

Home imaging diagnosis around the world: market research and documentary analysis

Diagnóstico por imagem em domicílio no mundo: uma pesquisa de mercado e análise documental

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Resumo: Apesar do crescimento da realização de diagnósticos por imagem em domicílio, com o avanço da telemedicina, ainda faltam diretrizes e padrões de segurança bem definidos. **Objetivo:** Mapear e caracterizar empresas que realizam diagnósticos por imagem em domicílio, e as legislações que regulamentam esses serviços no mundo. **Métodos:** O estudo utiliza análise documental com abordagem quantitativa e qualitativa. Realizou-se uma pesquisa de mercado que incluiu empresas que ofereciam serviços de diagnóstico por imagem em domicílio e uma pesquisa documental que abrangeu leis e regulamentações nacionais sobre esses serviços. Ambas as pesquisas foram feitas via Google, baseadas na relevância. Os dados quantitativos foram analisados por frequência absoluta e relativa, e os qualitativos, pela análise de conteúdo de Bardin. **Resultados:** Doze países apresentavam empresas que realizavam esse tipo de serviço, sendo distribuídas em diversos contextos socioeconômicos e realizavam em grande maioria raio-x e ultrassom. Dezesesseis documentos de regulamentações referentes a nove países foram incluídos. Os resultados apresentaram diferentes enfoques agrupados nas categorias: segurança, privacidade, documentação clínica, critérios de aplicação, equipamentos e equipes de diagnóstico. **Conclusão:** Essas descobertas ressaltam a importância de desenvolver e regulamentar serviços de diagnóstico domiciliar para atender às necessidades específicas da população, garantindo maior qualidade de serviço.

Palavras-chave: Diagnóstico por imagem. Portátil. Assistência Domiciliar.

Abstract: The performance of diagnostic imaging at home has grown with the advancement of telemedicine. However, there is a lack of well-defined guidelines and safety standards. **Objective:** To map and characterize companies that perform diagnostic imaging at home, and the laws that regulate these services worldwide. **Methods:** The study uses documentary analysis with a quantitative and qualitative approach. A market survey was conducted that included companies that offered diagnostic imaging services at home and a documentary survey that covered national laws and regulations on these services. Both surveys were conducted via Google, based on relevance. Quantitative data were analyzed by absolute and relative frequency, and qualitative data were analyzed by Bardin's content analysis. **Results:** Twelve countries had companies that performed this type of service, distributed in different socioeconomic contexts and mostly performed x-rays and ultrasounds. Sixteen regulatory documents related to nine countries were included. The results presented different approaches grouped into the following categories: security, privacy, clinical documentation, application criteria, equipment and diagnostic teams. **Conclusion:** These findings highlight the importance of developing and regulating home diagnostic services to meet the specific needs of the population, ensuring higher quality of service.

Keywords: Diagnostic Imaging. Portable. Home Care.

The COVID-19 pandemic has brought a new perspective to

Introduction

the development and adoption of *eHealth*, defined by the World Health Organization (2022) as the “safe and cost-effective use of Information and Communication Technologies (ICT) in support of health and related areas.” These technologies include telehealth, telemedicine, mobile health (*mHealth*), electronic medical records (eMR/eHR), big data, *wearables* and artificial intelligence. An *eHealth* can be a promising solution to challenges in providing care, especially to the older people, due to mobility and safety issues. These technologies can reduce travel time and exposure to new health risks in hospital centers (Bujnowska-Fedak; Pirogowicz, 2014).

Home diagnostic imaging services require healthcare professionals with skills in *eHealth* (Barakat *et al.*, 2013) and confidence in using these skills (Van Houwelingen *et al.*, 2019), ensuring alignment with user needs (Antonietti *et al.*, 2013). The importance of remote technology for healthcare is highlighted by the growing amount of *eHealth* solutions during the COVID-19 pandemic.

Home imaging diagnosis is an important tool in medical practice, allowing the detection of pathologies in a non-invasive and comfortable way, providing greater calm and safety to patients (Bisgaard *et al.*, 2021). Furthermore, it reiterates the provisions of Ordinance 825 (Brasil, 2016), eliminating mobility barriers and contributing to access to healthcare for older people with reduced mobility, reducing hospital demand.

