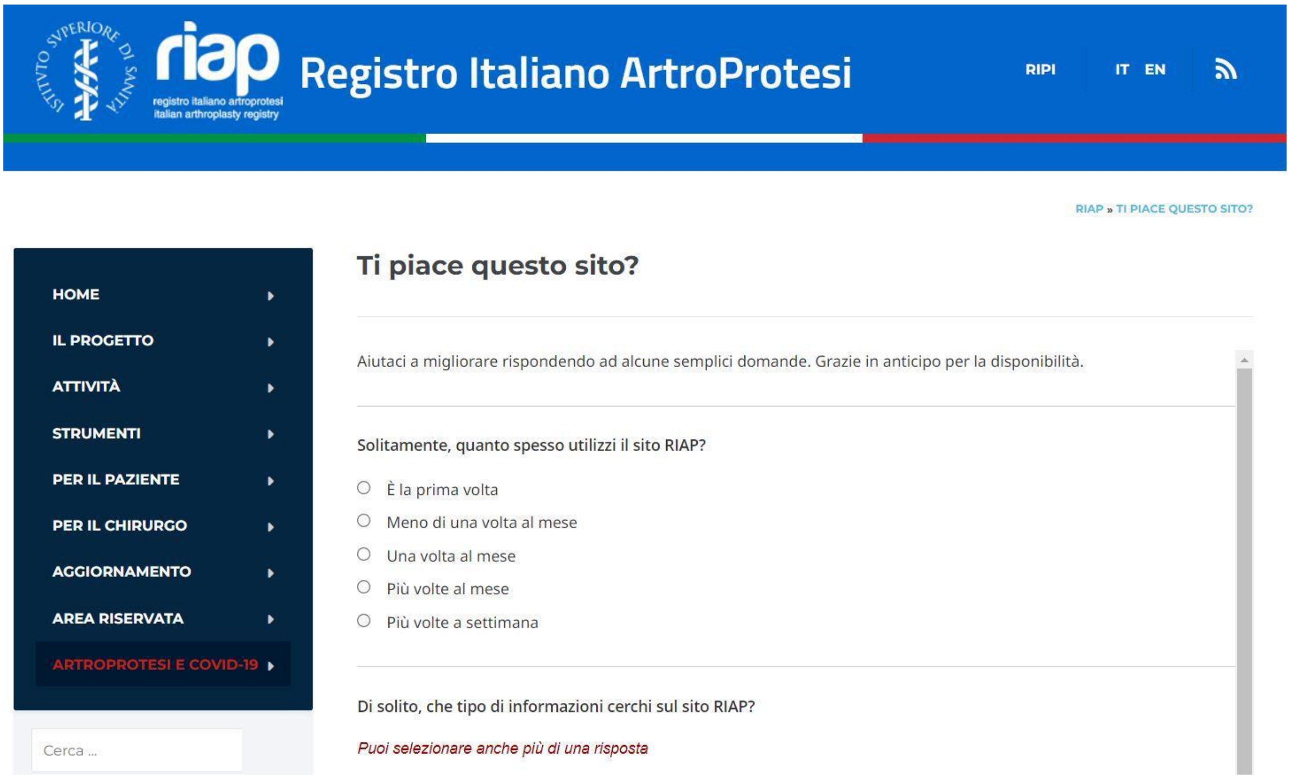
**Dario Pirovano, MedTech Europe**
1. Per MedTech, chi sono gli stakeholder in termini di comunicazione esterna? Che posto hanno i progetti istituzionali nazionali come il RIPI?
2. Che tipo di dati, analisi e informazione aspettate di ottenere dai registri come il RIPI?
3. Il nuovo regolamento sui dispositivi medici, MDR, entrerà in vigore dal 26 maggio. Secondo Lei, bisogna organizzare qualche attività di divulgazione?
4. Che tipologia di informazione generata dal MedTech pensate sia utile per i registri e le sorveglianze nazionali?

