

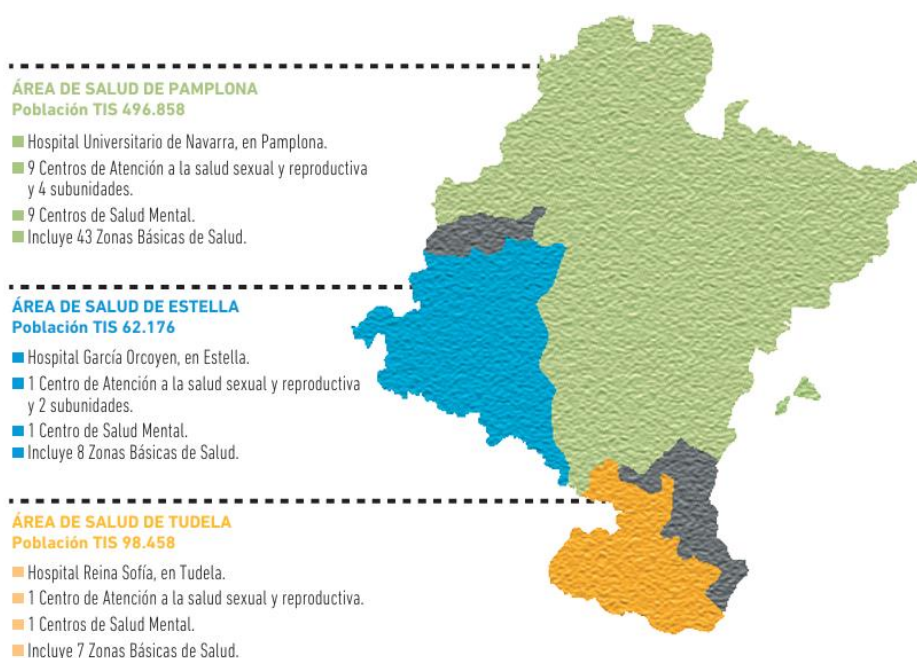
# ANNEX 1: ACCESS TO URGENT ULTRASONOGRAPHY AS A FUNDAMENTAL PART OF COMPREHENSIVE AND CONTINUOUS ASSISTANCE TO THE CITIZEN

## BACKGROUND

The Navarra Health Service - Osasunbidea, hereinafter SNS-O, is an autonomous body that assumes responsibility for managing the public health services of Navarra. It acts under the guidelines and strategic objectives of the Department of Health, to which it is attached, and must be accountable for its results in terms of efficiency, effectiveness, safety and satisfaction of citizens and patients.

Navarra divides its territory into geographical demarcations in order to facilitate health care, taking into account the health needs of each territory and a rationalization of resources. Primary and Specialized Care is divided into three Health areas, in each of which there is a reference Hospital: Hospital Universitario de Navarra (HUN) in the Pamplona Area, García Orcoyen Hospital in the Estella Area (HGO) and the Reina Sofía Hospital in the Tudela Area (HRS).

The distance between HUN and HGO is 42 km (36 minutes), between HUN and HRS is 96 km (1 hour and 3 minutes) and between HGO and HRS is 98 km (1 hour and 10 minutes). The HGO is located in the western part of the territory, the HRS in the south.



DISTRIBUTION OF INFRASTRUCTURES. EQUIPMENTS AND TIS POPULATION BY HEALTH AREAS. Source: SNS-O 2022 Report.

The HUN is a public hospital that emerged in 2010 from the integration of the Specialized Care health centers located in Pamplona and its region and constitutes a tertiary hospital for all of Navarra and, sometimes, for populations in neighboring communities.

The three centers have Radiology services with the following human resources:

HOSPITAL	RADIOLOGISTS
HUN	54
HGO	2
H.R.S.	6

Currently, the lack of radiologists is a reality in European countries. In some, such as the United Kingdom (especially after Brexit), the British Health Service (NHS) is outsourcing its radiological tests to specialists in other countries due to staff shortages and backlogs. wait after the pandemic.

In Spain, rural areas have the greatest shortage of professionals, and this problem may increase in the coming years, as the Spanish Society of Medical Radiology (SERAM) has been announcing.

Tele-radiology, defined as the electronic transmission of radiological images from one location to another with the main purpose of interpreting or consulting a diagnosis, can help solve this problem. Thanks to this technology, radiologists have the possibility of making remote reports, for example, of a CT scan, MRI or an x-ray that a person had at another center.

