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TITLE PAGE

Title: Telemedicine efficiently improves access to Hepatitis C management to achieve HCV elimination in the penitentiary setting.

Running title: Telemedicine offers cost-saving opportunities in prisons.

Antonio Cuadrado[1,2*], Carmen Cobo[3], Miguel Mateo[4], Antonio J Blasco[5], Joaquin Cabezas[1,2], Susana Llerena[1,2], José I Fortea[1,2], Pablo Lázaro[5] and Javier Crespo[1,2,*]

[1] Department of Gastroenterology and Hepatology, Marqués de Valdecilla University Hospital, School of Medicine, University of Cantabria, Spain;

[2] Marqués de Valdecilla Research Institute (IDIVAL, initials in Spanish); antonio.cuadrado@scsalud.es; joaquin.cabezas@scsalud.es; susana.llerena@scsalud.es; joseignacio.fortea@scsalud.es; javiercrespo1991@gmail.com

[3] Medical Department of "El Dueso" Penitentiary Center, Cantabria, Spain; carmencobopelayo@hotmail.com

[4] Medical Department of the "José Hierro" Social Integration Center of Santander (Cantabria), Spain; miguel.mateo.soler@gmail.com

[5] Independent Researcher in Health Services Research, Madrid, Spain; antoniojblasco@hotmail.com; plazaro@gmx.es

* Correspondence: javiercrespo1991@gmail.com; Tel.: +34 942202544 (Department of Gastroenterology and Hepatology, Marqués de Valdecilla

University Hospital, School of Medicine, University of Cantabria, Spain. Avda. de Valdecilla s/n. Santander 39008. Cantabria. Spain); antonio.cuadrado@scsalud.es (A.C.); Tel.: +34 942 202 544 (Department of Gastroenterology and Hepatology, Marqués de Valdecilla University Hospital).

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HCV = Hepatitis C Virus; TCP = Telemedicine Clinical Practice; UCP = Usual Clinical Practice; TC = Telemedicine Consultation; FFC = Face-to-face Consultation; TE = Transient Elastography; kPa = Kilopascals.

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ABSTRACT

Introduction: Linkage to care for hepatitis C includes a new tool: teleconsultation. Micro-elimination in prison is a recommendation and is feasible. An economic evaluation of telemedicine for hepatitis C virus (HCV) treatment in prisons has not yet been performed. This study aimed to provide a cost-minimization analysis comparing two strategies of HCV treatment in a prison: telemedicine clinical practice (TCP) and the usual clinical practice (UCP).

Methods: An observational cost-minimization study was carried out on a cohort of inmates who received anti-HCV treatment in El Dueso prison (May 2016–November 2017). A decision tree was constructed, incorporating different clinical profiles according to the severity of the disease, the results of diagnostic tests, and treatment outcomes as well as the costs of each profile. Satisfaction with telemedicine was evaluated through an 11-question questionnaire with a 5-point Likert scale.

Results: Seventy-five inmates were treated and underwent TCP with a follow-up of one year. The average cost per patient with the TCP strategy was €1,156 (€1,136 direct costs). Had UCP been carried out, the cost would have been €1,665 (€1,608 direct). Telemedicine consultation practice produced savings of €509 (30.6%) per patient, with total savings of €38,677. The transfer costs from prison to hospital represented the most important saving item, accounting for 99.3% of the TCP-related savings. The questionnaire revealed high levels of satisfaction with TCP, with a median score of 5 in each question. Sustained virological response rates were 94.7% after the first treatment and 100% after retreatment of the four relapses.

Conclusion*:* Telemedicine consultation practice is a more efficient strategy than UCP, mainly due to the reduction of transfer costs while preserving effectiveness and user satisfaction.

INTRODUCTION

The hepatitis C virus (HCV) is a leading cause of liver-related morbidity and mortality worldwide, especially in Mediterranean countries (Blachier, Leleu, Peck-Radosavljevic, Valla, & Roudot-Thoraval, 2013; "World Health Organization, 2017. Hepatitis C fact sheet. ,"). An estimated 30% of all patients with HCV are reported to have been incarcerated at some point (Redman & Sterling, 2018). Consequently, prisons have become concentrated HCV microenvironments, exhibiting a markedly high burden of the disease up to ten times of that in the general population (Larney, et al., 2013). Seroprevalence in Western European and US prisons is 15.5% and 15.3%, respectively (Dolan, et al., 2016); in Spain, recent data have shown anti-HCV and viraemia prevalence rates of 13.0% and 10.9%, respectively (Cuadrado, et al., 2018). Conversely, recent estimations in the Spanish general population showed a seroprevalence of 1.1%, whereas the prevalence of viraemia was 0.3% (J. Crespo, et al., 2019).