**Paola De Castro, ISS**
1. Secondo Lei, dov'è il confine tra comunicazione scientifica e comunicazione pubblica dell'ente di ricerca come l'ISS? (visto che la comunicazione scientifica ha anche la funzione divulgativa)
2. Con quale termine descriverebbe l'attività comunicativa dell'ISS attraverso vari pubblici? Divulgazione? Disseminazione di conoscenza scientifica? Comunicazione? Altro?...
3. Quali sono gli obiettivi e le audience di comunicazione scientifica dell'ISS?
4. Premesso che, come Lei diceva in varie occasioni prima, non è controllabile chi accede alle pubblicazioni dell'ISS (prima di tutto la letteratura "grigia"), quali caratteristiche (di linguaggio, di struttura, di approccio in generale) devono avere tali pubblicazioni?
5. Se parliamo del RIPI e degli altri registri ISS, come secondo Lei dovrebbe essere organizzata l'attività di comunicazione?
6. L'unità dell'ISS come RIPI può avere la sua strategia comunicativa, visto che probabilmente ha dei pubblici più specifici rispetto all'ISS in generale?
7. Lei partecipa al rilancio del portale dell'ISS, che ne pensa della sua efficacia e su

cosa si basa la sua opinione?
8. Una volta aveva detto che nella quasi totalità dei casi la valutazione dell'efficacia di comunicazione è empirica nell'ISS. è solo per la mancanza delle risorse o anche per la mancata metodologia? C'è un'intenzione di introdurre nuovi strumenti di valutazione? Secondo Lei, possono essere utili in tal senso i manuali sviluppati dall'OMS e dalla Commissione Europea?
9. Avete mai fatto un benchmarking con gli enti di ricerca all'estero, come sono organizzate le loro comunicazioni?
10. Come possiamo controllare se le attività di comunicazione rispondono ai bisogni degli stakeholder?

**Deirdra Taylor, NJR**
1. What are the underlying principles and key elements of NJR communication strategy?
2. Who do you consider to be key stakeholders for NJR?
3. Do you have / plan a dedicated communication team for NJR, and if yes, how many people work there?
4. How important is the concept of effectiveness of communication for you? Are the communication strategy and plans guided by effectiveness or rather by other values such as utility, user satisfaction, efficiency, or else?
5. How do you evaluate the success of communication interventions/campaigns? What are the criteria? Especially if quantitative metrics are not applicable.
6. Will the evaluation be campaign-based or do you apply any techniques for evaluating routine ongoing activities (beside the digital metrics)?
7. Could you please give some examples of recent NJR communication campaigns that you consider particularly successful? Are there some related documents available to study them? Could you please share some metrics (like, the outreach in numbers)?
8. Is the current activity of NJR social media accounts characteristic of NJR communication approaches? Or do you think there is something that should be changed in your social media management?

# Appendix 2. Survey of user experience conducted on the RIAP website



Ti piace questo sito?