Public policies that promote, develop and regulate home health diagnostic services are essential to meet the specific needs of the population, ensuring inclusive and quality access (World Health Organization, 2021; Brazil, 2020). These services even benefit bedridden older people, allowing full access to health services within their limitations (Deoni *et al.*, 2022; Płońska-Gościński *et al.*, 2019). It is important to identify companies that perform this type of service and evaluate the relevant legislation to ensure patient safety and privacy.

To date, we have not found studies in the literature that bring together companies providing home diagnostic imaging services, or which map the laws that regulate these services. The objective of this study is to map the companies that offer these services and the existing legislation, contributing to the discussion of feasibility and basic implementation guidelines in public health.

Material and methods

The present study falls within the perspective of document analysis with a quantitative and qualitative approach. The study had three stages: eligibility phase of literature scoping review, market research of companies that perform diagnostic imaging services at home and documentary review of legislation on the provision of diagnostic imaging services at home. This study was approved by the Human Research Ethics Committee of the Federal University of São Carlos

(UFSCar), under number CAAE: 69013223.2.0000.5504, approval opinion N° 6.454.104.

Initially, the scoping review stage of the literature registered in: Open Science Framework under DOI 10.17605/OSF.IO/7UV5D was carried out, with the following search terms: diagnostic imaging, portable, home and perspectives, as well as their related terms. Other information from the literature scoping review, such as databases investigated, eligibility, inclusion and exclusion criteria, as well as the review stages are specified in this same DOI.

The market research phase was conducted based on the 45 countries identified in the literature scoping review. The research question of this phase was: “Which companies provide home imaging diagnostic services in the selected countries?”. To locate companies that perform diagnostic imaging services at home, we used the Google search tool with the *string* search: “image diagnosis” AND (*mobile OR portable OR “at home”*) AND company AND “name of the country”, for each of the 45 countries. This search string was searched in the primary language of each country. There was no date restriction during the search. It was selected the first company to appear in the search that offered home diagnostic imaging services, according to the first 20 results, following the relevance algorithm. The search was carried out from March to April of 2024. One reviewer read the search results to include the companies. Any doubts were resolved through discussion with other reviewers.

The companies' inclusion criteria were: providing diagnostic imaging services at home and having a website or social network with company information.

The included companies were registered in a data extraction form, in an Excel spreadsheet, with the following domains: identification (name, email address, opening hours); location (country with income classification and city where the headquarters is located with number of inhabitants); branch of activity of the company (for example, mobile digital diagnosis, health plan); nature of the service (distinction between public and private); types of mobile diagnostics performed; professionals who work in the company; technical professionals involved in carrying out diagnostic imaging services at home; target audience (distinction between general and specific); ways of paying for the service; all services that the company performs; and other observations about the company.

In addition to the steps mentioned above, in this study documentary research of legislation was carried out to identify documents from official bodies in each country in which the companies were found to verify laws and regulations regarding the operation of diagnostic imaging services at home in the country. The research question of this phase was: “Which laws regulate the performance of diagnostic imaging exams at home in the selected countries?”.

For this documentary research, a Google search was carried out using the search string: *home-based diagnostic imaging guidelines OR regulations OR standards OR protocols OR legislation OR directives AND "name of the country"*, with terms translated into the languages of the respective countries. This search string was searched in the primary language of each country. There was no date restriction during the search. The first twenty search results were checked according to Google's relevance algorithm, checking all the results that appeared. The search was carried out in an anonymous Google Chrome tab in July 2024. Two reviewers independently read the search results in order to include the legislation. Any doubts were resolved through discussion between the reviewers. In addition to the search, e-mails were sent to the contacts of the companies included in the previous phase, asking them to inform us of the legislation that governs the performance of diagnostic imaging in the country. Two companies returned informing what the legislation was.

Documents were included if they were laws or regulations of agencies in the country researched and if they promoted or determined the provision of diagnostic imaging services at home. Information such as identification of the Law (country, name, responsible body), provisions and determinations on the provision of diagnostic imaging/graphics services at home and other important observations about the law were extracted from the legislation.

The study's quantitative data, referring to market research, were recorded using absolute and relative frequencies. In relation to qualitative data, regarding the documentary analysis of legislation, a content analysis by Bardin (2011) was carried out. First, a pre-analysis of the documents was carried out according to the inclusion criteria. The content was organized based on similarities in meaning, generating thematic categories. These categories were then analyzed and synthesized to present the results, aiming to identify patterns, meanings and trends.

