Programme for the Use of Real World Data in Health Technology Assessment.

Potential uses for Real World Data (RWD) in the Spanish HTA Network

Line of methodological developments of the Spanish Network of Health Technology Assessment Agencies and National Health System Services

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Abbreviations

BVS:	Bioresorvable Vascular Scaffold
SD:	Standard Deviation
RWD:	Real World Data
ENDS:	National Health Data Space
HTA:	Health technologu Assessment
GRADE:	Grading of Recommendations, Assessment, Development, and Evaluation
HIFU:	High-Intensity Focused Ultrasound
PREM:	Patient-reported Experience Measures
PROM:	Patient-reported Outcome Measures
RedETS:	Spanish Network of Health Technology Assessment Agencies and National Health System Services
SNS:	Spanish National Health System
HT:	Health Technology

Summary

This document proposes different uses for real-world data in the evaluation of health technologies carried out by the Spanish Network of Health Technology Assessment Agencies and National Health System Services (RedETS) and analyses the added value that these uses would represent for the performance of the evaluation activity of the agencies form it. The aim is to anticipate the creation of the National Health Data Space (ENDS). This document represents a starting point for the Programme for the Use of Real World Data (RWD) in Health Technology Assessment.

Introduction

Since its creation, the Spanish Network of Health Technology Assessment Agencies and National Health System Services (RedETS) has focused on providing a basis for decision-making on the adoption/de-adoption and/or change of use of health technologies (HTs), seeking to promote equality and sustainability in the Spanish National Health System (SNS). Health technology assessment (HTA) is a multidisciplinary process in which explicit methods are used to determine the value of an HT at various times in its lifecycle (from before market entry and during the approval process to the phases of obsolescence and disinvestment). In line with this, in the RedETS, we work to support decision-making to favour access to innovations that are really beneficial and efficient and avoid the promotion of those that have not shown to be effective, safe and cost-effective. In this sense, we are a cornerstone in the continuous updating of the common services portfolio of the SNS.

Worldwide, healthcare systems face increasingly complex challenges. In the healthcare sector, there are continuous technological advances and there is often a high degree of uncertainty regarding their real utility in clinical practice[1]. Healthcare policymakers need a basis, sometimes without delay, for decisions regarding coverage and resource assignment. The recommendations that we make in the RedETS are based on the best available scientific evidence. To date, this has required us to carry out, above all, systematic reviews of the literature, in which we assess the quality of the evidence using established methods, and then synthesise the data, all this in collaboration with the stakeholders (SNS professionals, patients, caregivers, scientific societies, and the industry). These reviews address various dimensions of the value of an HT compared to other options available. The dimensions of interest tend to be: clinical efficacy, safety, and efficiency; cultural, ethical, legal and social issues; organizational and environmental considerations; and in a wider sense, the potential implications for patients, their families and caregivers and the population. Through this analysis, we assess the current degree of uncertainty; and it is this uncertainty that accompanies the recommendations, and subsequently, the decision-making. To strengthen our efforts to support decision-making at key points, the RedETS is currently working on a new rapid response product line.

Real-world data (RWD) refer to those generated routinely in a health system. Making such data available and having the ability to analyse them,

thereby generating real-world evidence, would enable the RedETS to develop an assessment process that is rapid, can be revised, and provides more features such as the detection of unmet needs or the continuous updating of recommendations, making it possible to reduce the uncertainty (with respect to the level initially identified). With this, we will strengthen our ability to provide timely answers to the health system for decision-making, throughout the lifecycle of HTs.

Components 11 (Modernisation of public administration) and 18 (Renovation and expansion of the capabilities of the National Health System) of the Spanish Recovery, Transformation and Resilience Plan[2-4], propose the development of a data lake or Spanish Health Data Space (SHDS) that gathers data from health information systems and can respond to the need to improve diagnosis and treatment decision-making, determine risk factors, analyse trends, identify patterns, and predict situations that pose risks to health and/or healthcare provision.