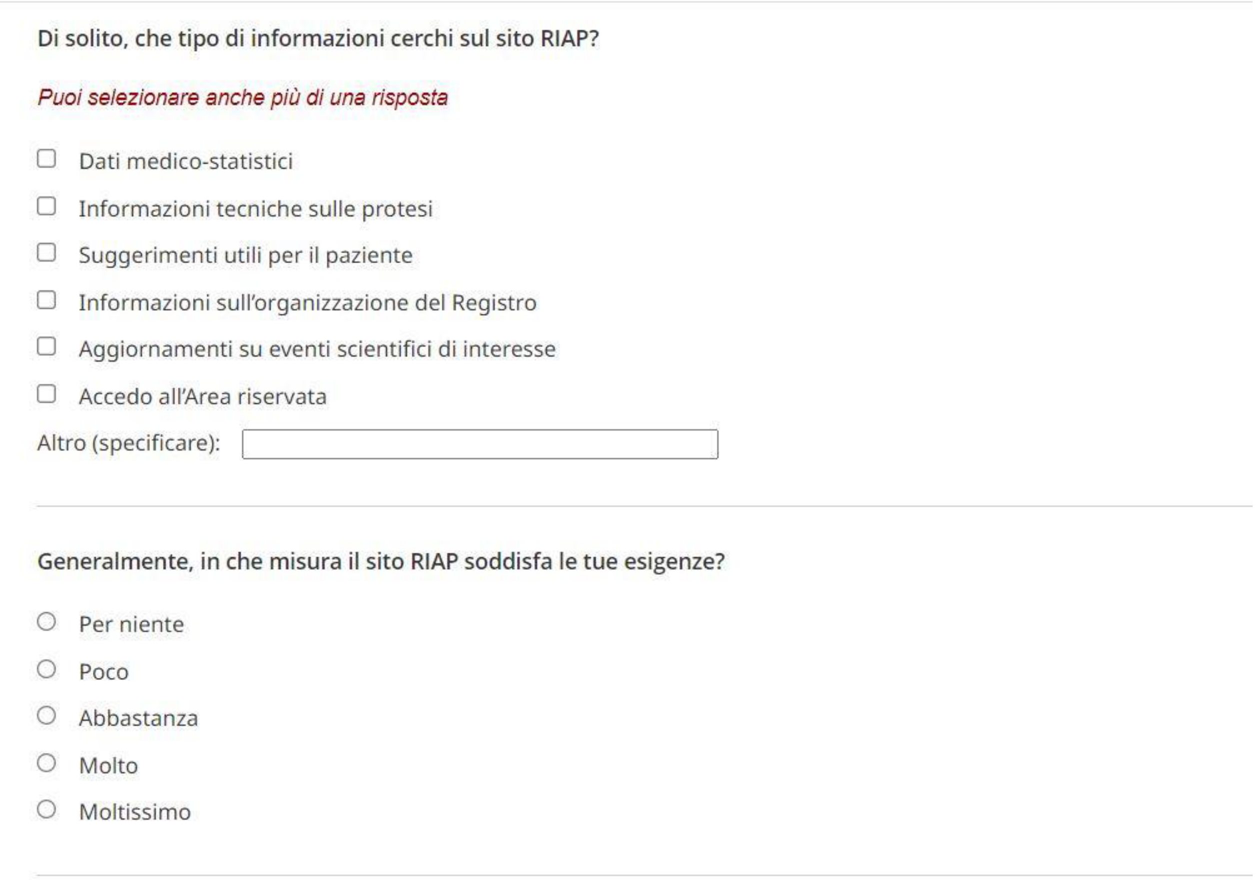
Aiutaci a migliorare rispondendo ad alcune semplici domande. Grazie in anticipo per la disponibilità.

Solitamente, quanto spesso utilizzi il sito RIAP?

○ È la prima volta
○ Meno di una volta al mese
○ Una volta al mese
○ Più volte al mese
○ Più volte a settimana

Di solito, che tipo di informazioni cerchi sul sito RIAP?

*Puoi selezionare anche più di una risposta*



Di solito, che tipo di informazioni cerchi sul sito RIAP?

