# Title:

Current state of telemedicine in the field of Hepatology in Spain: challenges, threats and next steps to follow for an intelligent digital transformation

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Current state of telemedicine in the field of Hepatology in Spain: challenges, threats and next steps to follow for an intelligent digital transformation

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#### ABSTRACT

Medicine and technology are constantly evolving. The COVID-19 pandemic has accelerated the development of digitalization in the health sector and specifically of telemedicine. Through a structured bibliographic review following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) methodology, in this study, the concepts related to telemedicine, its application and the legal regulatory context are defined. With this information, some recommendations and codes of good practice are proposed for their effective implementation in the field of Hepatology.

**Keywords:** Telemedicine. Teleconsultation. Telehealth. Hepatology. MAFLD. Hepatitis C. Hepatitis B.

#### INTRODUCTION

Innovation is a key element to promote progress in any activity, sector and country, as it is a tool for generating value. In the health field, innovation is also a fundamental component for improving health care and health in general (1,2). In this area, innovation has traditionally been directed towards research and the development of new therapies to increase life expectancy and improve quality of life. However, in health systems that face an increasing expense over the years (3), a marked aging population (3), offering quality guarantees regardless of the disease and the region where the patient resides (4) or the inclusion of new products with a guaranteed access and sustainability of the system (5), the need to scrutinize new avenues of innovation becomes undeniable. Among the new areas of innovation, it is worth highlighting the adequacy and adaptation of health systems to current digital and

technological development.

The digitization of the health sector has fostered the emergence of new disciplines, such as telemedicine. This is a broad concept that includes a multitude of health care services focused on combating diseases and their limiting factors, as well as achieving greater patient well-being and prevention (6). The term telemedicine was first used in the 1960s, referring to the use of telecommunications at the service of the patient and health, in order to overcome the geographical distance barrier between the interlocutors (7). The continuous development and technological advances have given rise to new terms, such as eHealth, a term that refers to health initiatives that are based on the use of any type of information and communications technology (ICT) (8); mHealth, which considers the specific use of mobile devices to support medical practice and public health (9); or the more recently introduced Digital Health, a broader term that addresses the use of digital technologies to improve health, incorporating aspects such as e-health, genomics, artificial intelligence (AI), big data and robotics (10) (Fig. 1).

Due to the continuous technological progress which, as already shown, is in turn associated with a terminology that is also in constant evolution, it is important to note that there is no definitive definition of telemedicine. According to a study carried out in 2007, more than 104 different definitions of the term telemedicine were found in the literature (11). Taking the definition proposed by the World Health Organization (WHO) as a starting point, telemedicine is understood as the provision of health services, in which distance is a determining factor, by health professionals via the use of ICT for the exchange of valid information for the diagnosis, treatment and prevention of diseases, for research and evaluation, and for the continuous training of health professionals, all with the ultimate goal of improving the health of the population and communities (12).

Based on this definition, two widely accepted modalities of telemedicine are considered:

 Synchronous telemedicine: the interaction takes place in real time and the support is immediate (13).



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Regardless of the telemedicine modality chosen, telemedicine applications are very diverse, allowing remote monitoring, remote storage and sending of information or different interactive processes (interactive telemedicine) (15,16):

- Remote monitoring: it includes the term telemonitoring, which refers to the tracking of patient parameters through mobile devices or by telephone.
- Storage and remote delivery of information: storage of clinical data to send and share with other health professionals. Tele-education uses this concept of storing and forwarding information with the functionality of didactics and online teaching for patients and providers.
- Interactive telemedicine: it includes concepts such as teleconsultation, a discipline that allows collaboration between health professionals via telematics. Another term encompassing this discipline is teleconsultation, which offers the possibility of connecting health professionals and patients remotely through digital image and audio media.

Observing the applications that telemedicine presents, it is possible to expect important advantages derived from its use, such as time optimization, follow-up visits preventing long trips, data monitoring, healthcare provider coordination, remote educational programs and, as occurred during SARS-CoV-2 pandemic, usefulness in a health crisis (17).

#### **AIM AND METHODS**

The main objective of this review is to assess the current state of telemedicine in liver diseases in Spain and to analyze the challenges and steps to follow for its effective implementation. Carrying out the proposed study aims to provide a conceptual framework of useful information to identify the current situation of telemedicine in Spain and neighboring countries (Europe), as well as in other regions that may also be of reference (United States, Canada and Australia). In the same way, good practice guidelines are formulated for a correct implementation of telemedicine in Hepatology, and the basis for evaluating the current legal and regulatory context applicable to telemedicine are clarified.

This manuscript aims to advance the effective digital transformation in liver diseases, mainly for metabolic associated fatty liver disease (MAFLD), hepatitis C virus (HCV) and hepatitis B virus (HBV). To reflect the real state of telemedicine, a structured bibliographic review of the literature was proposed, following the international recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) (18) methodology, both in the Medline database (PubMed) and in Medes (*Medicina en Español*), reference database published in Spanish, dated March 2021 (Fig. 2). The aim of this search was to identify publications and "grey literature" related to telemedicine, which could help to set recommendations and guidelines of good clinical practice to achieve its effective implementation.

#### CURRENT SITUATION OF TELEMEDICINE IN THE FIELD OF HEPATOLOGY

Countries have faced, and are currently facing, the task of integrating technological advances into their respective health systems. In the case of Spain, the National Institute of Health (Insalud) recognized the importance of the contribution of ICTs in aspects of the health and well-being of society in the year 2000, betting on their incorporation in health centers (19). Since then, important advances have been made in terms of the digitization of the Spanish healthcare system, including the Avanza Plan (20), the Online Healthcare Program (21), the development of the digital medical record (22) or the electronic prescription (23), among others. Specifically, different health areas have moved ahead to digitalize the clinical practice. Among them, the Gastroenterology area is no exception, including the management of inflammatory bowel disease (24). The mobile application designed at Hospital La Fe in Valencia, TECCU (Telemonitoring of Crohn's Disease and Colitis), aimed at remote monitoring of patients with inflammatory bowel disease, has a long history in the field of telemedicine. In addition to the experience generated by TECCU in the field of mHealth, the great results at the level of control of inflammatory bowel diseases and the reduced consumption of resources destined for these patients position this initiative as one of the most important in the sector (25-27).