In anticipation of the development of the SHDS, this document aims to indicate in which parts of our work, throughout the lifecycle of HTs, there are information needs that might be better met by the secondary use of RWD and envisage the value it could add to our task of supporting decision-making. To this end, it describes the information needs of the RedETS that could potentially be met by RWD in the pre- and post-adoption phases of HTs, as the starting point for the Programme on RWD Use in HTA.

Preadoption phase

The availability of RWD related to epidemiology, healthcare burden, variability in clinical practice, and key comparators or outcomes, among other factors, provides a unique opportunity in the phase before the adoption of an HT. In this phase, we identify the prioritisation of technologies to be assessed and the contextualization of the assessment, in particular, as key issues. Regarding these issues, the use of RWD potentially enables the RedETS to focus its attention on the technologies that are most important and necessary in the population seen by the SNS and tailor its work to the reality of this population, as well as identify the profile of potential users of new technologies and develop the detection of unmet needs.

A. Prioritisation of health technologies for assessment

Assessment needs are currently identified at national (Spanish) and regional levels. The bodies in charge of identifying and prioritising HTs complete HTA request forms to guide the development of the annual work plan of the RedETS, providing information to warrant the assessments[5]. These request forms are filled out manually with data on the characteristics of the technology, its indications and target population, alternative options, economic implications, etc.

After the submission of assessment requests, the prioritisation processes are key to identifying which technologies are going to be evaluated and which evidence-based products should be produced under each work plan. Currently, the RedETS has provided the HTA working group (part of the Commission for Services, Quality Assurance, and Funding) with the PriTec tool, which is a multicriteria analysis tool, with prioritisation domains that are selected and weighted, to guide the choice of which technologies to consider in given healthcare settings[6]. The PriTec tool is fed with the information provided in the requests submitted, and this approach is sometimes limited by uncertainties regarding how the technology would behave after adoption.

Access to RWD could provide the RedETS with a systematic process for collecting such information in a way that is more complete and better

suited to the context, thereby helping select the technologies for assessment and evidence-based products that are most urgently needed by the system.

Example: Table 1 lists the domains and criteria of the PriTec tool. Based on each of these, we can pose questions to the SHDS concerning each of the technologies for which assessment is requested. Based on analysis of the RWD, we would be able to estimate how many patients per year, in each level of care (hospital inpatients, outpatients, and primary care), have certain clinical characteristics and/or would be candidates for the use of given HTs being prioritised. Therefore, the Commission for Services, Quality Assurance, and Funding would have information for contextualising and prioritising technologies, for example, more detailed data on the severity and prevalence of specific clinical conditions, and the healthcare costs of interventions currently used.

Table 1. Domains and criteria in the PriTec tool

DOMAIN	CRITERION
Illness or medical condition	Severity of the illness/clinical condition
	Unmet needs
	Prevalence of the illness/medical condition
	Vulnerability
Comparative results	Safety
	Effectiveness
	Risk to health professionals or the environment
Economic impact	Healthcare costs associated with material resources used
	Other costs associated with care provision
	Non-healthcare-related costs
Feasibility of implementation	Organisational/structural impact
	Budget impact
	Cultural, ethical, legal and social implications
Considerations related to deployment	Benefits in terms of healthcare/efficiency
	Improvement in professional practice
	Interest/demand at social, political and professional levels
	Level of adoption

B. Contextualisation of the assessment

Once HTs to be assessed have been identified and prioritised, the next step is to define the scope, objectives and methods for their assessment. This phase is vital, as it involves starting to consider the context in which the technology will be applied, namely, the population, indications and treatment options.

Below, we describe the information needs related to the scope and objectives of an assessment and how the use of RWD could improve their definition.

- Identification of the relevant population

Generally, we use the information provided in the request form to set the objectives and formulate the research questions we seek to answer in our assessments.