Diagnosis by ultrasound, however, continues to require the presence of the professional and the patient in the same place and is a limitation in the case of not having said professional. The problem is aggravated if the pathology is urgent.

When an urgent ultrasound is required and there is no radiologist in Navarra, three situations can arise:

- Delay of the examination until a radiologist can be reached (generally until the next day).
- Performing computed tomography, an alternative test that uses ionizing radiation and sometimes requires intravenous contrast.
- Transfer to the tertiary hospital for urgent ultrasound.

And, of course, all this generates a series of additional uncertainties and inconveniences for patients, associated costs for the SNS-O and a reduction in healthcare quality.

For all these reasons, the SNS-O plans to go beyond the current conventional ultrasound model and evaluate new systems that guarantee care for SNS-O patients, contributing to the efficiency and equity of the system.

## STATE OF THE ART ALREADY IDENTIFIED TELE-ULTRASONOGRAPHY

Tele-radiology consists of the electronic transmission of radiological images from one place to another, for interpretation and/or consultation. It has the following objectives:

- Provide radiological consultations to medical services that do not have local radiological support.
- Facilitate radiological interpretations in on-call situations.
- Provide availability of evaluation and interpretation of radiological images in emergency and non-emergency situations.
- Provide consultative and interpretive radiology services.
- Supervise imaging studies remotely.
- Provide support to radiological subspecialties.
- Improve radiological training.
- Promote efficiency and improve the quality of reporting.

Ultrasounds and interventional procedures are the only modalities that require in-person medical professionals.

Tele-ultrasound combines the use of ultrasound with telemedicine, allowing it to be interpreted by outsiders. It can be done in two ways:

1. With synchronous transmission, in which the examiner and the specialist are connected through a real-time connection. A specific modality of synchronous transmission is robotic tele-ultrasound, where the remotely connected specialist remotely operates a robot that performs the test on the patient in situ.
2. With asynchronous transmission, in which the images are acquired by a sonographer and subsequently transmitted to a specialist for review.

There are currently examples of robotic systems for tele-ultrasound.<sup>1</sup> The fundamental information available about them comes directly from marketing companies, and sometimes it cannot be established whether these systems are capable of carrying out all the tests that are currently carried out with conventional ultrasound machines, as well as their precision, quality, usability, , etc.

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<sup>1</sup> Some examples (not exhaustive), already identified:

A) MELODY – Telerobotic ultrasound solution. <https://www.adechotech.com/products/>

B) Tele-ultrasound system for ROSE abdominal ultrasound  
<https://www.medicaexpo.es/prod/sensing-future-technologies/product-118872-957025.html>

C) Tele-ultrasound system for general ultrasound MGIUS  
<https://www.medicaexpo.es/prod/mgi-tech/product-128605-1027886.html>

D) Tele-ultrasound system for general ultrasound MGIUS-R3  
<https://www.medicaexpo.es/prod/mgi-tech/product-128605-1026070.html>

E) ARTHUR musculoskeletal ultrasound tele-ultrasound system  
<https://www.medicaexpo.es/prod/ropca-aps/product-4579083-1099661.html>

There are few studies<sup>2</sup>available that show clinical results with some of these diagnostic tools. They focus on evaluating the suitability of performing specific types of ultrasounds using tele-ultrasound.

However, the quality of evidence on the effectiveness and accuracy of tele-ultrasound remains unknown. Therefore, there are some reviews<sup>3</sup>carried out with the objective of evaluating through scientific literature the evidence that exists regarding the use of telemedicine for ultrasound.

The authors conclude that, despite the promising position of tele-ultrasound within telemedicine, studies with reasonable methodological quality have not yet been carried out. Studies with greater methodological rigor, and preferably large-scale randomized clinical trials that evaluate the diagnostic accuracy of the methodology, using comparisons with the traditional methodology of the procedure, are still necessary to establish definitive conclusions.

In our country, there are beginning to be some experiences of using tele-ultrasound. The following have been identified:

- 1) In Andalusia, a training experience in a remote ultrasound system has been carried out specifically at the Virgen de las Nieves University Hospital in Granada. It is a robotic system that tries to alleviate the lack of sonographers in rural areas, avoiding travel to offer a diagnosis or screen the severity of an ailment. According to the Health Technology Park Foundation, promoter of this initiative, the aim would be to achieve the deployment of the first remote ultrasound system in Spain.