Results and discussion

Market research:

The scoping review of the literature identified, through eligibility criteria, 199 studies that had performed diagnostic imaging at home. These studies were carried out in 45 different countries, the most prevalent being the United States (31), United Kingdom (23), Germany (11), Canada (10), China (10), Japan (10), Italy (9), Switzerland (9), Australia (7), Netherlands (7). The 45 countries identified are represented in Figure 1.

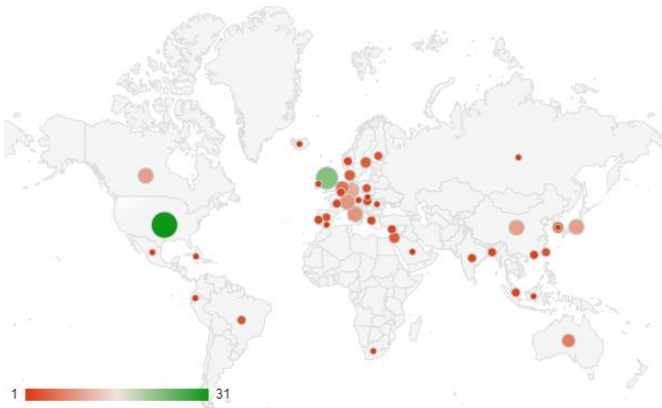


Figure 1 | Global distribution of studies on home-based diagnostic imaging services.

Note: The size of the bubble and the hue of the colors indicate the frequency with which the countries appeared. Source: Developed by the authors.

These 45 countries were researched to identify the existence of companies that performed diagnostic imaging services at home. It was identified through a Google search that only 12 countries had companies that performed this type of service. Table 1 shows all countries, company names and the types of home imaging diagnostics they perform.

Table 1 | Description of companies that provide home imaging diagnostic services in the 45 countries identified.

Countries	Companies	Diagnostics
Australia	Mobile Radiology Australia	X-ray; US
United States	TridentCare	X-ray; US; ECG
United Kingdom	Medneo	CT
Canada	StL Diagnostic Imaging	X-ray; US
Italy	Diagnostica Domiciliare	X-ray; ECG; ECHO; US
Brazil	Mobi Diagnósticos	X-ray; ECG; ECHO; US; Holter; Map
Spain	Comitas e-health	X-ray; US
France	Echoradom	X-ray; US; US Doppler
Mexico	Salud Móvil	X-ray; US; ECG
Ecuador	Imax Móvil	X-ray
Greece	Oikoiatriki	X-ray; US
Singapore	Sata CommHealth	X-ray; Mammography; Audiometry

Note: US = Ultrasound; ECG = Electrocardiogram; CT = Computed Tomography; ECHO = Echocardiogram; MAP = Ambulatory Blood Pressure Monitoring. Source: Own authorship.

The data indicates that these companies are distributed across diverse socioeconomic contexts, from high-income economies, such as Australia, USA, United Kingdom, Canada, Italy, Spain, France, Greece and Singapore, to middle-income

economies, such as Brazil, Mexico and Ecuador.

Predominantly private in nature, these companies offer different types of diagnoses. The number of diagnoses offered by an organization does not depend on the economic classification of your country or the number of inhabitants covered by the services.

Furthermore, it was identified that the opening hours of these companies varied according to local demand, and, except for two companies that operated 24 hours a day, located in Greece and Italy, services were offered during business hours, from Monday to Saturday.

Most companies (66.67%) did not report in their *websites* the professionals involved in carrying out the diagnostic service at home, as well as those who reported, reported different professions, such as radiologists and radiology technicians, doctors from different specialties such as rheumatologists, cardiologists, urologists and neurologists. In addition to being a dentist and secretary responsible for scheduling appointments.

Most companies offered home imaging diagnosis as their main service, but two companies, from the United States and Greece, offered a wider variety of home care health services. The companies served people of any population profile who needed the service, as well as some corporate clients.

Documentary research of legislation:

Sixteen legislation or regulatory documents were included regarding the provision of diagnostic imaging services at home, which referred to nine countries, namely Australia (4), United Kingdom (2), United States (2), Mexico (2), Singapore (2), Canada (1), Italy (1), Greece (1) and Brazil (1). In relation to other countries, the documents were not included because they did not meet the inclusion criteria. The results revealed different focuses and themes, which were grouped into six categories: security, privacy, clinical documentation, application criteria, equipment and diagnostic teams.

Security refers to the implementation and maintenance of strict and regulated measures that guarantee the protection and well-being of patients and healthcare professionals when performing diagnostic imaging services at home. It was observed in documents from the countries of Australia, Canada, the United States, the United Kingdom, Mexico and Greece.