In conducting our reviews of the literature, we observe that very strict inclusion criteria are applied to the populations included in research studies, making them "ideal populations", with a health status that differs from that of the population who would receive the HT in the context of routine practice. This information gap tends to be covered by seeking help from professionals who are very familiar with the health status and characteristics of the population of interest or consulting sources of administrative or research-related information (Spanish National Statistics Institute, minimum data sets, atlases of variation in healthcare, etc.).

Data mining of the SHDS, due to its ability to link different sources, can provide us with more accurate data on the populations of interest. It would enable us to:

- Measure the degree of similarity between populations analysed in the literature, to perform the necessary adjustments
- Focus our attention on certain groups according to disease severity, common comorbidities, sociodemographic characteristics, etc.
- Determine how many patients might benefit from the adoption of the new technology and at what levels of care, which will help us develop more reliable simulations of the technology's resource use, economic implications and budget impact.

Example: In an HTA report on the detection of diabetes complications, specifically, diabetic retinopathy, and the economic evaluation of ophthalmoscopic examination using ultra-widefield fundus imaging, the volume of patients who would be affected by the adoption of this new technology was determined using microdata from the 2014 European Health Interview Survey for Spain and the Atlas of Variation in Healthcare for people with diabetes concerning monitoring of their care[8]. Analysing microdata from the aforementioned survey, the number of patients eligible for diabetic retinopathy screening was estimated, and it was found that 81.62% of over-40-year-olds had had at least one medical consultation per year. Then, analysing the data from the Atlas on monitoring of diabetes care in five Spanish regions (Aragón, the Basque Country, Valencia, Canarias and Navarra), it was found that, among all over-40-year-olds seen during the 1-year study, 13.31% (SD=4.19) had diabetes, and of these, 34.72% (SD=27.34) had undergone fundus imaging within 3 years before the analysis, and hence, it was assumed that, in a year, fundus imaging was performed in 11.57% of diabetic patients. In this way, it was estimated that for a hypothetical cohort of 200,000 people (the mean catchment population of a health area), 2,514 patients would be screened per year.

The use of RWD would provide much more real data, gathered from routine clinical practice. We would not just have the real number of patients screened per year; in addition, we would be able to analyse the characteristics of the population (time since diagnosis, whether it is under control, existence of other complications, etc.).

- Identification of relevant comparators

The selection of comparators is a key step in formulating suitable research questions regarding the assessment of technologies. Comparators can be other specific techniques, the usual treatment, or no treatment.

In the framework of the RedETS, to help us select the most suitable comparator, we are guided by clinicians specialised in the relevant healthcare area and tools such as a questionnaire developed by the Andalusian Health Technology Assessment Agency[9]. This questionnaire can used together with information from the HTA request form, which specifies the most widely used alternative to the new HT.

In some cases, the studies available at the time of drafting HTA reports use comparators that do not reflect usual practice in our setting or analyse the results using the intervention to be assessed without making comparisons with other options. For proper assessment, it is necessary to clearly identify

which technology or technologies usually employed will be replaced or complemented by the new one.

The reuse of data collected by the system through the SHDS has the potential to show us what happens in routine practice, in terms of the technologies that are used and conditions under which they are used, the most common patient trajectories, and the points at which clinical decisions are made. This information would enable us to:

- Make additional comparisons beyond those reported in the literature, in turn, allowing us to estimate comparative effects for all the options available
- Build models that are more sophisticated and better informed (e.g., concerning the order in which actions are carried out, and the time between events), providing more accurate recommendations regarding the deployment and use of technologies.

Example: In a report on the effectiveness and safety of transcatheter aortic valve implantation compared to surgical valve replacement in patients with surgical aortic bioprosthetic valves that are failing (due to stenosis, regurgitation, or both) at low surgical risk for prosthetic valve replacement by open surgery[10], it was stated that it was not possible to find evidence that addressed the question posed. This was attributable to the fact that this population is considered at high surgical risk, and hence, precisely because of this high risk, the comparison procedure (surgical valve replacement) would be contraindicated, and in line with this, the studies that were found had not chosen the usual option in the SNS (surgical valve replacement) as a comparator.