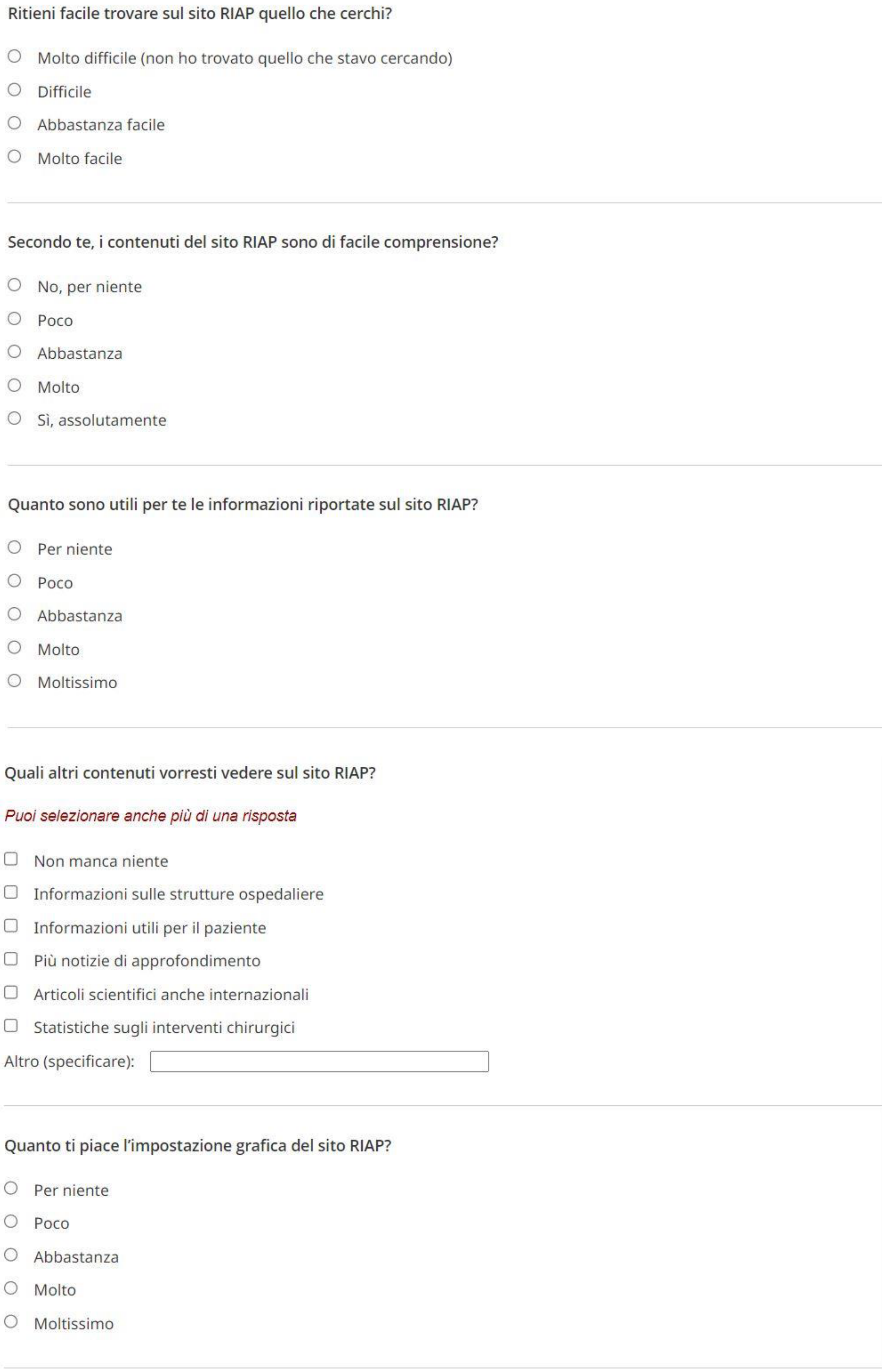
*Puoi selezionare anche più di una risposta*

☐ Dati medico-statistici
☐ Informazioni tecniche sulle protesi
☐ Suggerimenti utili per il paziente
☐ Informazioni sull'organizzazione del Registro
☐ Aggiornamenti su eventi scientifici di interesse
☐ Accedo all'Area riservata

Altro (specificare): ______

Generalmente, in che misura il sito RIAP soddisfa le tue esigenze?

○ Per niente
○ Poco
○ Abbastanza
○ Molto
○ Moltissimo



**Ritieni facile trovare sul sito RIAP quello che cerchi?**

○ Molto difficile (non ho trovato quello che stavo cercando)
○ Difficile
○ Abbastanza facile
○ Molto facile