Canadian and United Kingdom legislation converges on the need for clinical or home reports with specifications of the diagnostic imaging system, following safety protocols in non-hospital environments. Australia and the United Kingdom highlight the importance of accessibility in home diagnostic imaging services. Australia notes that people using mobility devices may have difficulty carrying out examinations without a lifting hoist. And the United Kingdom states that diagnostic imaging services must be suitable for different population profiles, including children, young people and

adults.

Some countries approach safety in terms of patient exposure to radiation. The United States documents states that professionals must minimize exposure to radiation. The United Kingdom requires mobile diagnostics to follow the same protection rules as fixed diagnostics. Mexico mandates that mobile x-ray equipment comply with regulations to protect the public. And Greece holds professionals responsible for safety and maintaining low radiation levels.

In this way, the analysis highlights both common topics and divergences in the regulations of the six highlighted countries. The convergence between these countries is the emphasis on ensuring personnel safety and minimum exposure to radiation, while the divergences reside in the specific approach and level of detail of the regulations, reflecting the needs of each national context. In addition to the particularities, it is expected that the guidelines contribute to organized action that ensures the quality of the service and minimum exposure of teams and patients (Acauan *et al.*, 2020).

Privacy involved the protection and respect for patients' personal and medical information, as well as their right to informed consent. It was verified in documents from the countries of Australia and the United Kingdom.

Legislation varies in its approach to privacy. When we look at this issue in legislation, we see that it is addressed by the United Kingdom, which deals with the issue in a more superficial way, linking privacy to the patient's dignity. Australia, in more detail, states that patients must have access to information about the procedure, risks involved and their health situation, in addition to needing to give consent for each procedure.

Since health information is considered intimate, personal and sensitive, it is crucial to ensure the reliability of the care provided and the patient's safety regarding the procedure that will be performed, an essential conduct for treatment adherence, positive health results and continuous improvement of work processes, as recommended by the International Code of Medical Ethics of the World Medical Association (Zaganelli; Filho, 2023). Furthermore, the ethical handling of sensitive information optimizes communication and the relationship between the healthcare team and service users, contributing to a solid interaction between both parties. Therefore, the protection and appropriate treatment of this information are central elements for excellence in professional performance and patient satisfaction.

Clinical documentation concerns the process of recording and maintaining detailed and accurate records of medical activities and procedures, with the aim of ensuring the quality of home care, was found in documents from the countries of Italy, the United States and Singapore.

Italy requires specific documents for this service, including

residence addresses, procedures performed, technical details of equipment and radioactive material, and interventions to prevent or limit consequences for the population. In the United States, clinical documentation includes the cost of transportation of portable x-ray equipment, with a single transportation payment per trip, prorated among patients at the same location based on insurance status. Singapore requires approved licenses for home diagnostic imaging, highlighting that some nursing homes already have licenses, in addition to other regulations to be followed.

According to Azevedo (2020), adequate documentation must include: the patient's personal information, complete nursing diagnoses, planned and executed interventions, record of the results obtained, and be accurate, complete and legible. These standards ensure the recording of each aspect of patient care, strengthening the comprehensiveness and continuity of care and eliminating interprofessional communicative barriers. Adherence to these standards optimizes efficiency and quality of service, increases patients' trust in the organization, and promotes high-quality and safe clinical practice. Therefore, a rigorous documentation system can be a significant differentiator for healthcare institutions looking to stand out.

Application criteria refers to the guidelines and regulations that determine the conditions under which radiological procedures can be performed, including the clinical justification for radiological exposure and the specific circumstances that permit or prohibit such procedures. This category was observed in documents from the countries of Brazil, Australia, Italy, the United States, the United Kingdom, Mexico and Greece.

Brazil allows the use of mobile x-ray equipment only in temporary conditions for urgency or emergency, but is open to exceptions with technical advice. Australia expects home imaging professionals to adhere to the same standards as face-to-face care, including confidentiality, informed consent and good patient care, with reduced fees when multiple services are performed on the same day. Italy records information on the temporary use of mobile radiation sources for each location, except for unauthorized radioactive substances and X-ray machines in mobile vehicles.