Regarding the area of Hepatology, digital initiatives in Spain have aimed at tackling HCV, motivated to a certain extent by the objective established by the WHO of eradicating the disease by 2030 (28). One of the greatest challenges to be undertaken is the difficult access of clinical workers to reservoirs of the virus. Faced with this reality, telemedicine is positioned as a useful tool to optimize follow-up and monitoring of patients who make up the main reservoirs (29). An example is the initiative carried out at Hospital Universitario de Canarias in Santa Cruz de Tenerife. In this case, a telemedicine program associated with treatment custody and viremia dried blood spot testing was offered to recover non-adherent patients in HCV screening programs in drug addiction care units. How this initiative was more effective for the micro-elimination of HCV than the conventional care model that consisted of a hospital visit was verified (30).

Another important reservoir of HCV in Spain is made up of people living in prison (31-34). In "El Dueso" Penitentiary Center, in Cantabria, telemonitoring programs were implemented for HCV-positive patients serving sentences in this facility (35). These programs consisted of monitoring inmates with active HCV infection telematically, thereby saving both costs derived from the transfer and escort of inmates, as well as time spent on administrative procedures (36). The initiative turned out to be positive and achieved good results in the micro-elimination and early diagnosis of HCV. The program resulted in achieving HCV cure in 71 of the 75 patients included in the program and was also associated with a reduction in total costs of &38,677. Finally, the patients responded adequately to the telemonitoring proposal, highlighting the ability of the program to avoid the stigmatization of HCV (35,36).

Another group in which access is compromised is that of judicialized patients who comply with alternative penalties and measures (community work and rules of conduct). To access this subgroup of patients, digital health programs have been implemented that allow telematic follow-up. This is the case of the initiative carried out in Santander, between "José Hierro" Center for Social Inclusion and specialists from Hospital Universitario Marqués de Valdecilla, which monitored 90% of these patients (37).



At the international level, projects aimed at managing HCV have been designed. They make elimination goals possible using telemedicine tools, which also reduce costs, as demonstrated in a Mexican experience (38). Unlike these projects oriented towards telemonitoring and televisits, projects have been designed for communication between health professionals (teleconsultation). Among these, the most relevant is the project developed by the Extension for Community Healthcare Outcomes group (ECHO) (39,40). This model facilitated direct contact between the health professionals who were on the front line and cared for patients with hepatitis in the first instance, with a multidisciplinary team specialized in HCV made up of hepatologists, microbiologists and pharmacologists. Communication was achieved through a digital platform, which constituted a teleconsultation tool as it is currently defined (41,42). Finally, it should be noted that at the international level, there are other projects aimed at addressing other pathologies within the field of Hepatology, such as MAFLD. One of the initiatives for the follow-up of patients with this pathology is the one developed in Bologna, where a telematic follow-up program was created. When evaluating the results, patients integrated into the digital program showed better results in liver enzyme reduction and weight loss compared to patients in traditional care (43).

In short, the use of "*telehepatology*" is a valid and complementary alternative to classic care models, where both health professionals and patients can take advantage of the multiple benefits provided by this care discipline. We highlight the most relevant ones, such as portability, real-time data collection, disease status education, patient reported outcomes (PRO) compilation, improved quality of care, improved adherence to medication and stricter control of diseases (44).

#### **REGULATORY AND LEGAL CONTEXT**

The digitization of health systems has not been accompanied by regulation at the legal level in Spain, so it is an area characterized by a lack of specific regulations that state the legal implications of digital health care initiatives in general, or telemedicine in particular. As there is no legal regulation in Spain specific to digital health, telemedicine faces different ethical and legal challenges (45):

- Guaranteeing the anonymity of the data of individuals and patients.

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- Protecting individual information.
- Avoiding bias when making decisions based on digital programs.

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- Ensuring that decision making is not automated.
- Ensuring transparency on essential elements and processes.
- Establishing who to assign and who should assume responsibilities.
- Creating a secure network of access to patient data for professionals.
- Guaranteeing that an established protocol for data management has been followed.

In any case, the authors who have opted for telemedicine agree that the same regulatory requirements as those contained in normal clinical practice must be guaranteed for this healthcare discipline. In addition, due to the telematic nature of this discipline, there are two legislative frameworks that apply to the development of activities encompassed in the field of telemedicine. These regulatory texts advocate for the protection of patient data and are: the General Data Protection Regulation (RGPD) (46) and the Organic Law on Protection of Personal Data and Guarantee of Digital Rights (LOPDGDD) (47). Both laws try to preserve the confidentiality of patient data, guarantee their autonomy in decision-making and register non-face-to-face medical acts in their medical records (as is the case with a face-to-face medical act) (48). In line with this regulation, there is a debate about the need for informed consent when carrying out a digital intervention with patients. Although it is true that there is no regulation that requires having this informed consent, numerous authors and scientific societies are inclined in favor of obtaining it, at least verbally (48-52). Some of the aspects that should be taken into account in this document, according to the criteria of the authors positioned in favor of informed consent are (48):

- Explaining the nature of the program, its limitations, risks, benefits and effectiveness.
- Exposing the security measures in terms of data protection and privacy.
- Listing the contingency plans and policies in case of technical breakdown or emergency.
- Informing and requesting authorization if consultations are recorded.