The treatment of the prison population should be governed by the same principles applied to the general population. There are some additional reasons, such as the high probability of spreading the infection both within the prison and to the community. However, there are administrative, epidemiological, physical, and behavioural barriers that prevent the treatment from being carried out on all prisoners infected with HCV (Larney et al., 2013; Mina et al., 2014). Persistence of indoor risk practices favouring intraprison transmission, high detainee turnover, limited capacity to access hospital-based hepatitis specialists, and dependence on complicated, expensive, and uncomfortable transfers are some of the barriers that inmates must face. However, there are also barriers related to patients themselves, including lack of perceived illness, lack of awareness of

HCV treatments, stigma and fear of discrimination, and ongoing alcohol abuse (Yap et al., 2014). To overcome some of these barriers, some healthcare practices that improve access to treatment have been implemented (i.e., universal screening of the prison population; health education programmes; intensification and extension of harm reduction programmes to the entire inmate population). On the other hand, centralised prescription in hospitals entails additional barriers. The use of new technologies like telemedicine can also improve access and quality of health services in this setting (Belperio, Chartier, Ross, Alaigh, & Shulkin, 2017; Gualano, et al., 2017). A combination of global 'test-and-treat' programmes, with the use of telemedicine, seems an appropriate strategy to achieve this goal, as recently revealed by our group in 'El Dueso' prison (Cuadrado, et al., 2018). Furthermore, providing care to all HCV-infected inmates is itself cost-effective, improving health in the community (Dalgic, et al., 2019).

Telemedicine is defined as the use of medical information exchanged from one site to another through electronic communication to improve the patient's health (Grosch, Gottlieb, & Cullum, 2011). Distance is a critical factor in the use of telematic tools for the improvement of health. However, telemedicine is not only used for geographical reasons, but economic, social, security, and even privacy issues can justify its use. Telemedicine bridges the gap regarding this important barrier of attending to inmates (Crespo, Llerena, Cobo, Cabezas, & Cuadrado, 2019). In addition, it enables communication to be improved among professionals, as demonstrated by the extension for community healthcare outcomes (ECHO) project used to bring HCV treatment closer to the community and the prison population (Arora, Thornton, Jenkusky, Parish, & Scaletti, 2007).

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This tool proven to be useful in the management of different clinical processes in prison including hepatitis C (Jimenez Galan et al., 2019) and, at the same time, avoids complicated transfers of inmates between prisons and hospitals that ultimately entail a loss of self-esteem produced by escorted transfers (Belperio, et al., 2017; Cuadrado, et al., 2018; Gualano, et al., 2017; Kassar, Roe, & Desimone, 2017; Morey, et al., 2019). However, any healthcare innovation must show efficiency in terms of both patient and economic benefits, and feasibility. To our knowledge, an analysis of the costs of this strategy while sustaining its effectiveness in this setting has not been performed so far.

The aim of this study was to evaluate whether clinical practice based on telemedicine (TCP) is more efficient (i.e., it has lower costs for the same effect) than usual clinical practice (UCP) based on face-to-face hospital consultations.

METHODS

Design

This was an observational cost-minimization study with a retrospective economic evaluation (through the construction of a decision tree model) about the use of telemedicine in the management of a cohort following HCV antiviral treatment in a prison. The cohort has been previously described (NCT02768961) and corresponds to all inmates in 'El Dueso' (Spain) experiencing a 'test and treat' HCV programme supported by telemedicine from May 2016 (Cuadrado et al., 2018). For the purpose of this study, the cut-off established in the screening programme was November 2017, and the follow-up period for the patients included was extended for a year, until November 2018.

Additional inclusion criteria for this study consisted of HCV viraemia, oral antivirals and having had at least one telemedicine consultation (TC).

All viraemic patients had a scheduled face-to-face consultation (FFC) at the Marqués de Valdecilla University Hospital (a tertiary hospital located 43 km away from El Dueso) with a hepatologist. A full characterisation of infected patients was performed, including a determination of disease severity by abdominal ultrasonography and transient elastography (TE; Fibroscan®). After that, a personalised IFN-free treatment was performed according to the current European guidelines (European Association for the Study of the Liver. Electronic address & European Association for the Study of the 2018), and a TCP follow-up was scheduled. In the TCP strategy, some clinical profiles required additional transfers between the prison and the hospital (i.e., performing an FFC, gastroscopy, ultrasonography, or TE). The UCP strategy was retrospectively modelled by reproducing the same chain of events as in the TCP strategy, but assigning to each TC the consumption of resources that a FFC would have involved.

Telemedicine Consultation

Telemedicine consultations were designed following the guidelines of the American Telemedicine Association ("American Telemedicine Association. Core Operational Guidelines for Telehealth Services Involving Provider-Patient Interactions May 2014. ,"). They consisted of a videoconference between the specialist, located in the hospital's office, and the inmate accompanied by the prison doctor, from a room in the prison. The SARA Network (Application Systems and Networks for Administrations) was used, which is a free system

that connects the networks of European Public Administrations, facilitating the exchange of secure information ("Technology Transfer Centre. Government of Spain. Red SARA.,"). This tool allows personal video collaboration through multidirectional voice and video over Internet Protocol, instant messaging, file and application sharing, chat, and session recording. As the traffic is encrypted, the system is compatible with the European regulation on Protection of Personal Data ("REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and the free movement of these data and repealing the Directive 95/46 / CE (General Data Protection Regulation),"). The quality and satisfaction of teleconsultations were evaluated through a self-administered 11-item questionnaire, answered on a 5-point Likert scale as previously described (Cuadrado, et al., 2018).