In the United States, the use of portable x-ray equipment depends on the patient's health circumstances and a doctor's request, with regulations regarding payment for transportation of the equipment. The UK requires specific protocols for home visits, ensuring safety and accuracy, with adequate space and continuous assessment and audit processes. Greece establishes instructions for regular quality checks and procedures to ensure the quality of the result. Mexico defines criteria for the safe use of X-ray equipment in fixed or mobile installations, prohibiting diagnostic imaging services at home, except when the patient cannot leave the bed, following specific standards.

The application criteria highlight the standards and procedures that must be followed to carry out diagnostic imaging at home, being specific according to the legislation and context of each country. Highlighting the importance of the existence of these documents that regulate and describe the processes that must be followed in the country, as reported by Azevedo (2020).

Equipment refers to devices and apparatus used for medical diagnoses, especially mobile diagnostic imaging devices, with an emphasis on standards and regulations that guarantee the quality, safety and effectiveness of their use. This category was identified in documents from the countries of Australia, Canada, the United Kingdom, Mexico and Greece.

In this category, Australia, Canada and Greece focus on regulating development and operation according to government standards. Australia recommends that companies design equipment with mobility device users in mind, in collaboration with the government. Canada requires that equipment follow the current digital image format. Greece allows home diagnostic imaging services for patients with limited access.

Mexico addresses the equipment category focusing on manual or motorized transport, and reports specifications for fixed and mobile x-ray, ultrasound, transducer and recording unit equipment. The United Kingdom also notes the specifications for home diagnostic imaging equipment, stating that medical radiology equipment can be fixed or mobile for medical use.

The analysis of this category raises the perception of the need for specific standards that guide the management of mobile diagnostic equipment, considering risks of transportation, depreciation, training and personnel training. The implementation of clear guidelines is essential to mitigate the risks inherent in transporting and handling this equipment, which can negatively impact diagnostic accuracy and patient safety. These protocols must include preventive and corrective maintenance routines, procedures for the correct calibration of devices, as well as continuous training and training programs for the technical team. Such measures not only ensure the useful life and proper functioning of equipment, but also promote excellence in patient care (Kumar *et al.*, 2023).

Finally, the **diagnostic team** means the group of qualified and trained professionals involved in diagnostic imaging procedures at home, with an emphasis on rigorous qualification standards, continuous training and staff availability. It was verified in documents from the United States and Greece.

When we look at the team aspect, we see that both the United States and Greece treat it in a similar way, listing the duties of professionals involved in home diagnostic imaging services, such as radiologists, radiology technicians, medical and non-medical physicists, as about safety and radiation exposure.

In view of this, detailed criteria for the selection and performance of technical teams can be noted, demonstrating the relevance of professional qualification in the context of home diagnosis. However, the same analysis highlights the absence of values and strategies that guide organizations regarding the development of innovative quality of care. To achieve this, a constant approach of reflection and ethical investments is required to broadly satisfy health needs, considering the capabilities and resources of local institutions (Lepri *et al.*, 2024). Therefore, it is essential that teams adopt humanized action in their skills profile, ensuring that care goes beyond technical aspects and incorporates a multidimensional perspective on the individual circumstances of patients.

One limitation of the study is that the search string used the term "image diagnosis" without specifying each type of diagnosis, such as X-ray, ultrasound, and others. As a result, some legislation specific to certain types of diagnostics may not have appeared in the search. Therefore, future studies should include terms related to specific types of imaging diagnostics in the search string.

Conclusion

The study highlighted the importance of providing home diagnostic imaging services and the need for healthcare professionals with skills in eHealth. The analysis of market research data revealed the presence of companies offering these services in various countries, predominantly in high-income economies, with different types of diagnoses and service models. The documentary research of legislation provided insights into the regulatory framework for home diagnostic imaging services, emphasizing safety, privacy, clinical documentation, application criteria, equipment, and diagnostic teams.

These findings underscore the importance of promoting, developing, and regulating home health diagnostic services to meet the specific needs of the population, ensuring inclusive and quality access to healthcare. Further research is needed to explore the impact of these services on patient outcomes, the cost-effectiveness of home diagnostic imaging, and the potential for integrating these services into existing healthcare systems.

Acknowledgments

We acknowledge the "Departamento de Gerontologia da Universidade Federal de São Carlos - UFSCar", the "Programa de Pós-Graduação Interunidades em Bioengenharia da Universidade de São Paulo (USP - EESC/FMRP/IQSC)", the National Council for Scientific and Technological Development, the São Paulo State Research Support Foundation (grant n° 2023/05218-6) and Coordination for the Improvement of Higher Education Personnel (CAPES) - Financial Code 001).

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