- Allowing the patient the option of refusing the service against face-to-face care.
- Specifying the credentials of the health professionals involved.

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 Detailing the care coordination procedures with other professionals, for example: specifying whether the session will be recorded or providing informed consent for the proposed procedures.

As shown, the absence of legal regulations in the field of digital health is patent. However, supranational organizations such as the WHO or the European Union (EU) have positioned themselves in favor of promoting digital programs such as telemedicine, since they consider that their development guarantees equitable access to health, optimization in the use of health resources of the national health services and improvement in the quality of care (4,53).

#### **GOOD PRACTICES IN DIGITAL HEALTH**

The great breadth that characterizes the field of digital health, together with the lack of common terms for all authors, make it difficult to identify guidelines or recommendations for the development of digital initiatives. However, various institutions have established recommendations for the effective implementation of telemedicine at the international level. This is the case of the United Kingdom (54), the WHO (55) or the American Association of Telemedicine (ATA) (56). In Spain, recommendations have also been published with the aim of providing guidelines for the design of digital interventions in health. Among these, it is worth highlighting the recommendations of the Canary Islands Health Service (57,58), the Valencian Society of Digestive Pathology (57,58) or the Digital Health Association (ASD) (59). In any case, the recommendations are oriented towards three aspects: televisit, which implies telematic interaction between health professionals and patients; teleconsultation, which involves telematic interaction between health professionals; and monitoring and evaluation of the digital intervention.

# Recommendations for the televisit

The televisit can be structured in three phases: pre-visit, intra-visit and post-visit. In all of them, it is advisable to follow a previously prepared protocol to provide a quality

digital health service (49):

- Phase 1: pre-visit. The pre-visit phase is characterized by the preparation of the patient for the service. Firstly, whether to refer a patient to a telematic visit must be decided. For this, it could be useful to develop guides to follow for the triage of visits. There is no standard of care for the inclusion of patients in the digital health project, so it will depend on the criteria of the health personnel (49). This health discipline is still new for a large percentage of patients, so it is assumed that it will be necessary to prepare the patient in the management of digital platforms. Similarly, it is also advisable to train health personnel in the handling of said technology (49). So much so, that some countries that have made a strong commitment to telemedicine, such as Australia, require a certificate that guarantees that health professionals are suitably trained to develop digital health programs (60).
- Phase 2: intra-visit. The first thing to manage in this phase is the scenario. The healthcare professional must create a healthcare environment, regardless of whether the televisit can be carried out from any location. It is recommended to carry it out in a private place, with low ambient noise, informing that a televisit is being carried out with a sign outside the room and wearing health care personnel clothing and an identification document. On the other hand, the patient must also be warned. Thus, it is recommended to make a call 15-30 minutes before the session to solve technical problems and confirm that the patient has downloaded all the necessary tools. Likewise, it is advisable to invite the patient to a virtual waiting room to make the televisit process look like the face-to-face visit process (49). The first televisits should always begin with a conversation that favors transparency, where the patient's informed consent is obtained and the patient's safety is guaranteed throughout the process (4,45,49) (Fig. 3).
  - *Phase 3: post-visit.* In this last stage, and after the televisit, transparency with the patient is essential, avoiding biased or stratifying decisions, ensuring that the healthcare personnel maintain their criteria as a priority and finally, identifying a responsible person for the decision made. In any case, if after the



televisit there are doubts about the health procedure to follow, the patient should be referred for a face-to-face consultation for further evaluation (45). Ultimately, the patient should be asked to evaluate the service and the degree of satisfaction with it (49).

#### **Recommendations for teleconsultation**

The recommendations for the effective implementation of teleconsultation initiatives do not differ greatly from the recommendations for televisits. However, the specific aspects of this modality can be extracted from the experience generated by the ECHO group in HCV (Table 1).

#### Monitoring and evaluation of results

All published recommendations agree on the importance of monitoring the results obtained through digital intervention. Feedback is needed throughout the development of digital initiatives to assess their proper functioning and development. Similarly, monitoring of digital health interventions is vital for the generation of solid, quality evidence that reflects the true impact and benefit of these programs (61). In light of the importance of these programs, the WHO has developed a guide with recommendations for proper monitoring and follow-up of digital interventions (55) (Table 2). The monitoring and evaluation programs allow to clarify how consistent a digital initiative is and the degree to which its planned activities are being implemented and meeting its objectives, with the understanding that this feeds a broader evaluation agenda to understand the real impact of the initiative in health and whether or not the ultimate goal has been achieved (55). This guideline emphasizes how diffusion and dissemination of findings is also essential, as this will contribute to a better understanding of the impact of interventions and encourage greater support and investment in digital health. Considering the lack of consensus about the appropriate method for disseminating the results of digital health interventions, the WHO developed the *mHealth Evidence Reporting and Assessment List*. With a total of 16 items, its objective is to improve transparency in reporting, promote critical evaluation of health research evidence, and guide authors in the development of



manuscripts that can be published in scientific journals (55,62).

### STRATEGIC FRAMEWORK IN THE FIELD OF TELEHEPATHOLOGY

Previous experience in telemedicine initiatives, both in hepatology and in related areas, sheds light on which healthcare settings could benefit the most from telemedicine in Hepatology. The actions aimed at the development of *telehepatology* are detailed in table 3.



#### CONCLUSION

The outbreak of the COVID-19 pandemic due to SARS-CoV-2 has prompted the implementation of telemedicine. However, throughout the consulted literature there are no specific recommendations and the legal framework for its development is not completely defined. Through this review, we highlight the detailed definitions of the terms involved in telehealth and how to carry out care for our patients with telemedicine tools; and more importantly, its specific application in Hepatology and highly prevalent diseases such as viral hepatitis, metabolic liver disease and their possible complications, such as hepatocarcinoma.