Statistical analysis

Economic Evaluation

The model compares the costs of applying care based on TCP with the estimated costs equivalent to UCP based on face-to-face consultations. It is assumed that the clinical outcomes are similar in each branch; therefore, only the costs have been considered. The efficiency has been estimated as a cost minimisation analysis that estimates the difference in costs of applying TCP and not applying it ("Serrano Aguilar P, Yanes López V, coordinadores. Guía de diseño, evaluación e implantación de servicios de salud basados en telemedicina. Madrid: Plan Nacional para el SNS del MSC Servicio de Evaluación del Servicio Canario de la Salud, 2009.," ; Snoswell, Smith,

Scuffham, & Whitty, 2017). The setting of the model is El Dueso, and the time horizon is one year. The perspective of the National Health System (considering only direct costs) and the social perspective (considering both direct and indirect costs) were used. Table 1 shows the type of costs included in the model (both direct and indirect), the unitary costs of each of the resources, and the official source consulted (Ministry of Health (Government of Cantabria). Order SAN / 12/2011; "Penitentiary Code. Official State Bulletin Government of Spain. Edition updated to September 3, 2018," ; "Royal Decree 1077/2017, of December 29, which established the minimum interprofessional salary for 2018."). In each of the branches, the variables that intervene in the cost production process (e.g., diagnostic tests, transfers, TC, FFC, etc.) were identified. The structure of the model, the variables it is composed of, and the probabilities of each node were obtained retrospectively from the real data of the study cohort. Costs were calculated from the first FFC up to one year later.

The model reproduced the events up to week 52. The profile that each patient had followed was traced by assigning the corresponding cost to each event identified in its corresponding random node. The events within each profile depended on different variables (i.e., severity of disease, achievement of sustained virologic response, need of portal hypertension treatment, etc.). The cumulative cost of each profile was calculated and then was multiplied by the number of patients in each profile. The cost of each strategy (TCP or UCP) was calculated as the sum of the costs of the patients of all profiles within each strategy. The consumption of resources of the first FFC, conventional blood tests (complete blood count and biochemistry), liver function tests, RNA-HCV quantification, ultrasound, TE, and gastroscopy (if needed) were identical within

each profile within either the TCP or UCP (Table 2). However, differences between the two strategies occurred in a number of successive FFC, TC, and transfers to hospitals. The transfer to hospitals, in the case of UCP, takes place as often as a new FFC, TE or gastroscopy is required; in the case of the TCP, only elastography, ultrasound, or gastroscopy require transfer to the hospital. For this reason, there are fewer transfers to hospital with TCP than with UCP (Table 2). The efficiency corresponds to the cost differences between the two strategies. This analysis reports on the savings (in euros) in absolute values (entire cohort) of TCP with respect to UCP. Savings between the two strategies were also calculated in relative terms (costs per patient).

Quality and satisfaction of teleconsultations

A descriptive analysis was performed. The mean, median, percentiles as well as the percentage of answers higher than three for each of the eleven questions were calculated. Statistical analysis was performed using SPSS Statistics for Windows, Version 21.0 (IBM Corp, Chicago, Armonk, NY, USA).

Ethics.

The study was approved by the Institutional Review Board of Cantabria on July 27, 2015, and was conducted in compliance with the Declaration of Helsinki of 1975, revised in 2013. All patients provided written informed consent.

RESULTS

Up to December 2017, 1,014 out of 1,019 inmates had agreed to participate in the programme (99.5%). One hundred and thirty-one participants were anti-HCV positive (12.9%), whereas ninety-nine (9.8%) had detectable viraemia. Eighty patients initiated the scheduled antiviral treatment out of which seventy-five patients fulfilled the inclusion criteria for the study. One patient rejected telemedicine, and TCP was not considered for another patient who suffered from severe deafness. Both patients were excluded from the study as well as another three patients who were lost to follow-up. The flowchart of the study is shown in Figure 1.

The decision tree describing the flow of patients and the events that comprised the 12 profiles found is shown in Figure 2. Fifty patients had a chain of events corresponding to profile 1; they corresponded to those with a basal TE ≤ 20 kPa, who achieved sustained virologic response and were discharged from follow-up on the basis of a final TE that revealed fibrosis ≤ F2. The distribution of patients for the rest of the profiles is shown in Figure 2 and Table 2. There were no patients in profiles 3, 4, 6, 7, and 8. One patient in profile 12 refused gastroscopy. For the rest of the profiles, the consumption of resources was the same for all patients within each profile.