**<https://granadaessalud.es/2022/03/25/radiologos-granadinos-proban-un-nuevo-sistema-de-ecografia-a-distancia-de-la-mano-de-la-fundacion-pts/>**

- 2) In Catalonia, at the Vall d'Hebron Hospital they have been testing tele-ultrasound for 9 months. In their experience, the learning curve for radiologists applying the system is very fast.

For now, they are specific experiences of a technology with a very great potential for evolution and development in the coming years. Especially when the need for its use is

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<sup>2</sup>a) Adams SJ, Burbridge BE, Badea A, Langford L, Vergara V, Bryce R, et al. Initial Experience Using a Telerobotic Ultrasound System for Adult Abdominal Sonography. *Can Assoc Radiol J.* 2017;68(3):308-314. doi: 10.1016/j.carj.2016.08.002.

b) Adams SJ, Burbridge B, Chatterson L, Babyn P, Mendez I. A Telerobotic Ultrasound Clinic Model of Ultrasound Service Delivery to Improve Access to Imaging in Rural and Remote Communities. *J Am Coll Radiol.* 2022;19(1 Pt B):162-171. doi: 10.1016/j.jacr.2021.07.023

<sup>3</sup>a) Duarte ML, Ribeiro dos Santos L, Iared W, Peccin MS. Telementored ultrasonography: a narrative review. *Sao Paulo Med J* 2022;140(2):310-319. DOI: 10.1590/1516-3180.2020.0607.R2.15092021

b) Marsh-Feiley G, Eadie L, Wilson P. Telesonography in emergency medicine: A systematic review. *PLoS ONE* 2018; 13(5): e0194840. DOI: 10.1371/journal.pone.0194840

c) Britton N, Miller MA, Safadi S, Siegel A, Levine AR, McCurdy MT. Tele-Ultrasound in Resource-Limited Settings: A Systematic Review. *Front Public Health.* 2019;7:244. DOI: 10.3389/fpubh.2019.00244

more imperative every day, given the problems described in the previous section of this document.

## PURPOSE OF THE CHALLENGE

The objective of the challenge is to find solutions and services that help the SNS-O to guarantee citizens access to urgent ultrasound in the hospital closest to their place of residence, maintaining the quality of the service and reducing unnecessary transfers, all of this counting on the available health resources.

Along these lines, although what is presented below could be written based on previous experiences, we want to emphasize that what we intend is to listen to the market about all types of solutions from the point of view of technology, service to receive, organizationally or from any other perspective that offers us a global vision to make the decision that we consider most appropriate.

Therefore, companies that submit information to this consultation must do so with the freedom to consider what could best adapt to the challenge posed without it being imperative that it adapt to the concept of supply, service or others.

The SNS-O has identified the following areas of action or specific objectives that must at least be addressed by the proposals that respond to this Preliminary Market Consultation

- 1) Support in the design and implementation of a solution that allows urgent tele-ultrasound to be performed on all patients who require it in the García Orcoyen and Reina Sofía hospitals (when they do not have an in-person radiologist). These solutions may be different alternatives to the background information presented in this document, as long as they meet the stated objectives.**
- 2) Provide tools for analysis and evaluation of the tele-ultrasound program for compliance with the established standards and indicators of the activity, as well as the contribution to scientific knowledge in its scope of application.**
- 3) Propose contractual formulas to guarantee continuous technological updating during the term of the eventual contract resulting from this Preliminary Market Consultation. This update must guarantee that at all times the diagnostic process occurs with the highest quality and efficiency.**

## BACKGROUND INFORMATION ON THE OBJECTIVES AND EXPECTED RESULTS

- 1. Support in the design and implementation of a solution that allows urgent tele-ultrasound to be performed on all patients who require it at the García Orcoyen and Reina Sofía hospitals (when they do not**

**have an in-person radiologist) throughout the duration of the contract.**

The organization of the Navarrese Health Service-Osasunbidea rests on the two organizational references for the provision of health care, the territorial one based on Health Zoning, which is developed by Foral Law 22/1985, and the functional one that differentiates Primary Care and Specialized Assistance. Currently in Navarra there are 57 basic health zones that are grouped into three health areas: Pamplona, Estella and Tudela.