#### REFERENCES

1. Organisation for Economic Co-operation and Development (OCDE). Frascati Manual 2002 - Proposed standard practice for surveys on research and experimental development: the measurement of scientific and technological activities. Paris: OCDE; 2002. Available from: https://www.oecdilibrary.org/content/publication/9789264199040-en

 Gadeikiene A, Pundziene A, Dovaliene A. How does telehealth shape new ways of co-creating value? Int J Organ Anal 2021;29(6):1423-42. DOI: 10.1108/IJOA-07-2020-2355

3. Organisation for Economic Co-operation and Development (OCDE), European Union HCV Collaborators. Health at a Glance: Europe 2016. OCDE, EU; 2016. Available from: https://www.oecd-ilibrary.org/content/publication/9789264265592-en

4. World Health Organization (WHO). WHO Guideline Recommendations on Digital Interventions for Health System Strengthening. Geneva: WHO; 2019.

5. Espín J, Oliva-Moreno J. Esquemas innovadores de mejora del acceso al mercado de nuevas tecnologías: los acuerdos de riesgo compartido. Gac Sanit 2010;24(6). DOI: 10.1016/j.gaceta.2010.07.011

6. García Cuyas F, Vázquez N, De San Pedro M, et al. State of the art of the telemedicine. Where are we and what is pending to be done? Med Clin 2018;150(4):150-4. DOI: 10.1016/j.medcli.2017.06.058

7. Meister S, Deiters W, Becker S. Digital health and digital biomarkers – Enabling value chains on health data. Curr Dir Biomed Eng 2016;2(1):577-81. DOI: 10.1515/cdbme-2016-0128

8. European Commission (EC). Telemedicine for the benefit of patients, healthcare systems and society. Bruselas: EC; 2008. Cited: February 23<sup>rd</sup>, 2021. Available from: https://ec.europa.eu/transparency/regdoc/rep/1/2008/EN/1-2008-689-EN-F1-1.pdf

9. World Health Organization Global Observatory for eHealth. mHealth: new horizons for health through mobile technologies: second global survey on eHealth. Geneva: WHO; 2011. Cited: February 23<sup>rd</sup>, 2021. Available from: https://apps.who.int/iris/handle/10665/44607

10. World Health Organization. Global strategy on digital health 2020-2025. Geneva: WHO; 2021. Available from: https://apps.who.int/iris/handle/10665/344249

11. Sood SP, Negash S, Mbarika VW, et al. Differences in public and private sector adoption of telemedicine: Indian case study for sectoral adoption. Stud Health Technol Inform 2007;130:257-68.

12. World Health Organization Global Observatory for eHealth. Telemedicine: opportunities and developments in Member States: report on the second global survey on eHealth. Geneva: WHO; 2010. Cited: February 23<sup>rd</sup>, 2021. Available from: https://apps.who.int/iris/handle/10665/44497

13. Wilson LS, Maeder AJ. Recent directions in telemedicine: review of trends in research and practice. Healthc Inform Res 2015;21(4):213-22. DOI: 10.4258/hir.2015.21.4.213

14. Waller M, Stotler C. Telemedicine: a Primer. Curr Allergy Asthma Rep 2018;18(10):54. DOI: 10.1007/s11882-018-0808-4

15. Bashshur R, Shannon G, Krupinski E, et al. The taxonomy of telemedicine. Telemed J E Health 2011;17(6):484-94. DOI: 10.1089/tmj.2011.0103

16. Piao C, Terrault NA, Sarkar S. Telemedicine: an evolving field in Hepatology. Hepatol Commun 2019;3(5):716-21. PMCID: PMC6492471. DOI: 10.1002/hep4.1340

17. Vidal-Alaball J, Acosta-Roja R, Pastor Hernández N, et al. Telemedicine in the face of the COVID-19 pandemic. Aten Primaria 2020;52(6):418-22. DOI: 10.1016/j.aprim.2020.04.003



18. Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med 2009;6(7):e1000097. DOI: 10.1371/journal.pmed.1000097

19. Instituto Nacional de la Salud (INSALUD). Plan de telemedicina del INSALUD. Madrid: Ministerio de Sanidad y Consumo; 2000. Cited: February 23<sup>rd</sup>, 2021. Available from:

https://ingesa.sanidad.gob.es/bibliotecaPublicaciones/publicaciones/internet/docs/tel emedicina.pdf

20.Ministerio de Sanidad, Consumo y Bienestar Social. Convenio Marco PlanAvanza. Madrid: Ministerio de Sanidad Consumo y Bienestar Social; 2005. Cited:February15<sup>th</sup>,2021.Availablehttps://www.mscbs.gob.es/organizacion/sns/servWebSNS/convenioMarco.htm

 Ministerio de Asuntos Económicos y Transformación Digital. Red.es. Madrid: Ministerio de Asuntos Económicos y Transformación Digital; 2021. Cited: February 15<sup>th</sup>,
 2021. Available from: https://www.red.es/redes/es/quienes-somos/redes

22. Ministerio de Sanidad y Consumo. Plan de calidad para el Sistema Nacional de Salud: Sanidad en Línea. Madrid: Ministerio de Sanidad y Consumo; 2006. Cited: February 15<sup>th</sup>, 2021. Available from: https://www.mscbs.gob.es/organizacion/sns/planCalidadSNS/pdf/tic/sanidad\_en\_line a\_WEB\_final.pdf

23. Ministerio de Sanidad Consumo y Bienestar Social. Sistema de Historia Clínica Digital del Sistema Nacional de Salud (HCDSNS) - Informe de situación 1 de octubre de 2020. Madrid: Ministerio de Sanidad, Consumo y Bienestar Social; 2020. Cited: February 15<sup>th</sup>, 2021. Available from: https://www.mscbs.gob.es/profesionales/hcdsns/contenidoDoc/Inf\_sit\_HCDSNS\_octu bre\_2020.pdf