**Secondo te, i contenuti del sito RIAP sono di facile comprensione?**

○ No, per niente
○ Poco
○ Abbastanza
○ Molto
○ Sì, assolutamente

**Quanto sono utili per te le informazioni riportate sul sito RIAP?**

○ Per niente
○ Poco
○ Abbastanza
○ Molto
○ Moltissimo

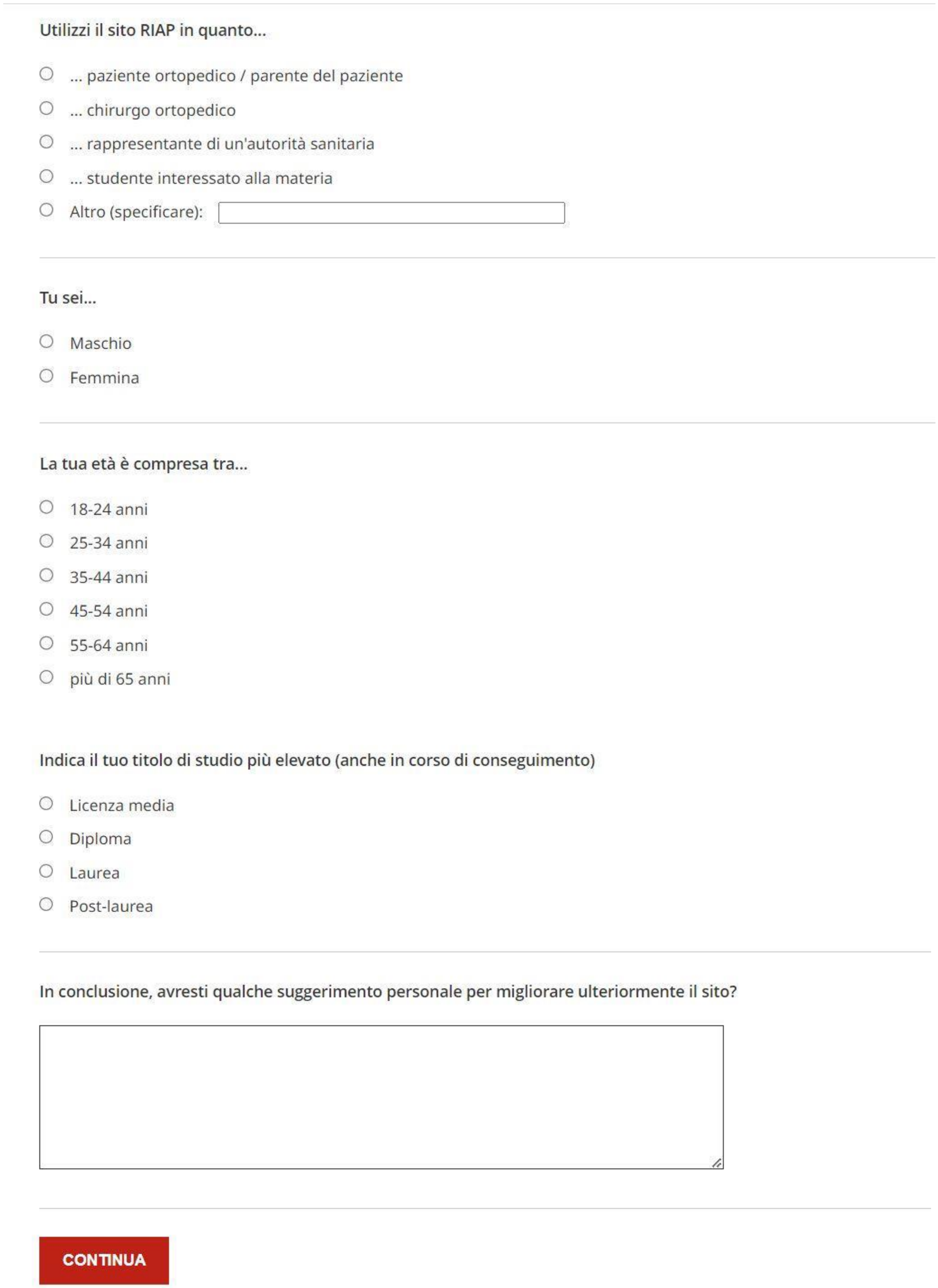
**Quali altri contenuti vorresti vedere sul sito RIAP?**

*Puoi selezionare anche più di una risposta*

☐ Non manca niente
☐ Informazioni sulle strutture ospedaliere
☐ Informazioni utili per il paziente
☐ Più notizie di approfondimento
☐ Articoli scientifici anche internazionali
☐ Statistiche sugli interventi chirurgici
Altro (specificare): ____

**Quanto ti piace l'impostazione grafica del sito RIAP?**

○ Per niente
○ Poco
○ Abbastanza
○ Molto
○ Moltissimo



Utilizzi il sito RIAP in quanto...