The HUN area includes 43 basic health zones, with a population of 496,858 people. The HGO includes 8 basic health zones, with a population of 62,176 people. And the HRS includes 7 basic health zones, with a population of 98,458 people.

The total emergency activity in hospitals in Navarra:

HUN: emergency activity 2022: 181,351, 17% increase compared to 2021.

HRS: Emergency activity 2022: 56,716, increase of 14.8% compared to 2021.

HGO: Emergency activity 2022: 27,999, increase of 22.1% compared to 2021.

Specifically, the urgent ultrasounds performed in the three hospitals in 2022 and 2023 were:

Hospital Universitario de Navarra				Hospital Reina Sofia				Hospital García Orcoyen			
2022		2023		2022		2023		2022		2023	
ECO	ECO Pediátrica	ECO	ECO Pediátrica	ECO	ECO Pediátrica	ECO	ECO Pediátrica	ECO	ECO Pediátrica	ECO	ECO Pediátrica
13.330	2.670	11.443	2.476	1.777	141	1.611	150	1.242	1	1.591	21
16.000		13.919		1.918		1.761		1.243		1.612	

The main indications for urgent ultrasound in adults are:

1. Abdomino-pelvic ultrasound
2. Echo-doppler of limbs
3. Testicular ultrasound
4. Musculoskeletal ultrasound
5. Soft tissue ultrasound

In the case of children:

1. Abdomino-pelvic ultrasound
2. Soft tissue ultrasound
3. Testicular ultrasound
4. Musculoskeletal ultrasound
5. Transfontanelar ultrasound
6. Extremity echo-doppler

It is also observed that the time slots in which the lowest number of emergency ultrasounds are performed both on weekdays and on holidays, in the HRS and HGO hospitals, are between 4 and 6 in the morning.

In anticipation of possible situations of absence of a radiologist, it is necessary to look for alternatives that allow patients who require urgent ultrasound in these centers to be treated by resorting to teleradiology.

According to teleradiology good practice guidelines:

**a) *The primary consideration of teleradiology should be the best interest and benefit of the patient.***

- 1- Attention to patients who require an urgent ultrasound: any urgent radiological test must be performed in less than 3 hours from its request.
- 2- Reduction of transfers attributable to the absence of an emergency radiologist.
- 3- Reduction of non-indicated scanners.

**b) *The quality and safety of the teleradiological act will be similar to that provided by in-situ radiology services.***

1. The ultrasound machine must be high-performance, with Doppler mode, with sufficient quality for the assessment of deep abdominal structures, with the possibility of connecting at least 2-3 low and high frequency transducers, and with storage and transmission capacity. images according to the DICOM standard.
2. The team must guarantee the visualization of the ultrasound image both at the execution site and remotely, with the same quality in both. The equipment must allow remote visualization of both the patient and the ultrasound equipment, especially the positioning of the transducer on the patient's surface. The patient must be able to visualize the radiologist directing the examination. In addition, real-time verbal communication between radiologist, auxiliary staff and patient must be guaranteed.
3. If the proposal includes remote robotic handling, the system must respond in real time to the radiologist's orders and be versatile enough to access all the patient's anatomical areas.

**c) *Preminent position of on-site services: teleradiology should be used as a complement and support of the on-site radiology service.***

The successful bidder must train the staff and make the necessary adjustments to make good use of the equipment's characteristics, so the proposal must include a training plan for all staff, both radiologists and auxiliary or TER personnel who work with the equipment. equipment in premises, in which the theoretical and practical training necessary for its correct use will be described.

**d) *Data protection and confidentiality***



1. The data can only be accessed by authorized personnel and the control of both access and permissions over them must be perfectly regulated (such as if only mere consultation is allowed, or if the user has enabled edition).
2. Data encryption must be guaranteed at all times, both during data communication and during information storage.

**2. Provide tools for analysis and evaluation of the tele-ultrasound program for compliance with the established standards and activity indicators, as well as the contribution to scientific knowledge in its scope of application.**

In addition to the program's own activity indicators available in the SNS-O information systems (number of urgent ultrasounds, types, transfers...), there are others required to evaluate program compliance that are more difficult to obtain: Organs visualized, pathological findings visualized, inconclusive ultrasounds, ultrasounds not feasible due to lack of patient collaboration (children, elderly, disabled...), transfers, conversion to CT...