The average cost of the consultations throughout the one-year follow-up in TCP (mostly telemedicine consultations) was higher than in UCP (all face-to-face consultations): €752.7 and €666.2, respectively. The overall cost of the UCP strategy for the cohort of 75 patients amounted to €126,537, with €122,243 (96.6%) corresponding to direct costs, and €4,295 (3.4%) to indirect costs

(Table 3). The overall cost of the TCP strategy amounted to €87,861€, with 86,312€ (98.2%) corresponding to direct costs, and 1,549€ (1.8%) to indirect costs. Therefore, the TCP strategy represented a saving of €38,677 (30.6%) in overall costs, by reducing direct costs by €35,931 (29.4%) and indirect costs by €2,746 (63.9%). The savings in direct costs of TCP occur despite the increase in direct medical costs (€6,577; 10.1%) with respect to UCP, as the former corresponds to a saving in direct non-medical costs (€42,508€; 74.4%). In terms of costs per patient, the average cost was €1,664.9, [€1,608.5 (96.6%) direct costs, and €56.5 (3.4%) indirect costs] for the UCP strategy (Table 3). Regarding TCP, the individual costs were €1,156.1, [€1,135.7 (98.2%) direct, and €20.4 (1.8%) indirect costs]. Hence, with TCP, there is an average saving per patient of €508.9€ (30.6%).

The responses of 253 satisfaction questionnaires were analysed, which implied an adherence to the completion of the survey by 82.7% (248/300) of patients who required a single treatment regimen and 50% (4/8) of those who received a rescue regimen (Table 4). The satisfaction of patients with TC was high, both with the technical and organisational aspects, and with the aspects related to the doctor-patient relationship.

Finally, all 75 patients who fulfilled the inclusion criteria had an assessment of the virologic response available. Seventy-one out of 75 (94.7%) showed sustained virologic response after the first scheduled treatment, whereas another four patients achieved virological cure after a salvage regimen.

DISCUSSION

The study revealed that TCP is feasible, has a great level of acceptance by the patients and also helps optimise the management of inmates experiencing a hepatitis C ‘test and treat’ strategy by preserving their medical attention while providing a 30.6% per patient cost saving (€508.9/patient). As a result, TCP appears to be an efficient tool that can contribute to the elimination of hepatitis C in prisons.

As proposed by the WHO, the goal of eliminating hepatitis C is technically possible, given the high efficacy of direct acting antivirals (World Health Organization, 2016b. Combatting hepatitis B and C to reach elimination by 2030. ," ; "World Health Organization, 2017. Hepatitis C fact sheet. ,"), but is a complex one from an organisational viewpoint. A pragmatic approach to achieve the elimination of hepatitis C would be to divide global objectives into smaller objectives. This concept is known as ‘micro-elimination’, and prisons are particularly attractive microenvironments for HCV treatment (Lazarus, Wiktor, Colombo, Thursz, & Foundation, 2017; Redman & Sterling, 2018). Since 2016, our group has been carrying out a sustained strategy of global test-and-treat in ‘El-Dueso’ supported by telemedicine, which has shown good results in terms of both individual and overall prison epidemiological goals (Cuadrado, et al., 2018). An added value to these micro-elimination programs consists of focussing on vulnerable populations that represent a greater burden of the disease. This vulnerability is proportional to the greater elusiveness of preventive and therapeutic health programs.

Linkage to specialist care strategies via telemedicine associated with universal screening of blood-borne viruses in inmates has been suggested to substantially increase rates of testing, diagnosis, and treatment of HCV (Cuadrado, et al., 2018; Morey, et al., 2018). In fact, telemedicine has also been successfully incorporated into other prison HCV micro-elimination programmes (Belperio, et al., 2017; Morey, et al., 2019). Even telementoring as a strategy to improve medical care for HCV in prisons has shown good results (Arora, et al., 2007; Neuhaus, et al., 2018). However, the costs of this strategy have not been evaluated so far. This cost minimisation analysis shows that the TCP strategy is more efficient than UCP: not only does it achieve good clinical results with high levels of satisfaction by the patients, but it also means an average cost saving of €509 (30.6%) per inmate treated. This was despite the slight increase in direct medical costs due to the need to have medical staff from the prison in the TC. The main cost savings are derived from the cost avoided in transfers between hospitals and prisons, which was also the most valued item in the satisfaction questionnaire filled in by telemedicine users. Additionally, telemedicine can also offer hidden savings such as time saving for physicians travelling to the prisons and getting in and out. If they do all the consultations from their office, they can do other work instead of travelling. In addition, prisons sometimes lockdown leading to a wasted trip. Telemedicine makes this much more efficient. It must be said that the SARA Network used in this telemedicine approach is guaranteed by the Spanish government and extended to all public administrations without any added cost. Therefore, in Spain, the technological costs of the implementation of any telemedicine program in public institutions are practically amortised from the start (in addition to the Sara Network, which