○ ... paziente ortopedico / parente del paziente
○ ... chirurgo ortopedico
○ ... rappresentante di un'autorità sanitaria
○ ... studente interessato alla materia
○ Altro (specificare):

Tu sei...

○ Maschio
○ Femmina

La tua età è compresa tra...

○ 18-24 anni
○ 25-34 anni
○ 35-44 anni
○ 45-54 anni
○ 55-64 anni
○ più di 65 anni

Indica il tuo titolo di studio più elevato (anche in corso di conseguimento)

○ Licenza media
○ Diploma
○ Laurea
○ Post-laurea

In conclusione, avresti qualche suggerimento personale per migliorare ulteriormente il sito?

## Appendix 3. Questionnaire of the survey of the RIAP Scientific committee on communication effectiveness

(online form in Italian)

**Questionario di valutazione dell'efficacia comunicativa del RIAP**

Vi pregherei di prestare attenzione in particolare alle domande aperte che prevedono una riflessione e una risposta libera. Vi inviterei anche ad aggiungere commenti nei campi predisposti.
Ricordatevi che non ci sono risposte giuste o sbagliate. Possiamo migliorare le comunicazioni del RIAP solo basandoci su un quadro veritiero della situazione.
Il questionario è anonimo, ma qualora voleste approfondire il tema trattato, vi pregherei di lasciare un indirizzo email.
Le informazioni ottenute attraverso il questionario saranno utilizzate solo ai fini della presente ricerca, non saranno riportati ai terzi se non in forma aggregata e anonima e in tale forma potrebbero essere utilizzate ai fini di pubblicazioni scientifiche.
Grazie per la partecipazione!
Iuliia Urakcheeva,
PhD Student
Registro Italiano Protesi Impiantabili - ISS
Sapienza Università di Roma

**Sezione 1**
Il Gruppo di Lavoro RIAP aggiorna il CS sulle tematiche del RIAP sia per email che attraverso Teams. Ai membri del Comitato vengono mandati il verbale e le presentazioni di ogni riunione, i Report, le notizie su nuove pubblicazioni sul sito ed altri aggiornamenti. In questa sezione si prega di valutare la propria esperienza quale destinatario di tali informazioni.

* Indica una domanda obbligatoria

1.1. Quanto si sente informato/a dal gruppo di lavoro (GdL) RIAP? (da 1 a 5)*

1 (Scarsamente) – 2 – 3 – 4 – 5 (Sono informato/a su tutto quello che voglio sapere)

1.2. Come valuta le seguenti caratteristiche riguardo all'informazione che riceve periodicamente dal GdL RIAP? (da 1 a 5)*

*Tempestività*

1 (non adeguata) – 2 – 3 – 4 – 5 (supera le aspettative/estremamente adeguata)

*Qualità dei dati*

1 (non adeguata) – 2 – 3 – 4 – 5 (supera le aspettative/estremamente adeguata)

*Completezza*

1 (non adeguata) – 2 – 3 – 4 – 5 (supera le aspettative/estremamente adeguata)

1.3. Come valuta la quantità e frequenza dell'informazione condivisa periodicamente con Lei?*

- ○ scarsa
- ○ adeguata
- ○ eccessiva

1.4a. Come valuta la selezione dei temi dell'informazione, dal punto di vista del proprio interesse professionale?*

- ○ Raramente ricevo dal GdL RIAP quello che ritengo importante per me
- ○ La maggior parte delle informazioni del RIAP sono utili e/o interessanti, ma mancano alcuni temi
- ○ La selezione è assolutamente adeguata
- ○ Non saprei

1.4b. Se ritiene che manchino alcune tematiche o che ci siano mancanze nelle modalità dell’informazione, potrebbe indicare quali?