On the other hand, it has been detected that there are not many studies on the use of this technology with reasonable methodological quality.

The evaluation of the tele-ultrasound program, launched by the SNS-O, must be designed with methodological rigor to contribute, not only to monitoring it, but also to improving existing knowledge about the use of this technology. The contribution of operators in the design and implementation of this evaluation is part of the comprehensive support expected of them.

**3. Propose contractual formulas to guarantee continuous technological updating during the term of the eventual contract resulting from this Preliminary Market Consultation. This update must guarantee that at all times the diagnostic process occurs with the highest quality and efficiency.**

As concluded in the state of the art section of this document, tele-ultrasound is a technology with a very important potential for evolution and development in the coming years.

Therefore, it is likely that the use of this in the SNS-O will contribute to the developments and technological evolutions of the solution that occur in the market and that can be provided by the contractor of the tender that may arise from this Preliminary Consultation to the Market.

Therefore, the proposal must include not only the maintenance of said technology but also contractual formulas for the implementation in the SNS-O of said technological evolutions (if they occur) during the term of the eventual contract.



Likewise, it is the object of the Preliminary Consultation to the Market to know what types of contract the market understands that may be more appropriate, within service contracts, or in the event that the SNS-O decides to acquire the equipment used to ultrasounds, in mixed supply and service contracts. That is, the SNS-O wants to know the approaches that the market proposes for the payment of the contract (pay per use, renting, leasing, etc.) and the amortization or acquisition of the equipment, as well as, as has already been said, its eventual replacement with more innovative technologies and better features that may arise during the term of this agreement. The duration of the ideal contract, from the market point of view, is another aspect that is consulted.

## **CONTRACT DURATION AND ESTIMATED MAXIMUM ANNUAL BUDGET**

The object of the preliminary consultation with the market is to ask market operators what the most appropriate period should be for the execution of the services described in the consultation. Only as a guideline, it is indicated that the contracting body assesses the possibility that the future contract may have a duration of up to 5 years.

Likewise, the object of the preliminary market consultation is to ask market operators what the most appropriate budget should be for the execution of the services described in the consultation. Only as a guideline, it is indicated that the contracting body assesses the possibility that the future contract may have a maximum budget of 1 million euros, VAT excluded (anticipated annual budget: €200,000, VAT excluded), assessing, however, proposals for a larger budget if they adequately justify the relevance of making a larger investment.

However, there is interest on the part of the contracting body to detect possible solutions to the challenge posed, which are as economical as possible for the sake of efficiency in public spending.

Solely, with the interest of providing information to the market, and at no time to guide or condition the solutions it proposes, some of the costs that we understand the eventual contractor could incur and the estimate that has been made are described below. to date, of these.

- 1) Support in the design and implementation of a solution that allows urgent tele-ultrasound to be performed on all patients who require it at the García Orcoyen and Reina Sofía hospitals (when they do not have an in-person radiologist) throughout the duration of the contract.**

As a reference for the market, it should be noted that a first estimate has been made of the possible cost of a device that could be operated from the University Hospital of Navarra, with a terminal (patient end) in each regional hospital, which would imply an investment of €650,000. , VAT excluded.

Likewise, other costs such as maintenance, training, supply, etc. will also have to be taken into consideration.

**2) Provide tools for analysis and evaluation of the tele-ultrasound program for compliance with the established standards and indicators of the activity, as well as the contribution to scientific knowledge in its scope of application.**

In relation to this objective, the initial cost estimates, made with the same safeguards as in the previous objective, are the following:

- Dashboard preparation: €50,000, VAT excluded.
- 1 Publication in an open-access journal on the results of the evaluation of the tele-ultrasound program: €4,000, VAT excluded.
- Annual presentation of the results of the tele-ultrasound program: €4,000, VAT excluded.

**3) Propose formulas to guarantee continuous technological updating during the term of the eventual contract resulting from this Preliminary Market Consultation. This update must guarantee that at all times the diagnostic process occurs with the highest quality and efficiency.**

It is expected that the participants in this Preliminary Market Consultation, as already indicated, will propose contractual formulas for technological updating, indicating the additional cost, if applicable, that it could have for the overall contract.

Initial estimates of this cost are €292,000, VAT excluded.