24. Ministerio de Sanidad, Consumo y Bienestar Social. Implantación de la receta electrónica en el SNS. Datos julio 2020. Madrid: Ministerio de Sanidad, Consumo y Bienestar Social; 2020. Cited: February 15<sup>th</sup>, 2021. Available from: https://www.mscbs.gob.es/profesionales/recetaElectronicaSNS/NIVEL\_IMPLANT\_julio \_2020.pdf

25. El Hajra I, Calvo M, Santos Pérez E, et al. Consequences and management of COVID-19 on the care activity of an Inflammatory Bowel Disease Unit. Rev Esp Enferm Dig 2021;113(2):98-102. DOI: 10.17235/reed.2020.7543/2020

26. Aguas M, Del Hoyo J, Faubel R, et al. Telemedicine in the treatment of patients with inflammatory bowel disease. Gastroenterol Hepatol 2017;40(9):641-7. DOI: 10.1016/j.gastrohep.2017.07.001

27. Del Hoyo J, Nos P, Faubel R, et al. A web-based telemanagement system for improving disease activity and quality of life in patients with complex inflammatory bowel disease: pilot randomized controlled trial. J Med Internet Res 2018;20(11):e11602. DOI: 10.2196/11602

28. Del Hoyo JD, Nos P, Faubel R, et al. Adaptation of TECCU app based on patients' perceptions for the telemonitoring of inflammatory bowel disease: a qualitative study using focus groups. Int J Environ Res Public Health 2020;17(6):1871. DOI: 10.3390/ijerph17061871

29. Organización Mundial de la Salud (OMS). Estrategia mundial del sector de la salud contra las hepatitis víricas 2016-2021: hacia el fin de las hepatitis víricas. Geneva: OMS; 2016.

30. Cabezas J, Llerena S, Crespo J. Telemedicine, time to change the paradigm of hepatitis C management: improve access and reduce costs. In reference to: Chronic viral hepatitis C micro-elimination program using telemedicine. The Mexican experience, by Pérez Hernández et al. Rev Esp Enferm Dig 2021;113(8):623-4. DOI: 10.17235/reed.2021.7809/2021

31. Morales-Arráez D, Hernández-Bustabad A, Medina-Alonso MJ, et al. Telemedicine and decentralized hepatitis C treatment as a strategy to enhance retention in care among people attending drug treatment centres. Int J Drug Policy 2021;94:103235. DOI: 10.1016/j.drugpo.2021.103235

32. Crespo J, Llerena S, Cobo C, et al. Is HCV elimination possible in prison? Rev Esp Sanid Penit 2017;19(3):70-3. DOI: 10.4321/S1575-06202017000300001

33. Jiménez Galán G, Alia Alia C, Vegue González M, et al. The contribution of telemedicine to hepatitis C elimination in a correctional facility. Rev Esp Enferm Dig 2019;111(7):550-5. DOI: 10.17235/reed.2019.6152/2018

34. Cerezo-Ruiz A, Montero-Álvarez JL, De Juan-Ramírez J. Implementation of a hepatology and gastroenterology teleconsultation for our penitentiary center. Rev Esp Enferm Dig 2021;113(10):736-7. DOI: 10.17235/reed.2021.7985/2021

35. Akiyama MJ, Kronfli N, Cabezas J, et al. Hepatitis C elimination among people incarcerated in prisons: challenges and recommendations for action within a health systems framework. Lancet Gastroenterol Hepatol 2021;6(5):391-400. DOI: 10.1016/S2468-1253(20)30365-4

36. Cuadrado A, Llerena S, Cobo C, et al. Microenvironment eradication of hepatitis
C: a novel treatment paradigm. Am J Gastroenterol 2018;113(11):1639-48. DOI: 10.1038/s41395-018-0157-x

37. Mateo M, Álvarez R, Cobo C, et al. Telemedicine: contributions, difficulties and key factors for implementation in the prison setting. Rev Esp Sanid Penit 2019;21(2):95-105. DOI: 10.4321/S1575-06202019000200005

38. Cuadrado A, Cobo C, Mateo M, et al. Telemedicine efficiently improves access to hepatitis C management to achieve HCV elimination in the penitentiary setting. Int J Drug Policy 2021;88:103031. DOI: 10.1016/j.drugpo.2020.103031

39. Cabezas J, Llerena S, Mateo M, et al. Hepatitis C micro-elimination beyond prison walls: navigator-assisted test-and-treat strategy for subjects serving non-custodial sentences. Diagnostics (Basel) 2021;11(5). DOI: 10.3390/diagnostics11050877

40. Pérez Hernández JL, Lehmann Mendoza R, Luna Martínez J, et al. Chronic viral hepatitis C micro-elimination program using telemedicine. The Mexican experience. Rev Esp Enferm Dig 2021;113(6):432-5. DOI: 10.17235/reed.2020.7425/2020

41. Arora S, Thornton K, Jenkusky SM, et al. Project ECHO: linking university specialists with rural and prison-based clinicians to improve care for people with chronic hepatitis C in New Mexico. Public Health Rep 2007;122(Suppl 2):74-7. DOI: 10.1177/00333549071220S214

42. Arora S, Thornton K, Murata G, et al. Outcomes of treatment for hepatitis C virus infection by primary care providers. N Engl J Med 2011;364(23):2199-207. DOI: 10.1056/NEJMoa1009370



43. Marciano S, Haddad L, Plazzotta F, et al. Implementation of the ECHO<sup>®</sup> telementoring model for the treatment of patients with hepatitis C. J Med Virol 2017;89(4):660-4. DOI: 10.1002/jmv.24668