____________________________________

____________________________________

1.5. Ogni comunicazione prevede che ci sia un dialogo, un feedback. Nella comunicazione tra il GdL RIAP e il CS si fa ricorso alla possibilità di dialogare attraverso email, telefono, riunioni periodiche. In tal senso, come valuta la sua esperienza di interazione con il GdL RIAP?*

- ○ non soddisfacente
- ○ mediamente soddisfacente
- ○ soddisfacente

1.6. Quando ha una domanda relativa al RIAP (es. un quesito di natura tecnica, dati, un chiarimento, un approfondimento statistico, ecc), di solito in quale modo procede?*

- Contatto la segreteria scientifica/GdL RIAP
- Contatto la responsabile scientifica (Ing. Marina Torre)
- Consulto i materiali che ho già ricevuto come un membro del CS
- Consulto il sito RIAP
- Scrivo all’indirizzo riap@iss.it

Altro:
______________

1.7. In tale caso (domanda 1.6.), di solito quanto è soddisfatto delle risposte che riceve? (da 1 a 5)*

*Tempestività della risposta*

1 (non adeguata) – 2 – 3 – 4 – 5 (supera le aspettative/estremamente adeguata)

*Facilità di reperimento dei dati*

1 (non adeguata) – 2 – 3 – 4 – 5 (supera le aspettative/estremamente adeguata)

*Qualità informativa*

1 (non adeguata) – 2 – 3 – 4 – 5 (supera le aspettative/estremamente adeguata)

1.8. Quanto è d’accordo con la seguente affermazione? “Credo che la mia opinione venga sempre ascoltata e presa in considerazione dal GdL RIAP” (da1 a 5)*

1 (assolutamente disaccordo) – 2 – 3 – 4 – 5 (assolutamente d'accordo)

1.9. Quali di questi “prodotti comunicativi” del RIAP ha utilizzato nel suo lavoro nel corso del 2020? (è possibile dare più di una risposta)*
*Seleziona tutte le voci applicabili.*

- Report Annuale RIAP 2018
- Addendum al Report Annuale RIAP 2018
- Report Annuale RIAP 2019
- Compendio del Report Annuale RIAP 2019
- Addendum al Report Annuale RIAP 2019
- Informazioni per i pazienti disponibili sul sito (inclusa la Locandina)
- Sito RIAP (al di fuori della consultazione sul sito dei prodotti sopra elencati)
- Verbali delle riunioni CS RIAP

Altro: _____________

1.10. Di quale altro "prodotto comunicativo" o di quale altro tipo di informazione Lei avrebbe bisogno che il GdL RIAP rendesse disponibile per il Suo lavoro? ____________________

1.11. Secondo Lei, dal punto di vista della comunicazione quanto sono state efficaci le riunioni CS svolte in modalità telematica nel corso del 2020 rispetto alle riunioni svolte precedentemente in presenza?*

- molto meno efficaci
- leggermente meno efficaci
- non è particolarmente cambiata l'efficacia
- leggermente più efficaci
- molto più efficaci

Se possibile, Le chiedo cortesemente di argomentare la sua risposta alla domanda precedente

____________________________

____________________________

**Sezione 2.**
Sito web

2.12. Quando è stata l'ultima volta che ha consultato il sito RIAP riap.iss.it?*

- questa settimana
- più di una settimana fa
- più di un mese fa

Altro: _________

2.13. Per quale motivo ha consultato il sito RIAP l'ultima volta?

________________

2.14. Come descriverebbe la Sua ultima esperienza? (ha trovato quello che cercava e con quale velocità, se è stato facile navigare sul sito, ecc)*

- non soddisfacente
- mediamente soddisfacente
- soddisfacente

2.15a. In generale, riguardo alla Sua esperienza del sito RIAP, quanto è d'accordo con le seguenti affermazioni?*

*Il sito è strutturato in maniera chiara*

1 (assolutamente disaccordo) – 2 – 3 – 4 – 5 (assolutamente d'accordo)