connects all Spanish public administrations through its own network, any mobile device that has the application, a camera, and microphone can be used for the connection without the need for internet access) and we must only take into account the costs of the staff who attend these medical consultations. Although telemedicine has shown comparable or even better results than conventional management of various clinical conditions, specifically in prisons, few studies have analysed its efficiency by considering economic aspects (de la Torre-Diez, Lopez-Coronado, Vaca, Aguado, & de Castro, 2015; Gualano, et al., 2017). The economic impact of telemedicine is a collaborative and complex process in which different economic, social, and political actors can be involved. A systematic review on the cost-effectiveness of telemedicine and other e-health procedures has revealed difficulties in evaluating this issue due to different factors: broad disparity of telemedicine modalities, disparate estimation methods, lack of randomised control trials, lack of long-term evaluation studies, small sample sizes, and absence of quality data and appropriate measures (de la Torre-Diez, et al., 2015). Although most studies in the literature have concluded that telemedicine systems are cost-effective (Crow, et al., 2009; Franzini, Sail, Thomas, & Wueste, 2011; Jackson, et al., 2008; Mistry & Gardiner, 2013; Naversnik & Mrhar, 2013), some have not come to the same conclusion (Mistry, 2012; Whitten, et al., 2002), and concerns that expanded coverage for telehealth may actually increase spending by adding to the overall use of care have been expressed (Licurse & Mehrotra, 2018). Our study suggests that TCP seems to be more efficient as a result of a more favourable economic impact while maintaining clinical outcomes and satisfaction standards. However, we must add that TCP is still far from being extensively

used as a routine practice in different clinical settings including prisons, which are characterized by impaired access to health resources (Gualano, et al., 2017). In fact, in Spain, only 1,456 out of 72,551 (1.2%) specialised care consultations that were delivered to inmates during 2016 used telemedicine ("General Report. General Secretary of Penitentiary Institutions"). We believe that extending the use of TCP to the management of many clinical processes, particularly hepatitis C, could improve efficiency especially in circumstances such as those derived from the current COVID-19 pandemic.

A model similar to the one described here has been carried out since January 2017 in another Spanish high security prison (Herrera de la Mancha) that serves a similar prison population. A recent report of their results on a sample of 20 HCV patients treated with direct-acting antivirals shows encouraging results similar to those described in El Dueso in terms of the acceptance of the programme, efficacy of the treatments, and level of satisfaction with telemedicine (Sánchez-Alonso M, 2018). These results reinforce the conclusions of our model and the applicability of telemedicine in the prison environment that can be extended to other Spanish and European prisons.

Users' acceptance of a new healthcare tool is one of the most valuable factors to support its use in addition to other aspects that influence its efficiency. Only one patient refused to follow TCP, and this practice was not considered for another patient suffering from severe deafness. Both underwent UCP. One of the most remarkable aspects of this TCP is the unanimously high level of satisfaction expressed by the participants. In particular, they strongly valued the possibility of receiving the best medical care without the need for displacements, thus preserving their privacy, intimacy, and self-esteem. This

high level of acceptance of telemedicine has been recently reported in another study (Galan et al., 2019).

This study had some limitations. UCP costs were not based on real data, but were modelled; however, the use of real TCP data and the applied methodology precluded overestimation or underestimation of the costs with either strategy. In addition, the plausibility of the choice of strategy influencing the clinical results was low, given that TCP did not affect the treatments decided by the hepatologist or its adherence. Moreover, as is already the case in the treatment of hepatitis C with direct-acting antivirals in the general population, a reduction in the number of visits (both in TCP and UCP), and therefore, in costs in prisons was also expected (compared to the number described in our model that collected data from a research study with multiple scheduled visits). At the time of developing this manuscript, we optimised the treatment program for these patients and almost all patients had their entire assessment in prison: for those with low fibrosis score [(FIB-4 below 0.93) (Kelly, Riordan, Bopage, Lloyd, & Post, 2018)], we started treatment with no visit to the hospital and perform analytical controls only at baseline and 12 weeks post-treatment. The rest of the inmates with an active HCV infection were evaluated with a TE/ultrasound as needed. Only decompensated cirrhotic patients or those who need gastroscopy were taken to the hospital. In this scenario, telemedicine will probably continue to be profitable, although further research is required to prove this. Finally, it is possible that there may be differences in other countries, taking into account the diversity of costs, distances from prisons to tertiary hospitals, severity of liver disease, etc. Thus, this points to the need for further research to confirm the adaptability of this model to other settings.

In conclusion, a TCP model such as that described here is feasible, well accepted by users and cost-saving, while safeguarding clinical effectiveness with regard to UCP, and also replicable for other penitentiary centres.

In summary, it is recommended that public administrations adopt these strategies to care for people facing difficulties in accessing health services, providing a single-step solution to evaluate infection and disease, induce treatment uptake, and eliminate infection.