In the end, the Delphi method was used to seek consensus from a panel of experts. In this process, panel members questioned the criteria for assigning surgical risk and stated that -in the light of the lack of alternatives- surgical treatment was used relatively often in these patients. The difficulty of finding studies with the comparator used in the SNS was attributable to the fact that, strictly speaking, patients who underwent surgery with the clinical condition under study should not have received this type of treatment (that is, the comparator). Additionally, such cases are rarely published even though they may be relatively common in practice.

Despite it not being possible to obtain data on safety and effectiveness in the SNS, as we are dealing with technology in the pre-adoption phase, the uncertainty reflected in the conclusions of the report could have been

redressed. That is, RWD could have provided relevant information, in particular, regarding the outcomes obtained with the comparator intervention in use in the SNS. With RWD, the report would have better reflected the reality in the SNS and provided a more robust response to the question posed. Such data would have complemented the opinions of the expert panel, and moreover, allowed it to issue recommendations based on more solid evidence.

- Identification of relevant results by group and characteristics

The Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) system suggests methods for selecting the most appropriate variables for assessment and their prioritisation[11]. This system, currently used in RedETS, is based on variables in the literature and the importance given to them and other variables by key agents, represented by individuals who participate in the HTA process - patients, clinicians and others-. This will determine which outcome variables are finally used in the process of evaluating the evidence.

Evidence extracted from the literature can have certain limitations, for example, results being presented exclusively in the form of clinical variables, with no use of final outcome measures or patient-reported outcome and experience measures (PROMs and PREMs respectively), or the time frame being too short to evaluate all relevant results, especially in the case of treatments for chronic diseases. At the start of the HTA process, the relative importance of outcomes is rated by participants in the assessment (clinicians and patients). This rating helps us select studies that report on final outcome measures related to the technology and exclude those that analyse effects on intermediate outcomes. Nonetheless, this process is at risk of not truly reflecting the reality of the condition assessed, in that it is subject to potential selection bias of participants, conflicts of interest, etc.

As mentioned above, our assessments address numerous dimensions, and for each of them, we must identify relevant outcome measures. As well as the health outcomes that inform us about efficacy/effectiveness and safety, we need to identify and quantify resource use (number of visits, length of hospital stay, use of drugs, etc.), adherence and persistence, organisational considerations, and patient values and preferences (treatment duration, discontinuation and reasons for discontinuation, etc.), types of data that are not so systematically recorded or are harder to access, or are less often reported in the literature.

Access to RWD would be useful to explore such variables of interest that are not reported at all or not reported in sufficient detail in the literature, to provide proof of the effects of the comparison technology and quantify adverse events that may not have been captured due to the limited time frames or sample sizes of the studies reviewed.

Post-adoption phase

Generally, on completion of an HTA report, decisions are made regarding the deployment of the new technology in the system. Nonetheless, as mentioned above, such decisions are made under conditions of more or less uncertainty as a function of the quantity and quality of the evidence available.

Therefore, the performance of the new technology in the context of the SNS (efficiency/effectiveness, safety and acceptance) may differ considerably from the estimates in an HTA based on published scientific evidence. For example, it may be that it is not deployed as expected, there are organisational limitations, or it is not well accepted by professionals and/or patients. In addition, it could be that the level of deployment differs between hospitals at different levels of care, generating unmet needs or inequalities in access to technological innovations.

The analysis of RWD could help us to assess health outcomes associated with the use of technologies after their deployment, the entire process of patient care, and the degree of adoption of HTs by different subgroups and at different levels of care within the SNS.