*L'impostazione grafica del sito mi piace*

1 (assolutamente disaccordo) – 2 – 3 – 4 – 5 (assolutamente d'accordo)

*Di solito trovo velocemente quello che cerco*

1 (assolutamente disaccordo) – 2 – 3 – 4 – 5 (assolutamente d'accordo)

*Le informazioni pubblicate sul sito sono utili per il mio lavoro*

1 (assolutamente disaccordo) – 2 – 3 – 4 – 5 (assolutamente d'accordo)

*Le informazioni pubblicate sul sito sono utili per gli utenti esterni(medici, operatori sanitari, pazienti ed altri)*

1 (assolutamente disaccordo) – 2 – 3 – 4 – 5 (assolutamente d'accordo)

*Nel corso del 2020, il sito è migliorato*

1 (assolutamente disaccordo) – 2 – 3 – 4 – 5 (assolutamente d'accordo)

2.15b. Le chiedo, cortesemente, di riportare un commento libero riguardante le risposte date nella domanda precedente (ad esempio, se ritiene che qualcosa manchi sul sito RIAP, allora cosa vorrebbe che fosse migliorato, altro): ______________________________

2.15c. Se ritiene che la Sua esperienza dell'uso del sito, o la sua probabile efficacia per gli utenti (medici, operatori sanitari, pazienti ed altri) sia cambiata (sia in meglio che in peggio) durante il 2020, Le chiedo di indicare cosa sia cambiato di preciso: ______________________

**Sezione 3**
Il ruolo del CS nella veste di comunicatore con gli altri pubblici

3.1. In quale di queste occasioni e quanto spesso condivide le notizie/i dati del RIAP?*

*In uno scambio di notizie colloquiale tra i colleghi*

mai – raramente – spesso – ogni volta che ricevo informazione dal RIAP

*Nelle mie relazioni lavorative come presentazioni alle riunioni interne, rapporti, relazioni scientifiche a convegni/congressi, preparazione di seminari, lezioni agli studenti, ecc.*

mai – raramente – spesso – ogni volta che ricevo informazione dal RIAP

*Pubblicazione sui propri account social (LinkedIn, Facebook, Twitter)*

mai – raramente – spesso – ogni volta che ricevo informazione dal RIAP

*Pubblicazione sui canali del proprio ente (il sito istituzionale, LinkedIn, Facebook, Twitter)*

mai – raramente – spesso – ogni volta che ricevo informazione dal RIAP

3.2. In quali dei seguenti modi Le è capitato di utilizzare i dati analitici elaborati dal RIAP? (è possibile dare più di una risposta)*
*Seleziona tutte le voci applicabili.*

- ○ nelle presentazioni ai convegni
- ○ nelle pubblicazioni in giornali e riviste di settore
- ○ nelle pubblicazioni scientifiche
- ○ in interviste o altre forme di interazione con i giornalisti

Altro: ______________________

3.3. Nel corso del 2020, ha condiviso con qualcuno le informazioni del RIAP in lingua inglese? (è possibile dare più di una risposta)*
*Seleziona tutte le voci applicabili.*

- ○ No
- ○ Si, l'Addendum 2019
- ○ Si, l'Addendum 2018

Altro: ____________________

3.4. Di quale altro tipo di "prodotto comunicativo" del RIAP crede ci sia bisogno, e per quale destinatario? (ad esempio: i decisori regionali, i chirurghi ortopedici, gli operatori sanitari, i fabbricanti, i pazienti e loro famiglie, i ricercatori e gli studenti, eventuale pubblico internazionale) ______________________________________________

**Sezione 4**

Informazioni tecniche

4.1. Lei è:

- ○ membro effettivo del CS
- ○ membro del CS in qualità di sostituto
- ○ collaboratore attivo del CS

4.2. Lei è:
*Seleziona tutte le voci applicabili.*

○ Rappresentante di un'autorità sanitaria regionale o nazionale
○ Chirurgo esercente
○ Altro

4.3. Se ha piacere di essere ricontattato/a per un'intervista di approfondimento, può lasciare qui il suo indirizzo mail ____________________________