44. Mendizabal M, Ridruejo E, Ceballos S, et al. The ECHO model proved to be a useful tool to increase clinicians' self-effectiveness for care of patients with Hepatitis C in Argentina. J Viral Hepat 2019;26(11):1284-92. DOI: 10.1111/jvh.13172

45. Mazzotti A, Caletti MT, Brodosi L, et al. An internet-based approach for lifestyle changes in patients with NAFLD: two-year effects on weight loss and surrogate markers. J Hepatol 2018;69(5):1155-63. DOI: 10.1016/j.jhep.2018.07.013

46. Wu T, Simonetto DA, Halamka JD, et al. The digital transformation of hepatology: the patient is logged in. Hepatology 2022;75(3):724-39. DOI: 10.1002/hep.32329

47. Romeo C, Guillén E, Jerez JM, et al. Inteligencia artificial en salud: retos éticos y legales. Madrid: Instituto Roche; 2020. Cited: February 15<sup>th</sup>, 2021. Available from: https://www.institutoroche.es/static/archivos/Informes\_anticipando\_RETOS\_ETICOS\_DEF.pdf

48. Parlamento Europeo, Consejo de la Unión Europea. Reglamento general de protección de datos. Reglamento 2016/679. UE; 2016. p. 88. Available from: https://www.boe.es/doue/2016/119/L00001-00088.pdf.

49. Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y Garantía de los Derechos Digitales. Available from: http://www.jstor.org/stable/10.2307/j.ctv17hm980

Berg EA, Picoraro JA, Miller SD, et al. COVID-19-A Guide to Rapid 50. Implementation of Telehealth Services: А Playbook for the Pediatric Gastroenterologist. Pediatr Gastroenterol Nutr 2020;70(6):734-40. J DOI: 10.1097/MPG.000000000002749

51. Andrade A, Soares A, Palis A, et al. On the use of telemedicine in the context of COVID-19: legal aspects and a systematic review of technology. Res Biomed Eng 2022;38(1):209-27. DOI: 10.1007/s42600-021-00133-8

52. Hospital Universitario Torrecárdenas. Consentimiento informado en telemedicina (plataforma DIABETIC). Almería: Servicio Andaluz de Salud; 2017. Cited:

March24th,2021.Availablefrom:http://www.diabetesinfantilcht.com/resources/CONSENTIMIENTO%20INFORMAD0%2OTELEMEDICINA.pdf

53. Sociedad Española de Oncología Médica (SEOM). Posicionamiento SEOM sobre la telemedicina. Madrid: SEOM; 2020. Cited: March 24<sup>th</sup>, 2021. Available from: https://seom.org/images/Posicionamiento\_SEOM\_Telemedicina.pdf

54. European Union (EU). Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. Bruselas: EU; 2021. Cited: March 24<sup>th</sup>, 2021. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0024&from=FR

55. United Kingdom Government. Digital and data-driven health and care technology. London: Department of Health and Social Care; 2019. Cited: February 15<sup>th</sup>, 2021. Available from: https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology

56. World Health Organization (WHO). Monitoring and Evaluating Digital Health Interventions. Geneva: WHO; 2016. Cited: February 15<sup>th</sup>, 2021. Available from: https://apps.who.int/iris/bitstream/handle/10665/252183/9789241511766-eng.pdf.

57. American Telemedicine Association (ATA). ATA's QuickStart Guide to Telehealth during a Health Crisis. ATA; 2020. Cited: December 29<sup>th</sup>, 2021. Available from: https://cdn2.hubspot.net/hubfs/5096139/Files/Resources/ATA\_QuickStart\_Guide\_to\_ Telehealth\_4-10-20.pdf?\_\_hstc=223170372.93975c19f1d76429c16259812ea52c5b.16 40003804254.1640003804254.1640172624030.2&\_\_hssc=223170372.1.16401726240 30&\_\_hsfp=1551611665&hsCtaTracking=f11af118-6144-4193-9a9e-7cc3773c2b8b%7C 36ebfce7-8405-4789-959c-b1396226e32e

58. Mahtani Chugani V, Martín Fernández RL, Soto Pedre E, et al. Implementation of telemedicine programs in Spain: experience of the main actors involved in the decision-making process. Gac Sanit 2009;23(3):223e-9. DOI: 10.1016/j.gaceta.2008.06.005

59. Serrano Aguilar P, Yanes López V. Guía de diseño, evaluación e implantación de servicios de salud basados en Telemedicina. Santa Cruz de Tenerife: Servicio de Evaluación del Servicio Canario de Salud (SESCS); 2009. Cited: February 15<sup>th</sup>, 2021.

Available

from:

https://www3.gobiernodecanarias.org/sanidad/scs/content/688cf27e-1f35-11e0-964e -f5f3323ccc4d/2006\_27.pdf

60.Asociación de Salud Digital. Guía Básica de Recomendaciones para la<br/>teleconsulta. Madrid: Asociación de Salud Digital; 2021. Cited: December 29<sup>th</sup>, 2021.Availablefrom:https://salud-digital.es/wp-<br/>content/uploads/2020/05/Guia ASD mayo2020.pdf

61. National Health Informatics Conference, Cesnik B, Walduck K, et al. HIC 2004: handbook of abstracts. Twelfth National Health Informatics Conference: Let's make a difference with health ICT. Brisbane Convention Centre Australia 2004. Brunswick East, Vic.: Health Informatics Society of Australia; 2004.

62. World Health Organization (WHO), United Nations Foundation, UNDP/UNFPA/WHO/World Bank Special Programme of Research Development, Research Training in Human Reproduction, Johns Hopkins University. The MAPS toolkit: mHealth assessment and planning for scale. Geneva: WHO; 2015.