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Mateo, Antonio J Blasco, Pablo Lázaro and Javier Crespo; Writing – original draft, Antonio Cuadrado, Antonio J Blasco, Pablo Lázaro and Javier Crespo; Writing – review & editing, Antonio Cuadrado, Carmen Cobo, Miguel Mateo, Antonio J Blasco, Joaquin Cabezas, Susana Llerena, Jose I Fortea, Pablo Lázaro and Javier Crespo.

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Data accessibility statement

Accessible underlying research materials related to this paper may be consulted upon express request at the address (https://www.idival.org/es/). The petitions must be duly justified, they will be evaluated by a committee and they will be governed by the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on the protection of natural persons. regarding the processing of personal data and the free circulation of these data, and its regulation in Spain through Organic Law 3/2018, of December 5, on the protection of personal data and guarantee of digital rights.

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Table 1. Unit costs of the resources considered

Resource	Cost (€)	Source
Direct medical costs*		
Digestive consultation (first visit)	165.4	[1]
Digestive consultation (successive)	105.4	[1‡]
Telemedicine consultation†	124.9	[1]
Abdominal ultrasonography	75.4	[1]
Transient Elastography (Fibroscan®)	20.8	[1]
Upper digestive endoscopy	303.3	
Direct non-medical costs		
Transfer to the hospital from prison§	126.1	[‡]
Indirect costs‖		
Loss of work of the prisoner due to hospital discharge (5.33 hours)	27.7	[2,3,‡]
Loss of work of the prisoner due to telemedicine consultation (0.75 hours)	3.9	[2,3,‡]

*Public prices of the health services provided by the Cantabrian Health Service in force in 2016 and 2017 ([1]Ministry of Health (Government of Cantabria). Order SAN / 12/2011). Neither antiviral treatment costs nor costs derived from management of portal hypertension have been considered because they are not differential costs (i.e., the treatment is the same with both the strategies); †Includes the presence of the hepatologist at the hospital and one member of the medical staff of the prison in the penitentiary centre (lasting 30 minutes), a room with a computer/webcam connected to SARA Network (Red SARA). ‡Time estimated by the authors; §The cost of transferring the inmate to the hospital has been estimated by adding the costs of

the following items: administrative nursing management, procedure management, scheduling the departure, communication of the departure, stop-and-search at departure, time of civil guards involved in the transfer, stop-and-search at return, and vehicle fuel. Each of the concepts in which officials participated was assigned a time to which the labour cost corresponding to the level of the official was applied; [ll]Cost of working hours lost by the inmate because of having to attend either face-to-face consultation or telemedicine consultation; and applied to the proportion of inmates working in companies outside the penitentiary or in paid destinations (estimated by the administrative services of the penitentiary centre at an average of 34.2%). The labour cost equivalent to the remuneration module assigned to inmates who perform productive work in workshops (€4.07/hour in 2017) has been used; it is equivalent to the salary plus the percentages of common contingencies, unemployment coverage, wage guarantee fund, and professional training. (²"Penitentiary Code. Official State Bulletin Government of Spain. Edition updated to September 3, 2018," ; ³"Royal Decree 1077/2017, of December 29, which establishes the minimum interprofessional salary for 2018.,")

Table 2. Use of resources for each patient profile during the year of follow-up (number of times / year)

		Resources used in the same amount with UCP and TCP							Resources used in different amounts with the UCP and TCP				
									Successive FFC		Telemedicine Consultations	Transfer prison-hospital	
Profile	N	First visit (FFC)	CBT	LFTs	PCR	US	TE	Gastro	UCP	TCP	TCP	UCP	TCP
1	50	1	4	3	2	1	1	0	4	0	4	5	1
2	7	1	4	3	2	2	2	0	6	1	5	7	2
3	0	1	4	3	2	3	3	1	9	2	7	11	4
4	0	1	4	3	2	3	3	1	9	2	7	11	4
5	1	1	6	4	3	1	1	0	7	0	7	8	1
6	0	1	6	4	3	2	2	0	8	1	7	9	2
7	0	1	6	4	3	3	3	1	11	2	9	13	4
8	0	1	6	4	3	3	3	1	11	2	9	13	4
9	4	1	4	3	2	2	2	1	6	1	5	8	3
10	1	1	6	4	3	2	2	1	9	1	8	11	3

11	10	1	4	3	2	2	2	1	6	1	5	8	3
12	2	1	6	4	3	2	2	1*	9	1	8	11*	3*

UCP = usual clinical Practice; TCP = telemedicine clinical practice; N = number of patients within each profile; FFC = face-to-face consultation; CBT = conventional blood test; LFTs = liver function tests; PCR = HCV-RNA determined by PCR; US = abdominal ultrasound; TE = transient elastography by Fibroscan®; Gastro = gastroscopy; *One patient belonging to profile 12 refused to undergo gastroscopy.