Unlike traditional approaches that are based on ad hoc data collection, the use of RWD would allow us to observe the adoption of technologies in real time and reduce uncertainties about their value through their lifecycle. This would enable us to:

- Update recommendations regarding the use of a given technology while it is being used in the real population in the SNS, thereby encouraging more appropriate use and noting special characteristics of our system in relation to its use
- Identify potentially obsolete technologies or those which after deployment fail to produce the expected results and hence would no longer be recommendable for the SNS, in turn, enabling the RedETS to play a more proactive role and provide the system with a greater ability to anticipate issues in relation to decision-making.

Example: For a report on the use of birthing pools in childbirth care in SNS hospitals (covering the extent and manner of adoption, barriers, facilitators, lessons learned, effectiveness and safety), it was decided to collect data through a questionnaire sent to hospitals in all the regions across Spain12[12]. Nonetheless, despite several reminders being sent to

recipients and the insistence of the researchers, responses were not received even from all the hospitals in the SNS where there were known to be birthing pools. Given this limited response, the questionnaires provided incomplete data on several basic variables, for example, the number of hospitals in the SNS that have birthing pools.

If we had had access to RWD, the quality of the data collected would have been strengthened, allowing us to obtain a complete map of all the hospitals equipped with birthing pools. Further, we could have obtained data on organisational issues, effectiveness and safety.

A. More effective updating of HTA report recommendations

The evidence available at the time of deciding on the adoption of technology in the health system tends to be scarce and/or of poor quality. This implies the need for the decisions taken to revisable as and when new information becomes available. With the generation of real-world evidence at post-adoption stages, we would be able to obtain new knowledge that would help us reduce the degree of uncertainty, and guide future updating of our products, revising our recommendations and/or developing new ones that are more detailed and better set in context.

The aforementioned paucity of information can be the result of systematic differences between efficacy as measured in controlled clinical trials and effectiveness under real-world conditions, which is known as the efficacy-effectiveness gap. Generally, in the clinical trials included in systematic reviews, strict conditions have been applied to patient selection and the use of intervention and comparison technologies, seeking to reduce the risk of bias. Therefore, it can be said that there are contextual factors that may act as modifiers of effectiveness under real-world conditions. The evidence generated through the analysis of RWD may help us understand factors that play a role as modifiers at various levels. Specifically, it would enable us to:

- Observe the characteristics of patients in whom technologies are used and their health conditions (for example, age, sex, behavioural factors, disease severity, and comorbidities)
- Analyse how technologies are adopted within the health system (for example, their deployment in different regions, the professionals that use them, and the levels of care where they are deployed)

- Determine how the real use of technologies evolves in clinical practice (for example, adherence, dosage, treatment duration, combined use with other technologies, and usage rates)
- Retrieve information on resource use associated with the deployment of technologies, which tends to come from contexts other than ours (implying differences in the organisation of services, unit costs, etc.).

With all this, we would be able to construct "live" assessment models that include data from the SHDS. As new data are generated in routine practice, we would be able to reduce the uncertainty associated with each of the parameters. In this way, the assessment of an HT would not stop when it is adopted by the system; rather, it would be a dynamic process during which we continue assessing the impact of the technology in various dimensions after its deployment in the medium and long term.

Example: In an HTA report on the treatment of myoma with high-intensity focused ultrasound (HIFU) in women seeking pregnancy[13], no good quality evidence was found to assess the real effectiveness of HIFU compared to other treatments for myoma removal, such as surgery. The availability of RWD might have helped us operationalise retrieval of information from the SHDS and continual updating of the assessment models and recommendations based on their results. In this case, the availability of RWD could have helped characterise the women who undergo HIFU therapy, as well as their pregnancy and childbirth experiences, compared to those in a control group of women who had undergone the usual procedure. The gaps in the evidence base could be addressed by operationalisation of the aforementioned retrieval of health information system data (from the SHDS) and updating of assessment models and recommendations.