63. World Health Organization. WHO evaluation practice handbook. Geneva: WHO;2013.

64. Siegel CA. Transforming gastroenterology care with telemedicine. Gastroenterology 2017;152(5):958-63. DOI: 10.1053/j.gastro.2017.01.048

65. Camacho DR, Schlachta CM, Serrano OK, et al. Logistical considerations for establishing reliable surgical telementoring programs: a report of the SAGES Project 6 Logistics Working Group. Surg Endosc 2018;32(8):3630-3. DOI: 10.1007/s00464-018-6093-4

66. Riveiro-Barciela M, Gubern P, Roade L, et al. An electronic alert system increases screening for hepatitis B and C and improves management of patients with haematological disorders. Sci Rep 2020;10(1):3038. DOI: 10.1038/s41598-020-59476-4

67. Sampedro B, Hernández-López C, Ferrandiz JR, et al. Computerized physician order entry-based system to prevent HBV reactivation in patients treated with biologic agents: the PRESCRIB project. Hepatology 2014;60(1):106-13. DOI: 10.1002/hep.27103 68. Karlsen TH, Sheron N, Zelber-Sagi S, et al. The EASL-Lancet Liver Commission: protecting the next generation of Europeans against liver disease complications and



premature mortality. Lancet 2022;399(10319):61-116. DOI: 10.1016/S0140-6736(21)01701-3

69. Kleinert S, Horton R. An urgent challenge for Europe: from tackling liver diseases to protecting liver health. Lancet 2022;399(10319):7-9. DOI: 10.1016/S0140-6736(21)02726-4

70. Rodríguez M, Buti M, Esteban R, et al. Consensus document of the Spanish Association for Study of the Liver on the treatment of hepatitis B virus infection (2020). Gastroenterol Hepatol 2020;43(9):559-87. DOI: 10.1016/j.gastrohep.2020.03.011

71. Wang Y, Han SB. Hepatitis B reactivation: a review of clinical guidelines. J Clin Gastroenterol 2021;55(5):393-9. DOI: 10.1097/MCG.00000000001520



# Table 1. Key aspects to consider in teleconsultation programs that can be extractedfrom the implementation of the ECHO program

Take initiatives already developed as models to develop a new program:

This allows for a greater success of the program when applied in other contexts, as was the case with the implementation of the ECHO model in Argentina (41,42)

*Evaluate the area where the teleconsultation tool it is intended to be established:* The efficiency of this type of project has been shown to increase if it is directed to rural areas or other areas where the patient has difficulty in accessing specialized care (63)

Adaptation to the needs of health personnel:

The use of the teleconsultation tool will be optimized if the training offered is flexible in time. This has been demonstrated by the STMP from SAGES (64)

Having an adequate infrastructure:

The success of the program will be highly influenced by the infrastructure supporting

it (64). Likewise, health personnel who are going to benefit from the tool must be

provided with the necessary means, such as a mobile device with which to access the tool and adequate access to the internet (41,42)

ECHO: Extension for Community Healthcare Outcomes; SAGES: Society of American Gastrointestinal Endoscopic Surgeons; STMP: Surgical Tele-Monitoring Program. Modified from Siegel et al., 2017 (63).



# Table 2. Roadmap for monitoring a digital health intervention

- 1. Setting the stage
  - How, when and why?
  - Introduction and stages of development
  - Monitoring versus evaluation

# 2. Intervention monitoring

- What does the program claim to accomplish?
- Choose a framework to explain the process from  $\mathsf{A} \rightarrow \mathsf{B}$
- Development of indicators to measure the objectives
- 3. Evaluation of interventions
  - Qualitative design: user satisfaction
  - Quantitative design: measurement of the results
  - Economic evaluation: balance of costs
- 4. Evaluation of data sources
  - Assess the availability, quality and management of data
- 5. Publication of results
  - Final evaluation and publication of the results

Adapted from the Monitoring and Evaluating Digital Health Interventions report (World Health Organization, 2015) (55).

Actions	Clinical feature included	Target population	Description	Implementation
Creation of a televisit system for addiction centers	HCV microelimination	Patients with a history of addictive behaviors, which constitute an important reservoir and are susceptible to social stigmatization	Circuit of telematic assistance of patients who visit addiction centers (such as the program by Morales Arráez et al., aimed at addiction centers [30])	Design of a platform that allows telematic contact between hepatology specialists and selected patients. This platform should allow the hepatologist to assess the patient synchronously. Likewise, it should facilitate the prescription of treatments and the communication of simple instructions through a follow-up scheme, avoiding access to the hospital
Design of an interaction platform between Primary Care and Specialized Care in Gastroenterology	To optimize disease screening and encourage early diagnosis and treatment	Rural population with difficult access to hospital care (addressing their unmet needs through telemedicine)	Platform that contains three telematic pathways: one for teleconsultation between professionals, one for televisit with the patient and another for process	Design of a teleconsultation circuit that guarantees smooth communication between Hepatology specialists and Primary Care specialists. The objective of this circuit, based on the experience of the ECHO group, consists of the specific training of Primary Care staff, resolution of doubts or other related aspects

# Table 3. Actions aimed at the development of *telehepatology* in Spain

	automation	Design of a televisit circuit through a platform
		that allows the synchronous contact of the
		patient with Primary Care and Specialized Care
		simultaneously from the health center, for cases
		in which it is considered useful
		Design of a tool that allows the automation of the
		processes carried out with new patients, with a
		specific profile, who come to the Hepatology
		consultation and the request for complementary
		tests and follow-up appointments is generated in
		a homogeneous way