Table 3. Costs of the UCP and TCP strategies. Cost minimization analysis

Strategy		Direct costs			Indirect costs	Overall costs
		Medical	Non-medical	Total		
UCP	Cost of the cohort*	65,102.9	57,139.8	122,242.6	4,294.9	126.537,5
	% with respect to the overall cost	51.5	45.2	96.6	3.4	100,0
	Cost/patient	856.6	751.8	1608.5	56.5	1.664,9
TCP	Cost of the cohort*	71,679.9	14,631.8	86,311.8	1,549.1	87.860,9
	% with respect to the overall cost	81.6	16.7	98.2	1.8	100,0
	Cost/patient	943.2	192.5	1,135.7	20.4	1.156,1
Saving	In the cost of the cohort*	-6,577.1	42,507.9	35,930.8	2,745.8	38.676,6
	% saving	-10.1	74.4	29.4	63.9	30,6
	In the cost/patient	-86.5	559.3	472.8	36.1	508,9

UCP = usual clinical practice; TCP = telemedicine clinical practice; * Seventy-five patients followed for one year.

Table 4. The Telemedicine Satisfaction Scale (5-point Likert Scale) (n= 253 answers)*

Question	Mean	Median	P-25	P-75	Proportion > 3 (%)
1. I was able to see the doctor on the screen.	4.7	5	5	5	94.5
2. I was able to hear the doctor well through the speakers.	4.4	5	4	5	88.1
3. The doctor could hear me without problems.	4.6	5	4	5	94.1
4. I felt comfortable talking to the doctor via the screen.	4.7	5	5	5	94.5
5. When I started the consultation I was not more nervous than usual.	4.3	5	4	5	83.4
6. During the consultation I was relaxed.	4.5	5	4	5	89.7
7. I could explain what I wanted to the doctor.	4.6	5	4	5	93.7
8. I understood the instructions the doctor gave me.	4.7	5	5	5	94.5

9. I feel the timeliness of consultation was acceptable.	4.3	5	4	5	81.0
10. My privacy and confidentiality was respected.	4.6	5	4	5	95.7
11. Overall, I am satisfied with the service received.	4.8	5	5	5	96.8

P-25 = Percentile 25; P-75 = Percentile 75

*All 75 patients included answered the telemedicine satisfaction questionnaire in the first TC (TC 1: communication of results and initiation of treatment), 69 TC 2 (4 weeks after starting treatment), 64 TC 3 (at the end of treatment), 40 TC 4 (12 weeks after finishing the treatment), 2 TC 5 (start of rescue treatment or communication of results), and 2 TC 6 (4 weeks after starting the rescue treatment).

Figure legends

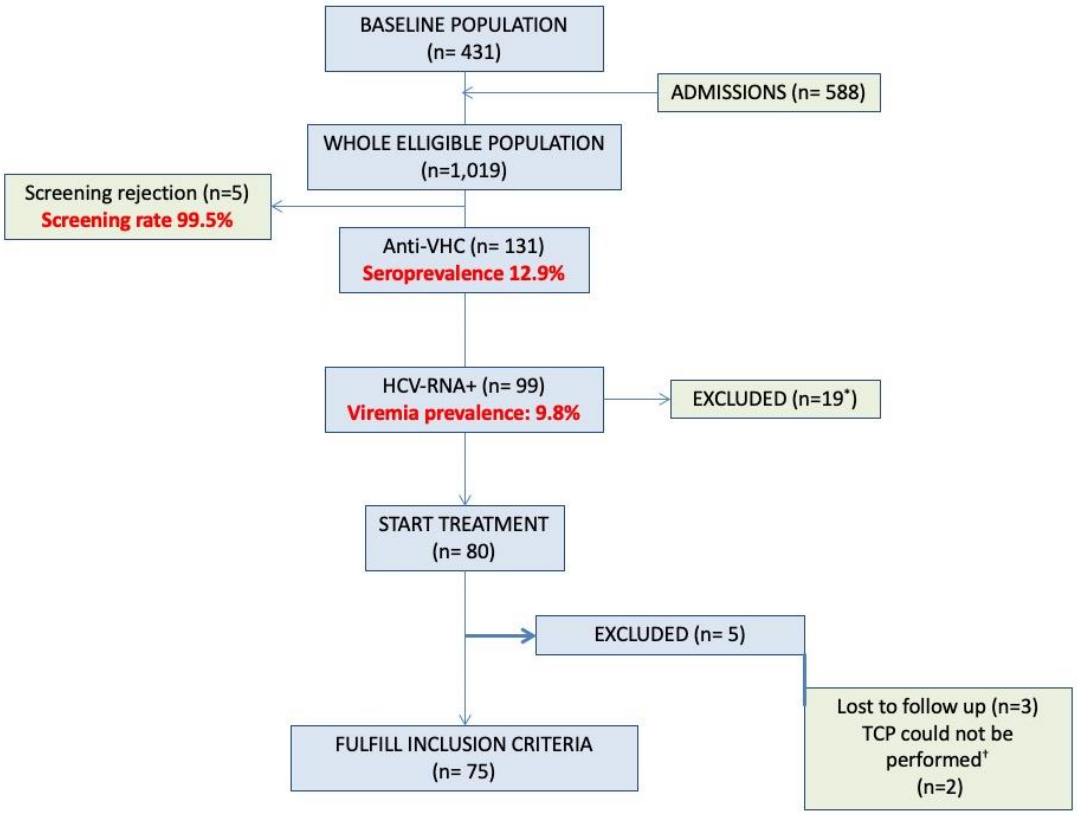


Figure 1. Flow-chart of the study.