B. Recommendations on disinvestment

Similarly, by allowing us to reduce the level of uncertainty assumed in the first assessment, post-adoption assessment would allow us to identify when technologies adopted are not having the expected or acceptable results for the SNS and should no longer be considered recommendable. This would be the case of, for example, a technology that once adopted is found to be unsafe or more expensive than estimated in the initial assessment. In addition, post-deployment assessment allows us to identify early technologies that may have become obsolete, whether because they have fallen out of use, are used little, or have been replaced in practice by others that perform better.

This would provide the RedEST with a greater ability to anticipate issues, allowing the network to recommend new assessments based on new indications for use detected or disinvestment in technologies considered obsolete.

Example: In an HTA report on the safety and effectiveness of bioabsorbable stents (bioresorb able vascular scaffolds, BVS) in the treatment of ischaemic heart disease due to de novo coronary lesions[14], published in 2013, it was concluded that BVS stents could be considered a promising technique, pending further evidence confirming the existing results. BVS stents were included in the SNS services portfolio with limited indications (service code VA 1 1 2: bioresorbable stent, for the treatment of ischaemic heart disease in patients with de novo lesions in the native coronary artery and with involvement of one or two vessels, beyond the acute phase of the myocardial infarction, with no contraindications to dual antiplatelet therapy and no involvement of the coronary trunk or history of aortocoronary bypass surgery)[15]. In 2017, data from the ABSORB III and AIDA trials as well as a meta-analysis were published demonstrating the inferiority of BVS stents compared to everolimus-eluting metal stents[16]. In this case, RWD might have been very useful for monitoring clinical outcomes of these devices, and based on these outcomes, determining whether the indications should be modified or the devices should be withdrawn. And today, RWD can help us assess how this technology is being used and influence the recommendation to disinvest.

Data from other sources

Further, we have identified other data sources that would provide information that could be important for us, in RedETS, to carry out assessments that are more comprehensive and better reflect the reality of our setting. Such data, since they are not generated routinely in the SNS, would not be part of the SHDS in its initial configuration.

- ## Integration of information systems of other government bodies

The incorporation of data collected systematically by other government bodies (such as the Ministries for Education, Development, Employment and the Ecological Transition) will improve our ability to analyse and quantify the impact of HT adoption in dimensions on which we have currently little information (environmental, ethical, and legal, among others), favouring the inclusion of a societal perspective in all our assessments.

References

1. Varela-Lema L, Ruano-Ravina A, Cerda Mota T. Observation of health technologies after their introduction into clinical practice: a systematic review on data collection instruments. J Eval Clin Pract. 2012;18(6):1163-9.
2. Gobierno de España. Plan de Recuperación, Transformación y Resiliencia. Componente 18 - Renovación y ampliación de las capacidades del Sistema Nacional de Salud. [Internet]. Madrid; 2021 [citado 21 de octubre de 2022]. Disponible en: https://www.lamoncloa.gob.es/temas/fondos-recuperacion/Documents/05052021-Componente18.pdf.
3. Gobierno de España. Plan de Recuperación, Transformación y Resiliencia. Componente 11 - Modernización de las Administraciones públicas. [Internet]. Madrid; 2021 [citado 21 de octubre de 2022]. Disponible en: https://www.lamoncloa.gob.es/temas/fondos-recuperacion/Documents/05052021-Componente11.pdf.
4. Gobierno de España, Ministerio de Sanidad, Secretaría General de Salud Digital Información e Innovación para el SNS. Estrategia de salud digital. Sistema Nacional de Salud [Internet]. Madrid; 2021 dic [citado 21 de octubre de 2022]. Disponible en: https://www.sanidad.gob.es/areas/saludDigital/doc/Estrategia_de_Salud_Digital_del_SNS.pdf.
5. Gobierno de España, Ministerio de Sanidad Consumo y Bienestar Social, Red Española de Agencias de Evaluación de Tecnologías Sanitarias y Prestaciones del Sistema Nacional de Salud. Memoria de actividades 2006-2016. Diez años cooperando en evaluación de tecnologías sanitarias. Madrid; 2019.
6. Varela Lema L, Maceira Rozas M, Prieto Yerro I, Arriola Bolado P, Asúa Batarrita J, Espargalles Carrera M, et al. Herramienta PriTec: adaptación para la selección de tecnologías a evaluar previa entrada en cartera de servicios. Santiago de Compostela: Agencia Gallega para la Gestión del Conocimiento (ACIS). Unidad de Asesoramiento Científico-técnico, Avalia-t; 2018.
7. Instituto Nacional de Estadística. Encuesta Europea de Salud en España 2014. Madrid; 2015.
8. Martín Sánchez JI, Muñoz Fernández C, Blas Diez MP. Detección de complicaciones de la diabetes. Retinopatía diabética. Evaluación