	•	•		-
			Platform that contains	
			three telematic	
			pathways: one for	
			teleconsultation	
			between professionals,	
			one for televisit with	
			the patient and	
			another for process	
			automation	
Creation of a mHealth application aimed at monitoring the weight and physical activity of patients with MAFLD	Monitoring, follow-up and promotion of healthy lifestyle habits in MAFLD	Patients diagnosed with MAFLD	Application for mobile devices (mHealth) that allows asynchronous telemonitoring of patients	Design of the mobile application that allows remote and asynchronous monitoring of the weight and physical activity of patients. The data obtained through this must be automatically integrated into the patient's medical records The app could not only facilitate patient monitoring, but also include a system that allows goals to be set in terms of weight loss or number of daily steps. In this way, a healthy lifestyle could be promoted

				patients with MAFLD at an international level have achieved great results. However, in Spain, the development of telemedicine aimed at these patients is scarce, which represents an important opportunity for this type of program. However, given that this is a rarely explored area in Spain, it would be advisable to first identify the digital skills of hepatologists, as well as their knowledge and expectations in this type of initiative
Implementation of a telematic circuit for hepatocarcinoma screening in patients with advanced chronic liver disease	Early screening for hepatocarcinoma	Patients with early- stage hepatocellular carcinoma or at risk of developing it	System that allows the automation of hepatocarcinoma screening processes in patients with advanced chronic liver disease	stages of the disease is essential to improve the prognosis of patients. In hepatocarcinoma screening, it is common that, given the availability of the patient and the care load in health centers, the availability of visits exceeds the recommended 6 months. Thus, making tools available to the patient that facilitate access to analytical tests and medical consultations favors

				the identification of patients at risk
				In this aspect, telemedicine plays a decisive role,
				allowing the automation of processes such as the
				management of medical appointments, the
				scheduling of ultrasound scans on a regular basis
				or arranging the telematic visit with the
				hepatologist to communicate the results
			Alert system integrated	
Prevention of HBV		Patients with past,	into assisted electronic	To develop an alert system in which the risk of
reactivation in		occult or active HBV	prescription and	the patient and/or the prescription of treatment
patients candidate to		infection receiving	electronic medical	that leads to a potential HBVr is recognized and
immunosuppressive,	HBVr prevention*	simultaneous	records, almost	that recommends the performance of serology
biological and/or		treatment with drugs	universal in Spanish	against HBV and/or the referral of the patient to a
chemotherapeutic		that induce	NHS hospitals (based	specific consultation with a Digestive Diseases
treatments		reactivation	on the achievements of	specialist
			pilot trials [65,66])	
Design of an	Early diagnosis of	Patients with early-	Liver disease is the	Development of an intelligent screening based on
automated	chronic liver	stage chronic liver	second leading cause of	four points:
(intelligent) circuit	disease	disease or at risk of	years of working life	

for the diagnosis of	developing it	lost in Europe. One of	1. Automatic implementation of two free
chronic liver disease		the most serious	fibrosis prediction tools
		problems has been the	2. An automated on-line survey aimed at all
		late diagnosis of liver	subjects with elevated transaminases
		disease, usually in	and/or indirect indices of fibrosis in the
		terminal liver disease	intermediate or high-risk zone who have
		stage (67,68). Thus,	not been previously evaluated
		there should be a	3. Referral of the on-line survey by the
		fundamental change to	general population to a tool based on
		prevent the	artificial intelligence that allows the
		development of	attribution of a high risk of liver disease
		advanced liver disease	based on a predetermined algorithm
		by adopting simple	4. Automated citation for analytics,
		methods for early	Fibroscan <sup>®</sup> and/or consultation (telematic
		identification of	or face-to-face)
		progressive liver	This extremely ambitious program, which must
		fibrosis along with	be piloted in advance with the collaboration of
		strategies for disease	the health services, would have an important
		prevention	added value: the direct participation of patients

		stage chronic liver disease or at risk of developing it	The situation of telemedicine in Spain is marked by the absence	The usefulness of SOPs will be determined by their content. In the specific case of televisits, below is a list of minimum contents that must be
Design of standard operating procedures (SOP) for carrying out televisits	All	Institutions and health-care professionals	of guidelines on how to carry out this type of service. Having guides or SOPs to carry out care processes telematically is essential for the development of telemedicine <sup>†</sup>	<ul> <li>included when designing a SOP:</li> <li>Mandatory and recommended requirements for carrying out televisits, both by specialists and by patients (it is advisable to include checklists of requirements, as well as standard questionnaires to determine the digital skills of patients and their technological resources)</li> <li>Procedures that could be carried out electronically</li> </ul>



ECHO: Extension for Community Healthcare Outcomes; MAFLD: metabolic associated fatty liver disease; SOP: standard operating procedures; NHS: National Health System; HBV: hepatitis B virus; HBVr: hepatitis B virus reactivation; HCV: hepatitis C virus. \*HBV reactivation is a phenomenon that occurs in patients who have past, occult or active viral infection and receive immunosuppressive, biological and/or chemotherapy treatments (69,70). <sup>†</sup>In line with this proposal, the European Health Informatics Committee has stated the goal of adopting the international standard "ISO 13131 Health informatics. Telehealth services. Quality planning guidelines" in the European standard. This standard aims to identify minimum quality standards. Among the relevant aspects to determine this quality are the informed consent or the communication channels accepted for the performance of digital health services, included in this SOP design proposal. Thus, the Spanish Standardization Association is designing a specific standard for Spain, including the points established in this ISO standard.



Fig. 1. Evolution and development of the terminology of the application of technology in the health field. Adapted from Mesiter et al., 2016 (7).



Fig. 2. Schematic representation of the bibliographic search and selection process. MEDES: *Medicina en Español*.



Fig. 3. Diagram of the process to introduce the patient to the televisit. Modified from the publication of Berg et al., 2020 (49).