económica de la oftalmoscopia por exploración con láser campo ultra-amplio. Ministerio de Sanidad, Consumo y Bienestar Social. Instituto Aragonés de Ciencias de la Salud; 2019. Informes de Evaluación de Tecnologías Sanitarias: IACS.

9. Agencia de Evaluación de Tecnologías Sanitarias de Andalucía. Guía para la elaboración de informes de síntesis de evidencia: medicamentos. Documento metodológico. Sevilla; 2015.

10. Jurado López A, Larman Telechea M, Moreno Gómez Raúl, Rodríguez Salvanés F, Novella Arribas B. Ventajas diferenciales de las distintas prótesis percutáneas de reemplazo de válvulas aórticas; Estudio de personalización. Red Española de Agencias de Evaluación de Tecnologías y Prestaciones del SNS. Unidad de Evaluación de Tecnologías Sanitarias de Madrid; 2017. Informes de Evaluación de Tecnologías Sanitarias.

11. Guyatt GH, Oxman AD, Kunz R, Atkins D, Brozek J, Vist G, et al. GRADE guidelines: 2. Framing the question and deciding on important outcomes. J Clin Epidemiol. 2011;64(4):395-400.

12. Reviriego E, Ibargoyen-Roteta N, Carregui S, Mediavilla L, Montero S, Ares G, Castelló B, Moreno A, Hernández N, Koetsenruyter C. Inmersión en agua durante el parto. Ministerio de Sanidad. Servicio de Evaluación de Tecnologías Sanitarias del País Vasco; 2022. Informes de Evaluación de Tecnologías Sanitarias: OSTEBA.

13. Vivanco-Hidalgo RM, Moharra M. US-HIFU en el tractament de miomes uterins. Informe de resposta ràpida. Barcelona: Agència de Qualitat i Avaluació Sanitàries de Catalunya. Departament de Salut. Generalitat de Catalunya; 2021.

14. Puñal Riobóo J, de la Fuente Cid R. Seguridad y efectividad de los stents biorreabsorbibles (Bioresorvable Vascular Scaffold, BVS) en el tratamiento de la cardiopatía isquémica debida a lesiones coronarias de novo. Santiago de Compostela: Red Española de Agencias de Evaluación de Tecnologías y Prestaciones del SNS. Axencia de Avaliación de Tecnoloxías Sanitarias de Galicia; 2013.

15. Orden SSI/1356/2015, de 2 de julio, por la que se modifican los anexos II, III y VI del Real Decreto 1030/2006, de 15 de septiembre, por el que se establece la cartera de servicios comunes del Sistema Nacional de Salud y el procedimiento para su actualización, y se regulan los estudios de monitorización de técnicas, tecnologías y procedimientos. Boletín Oficial del Estado núm. 162, de 8 de julio de 2015, páginas 56595 a 56625.

16. Sorrentino S, Giustino G, Mehran R, Kini AS, Sharma SK, Faggioni M, et al. Everolimus-Eluting Bioresorbable Scaffolds Versus Everolimus-Eluting Metallic Stents. J Am Coll Cardiol. 2017;69(25):3055-66.