*Patients whose confinement period at the centre was expected to be less than 30 days were excluded from the study. They were informed of their disease and possibilities of treatment in other centres or after leaving the prison; †TCP could not be performed (one patient had severe deafness that prevented correct hearing in the teleconsultation; another patient rejected teleconsultation).

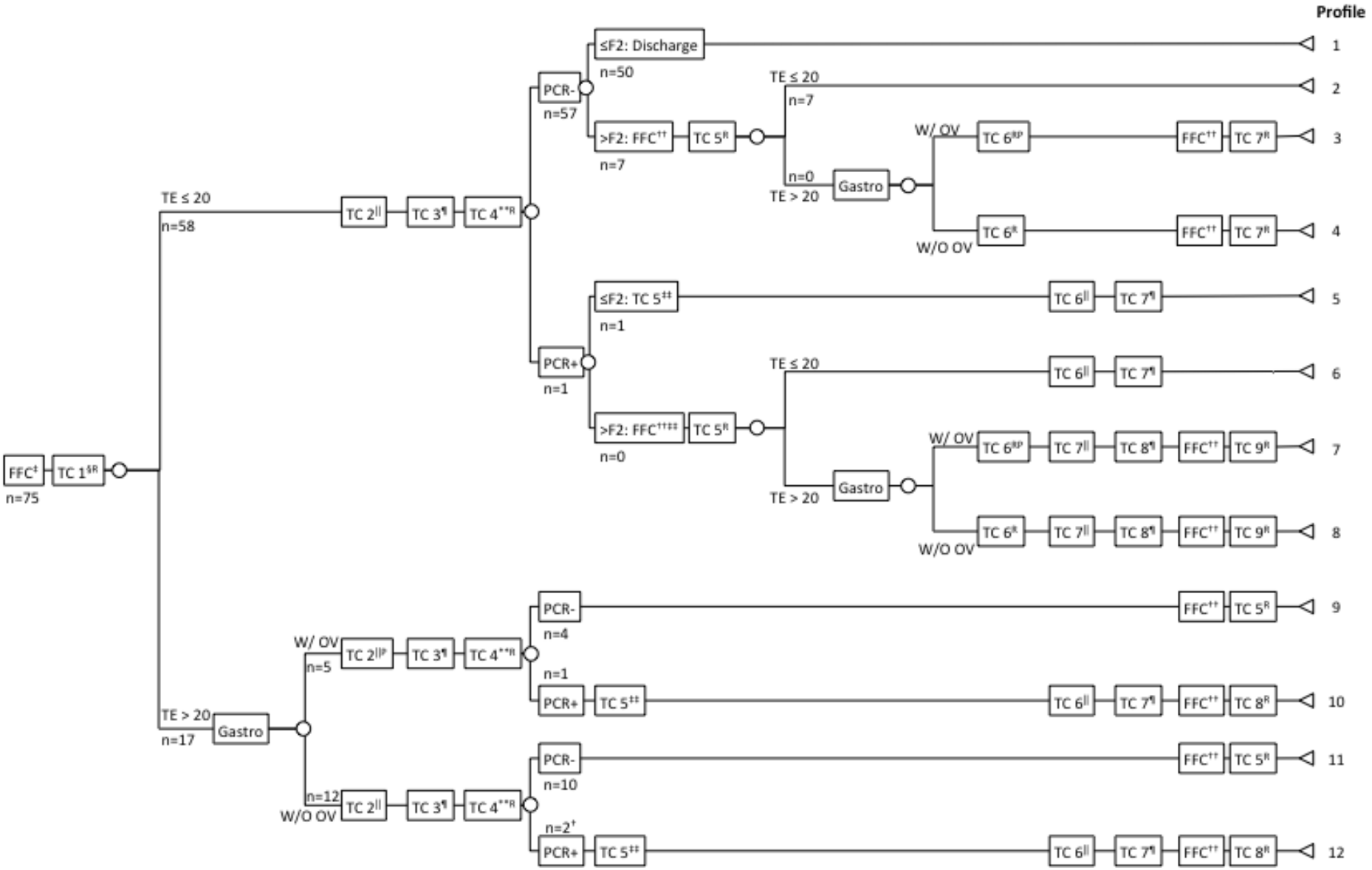
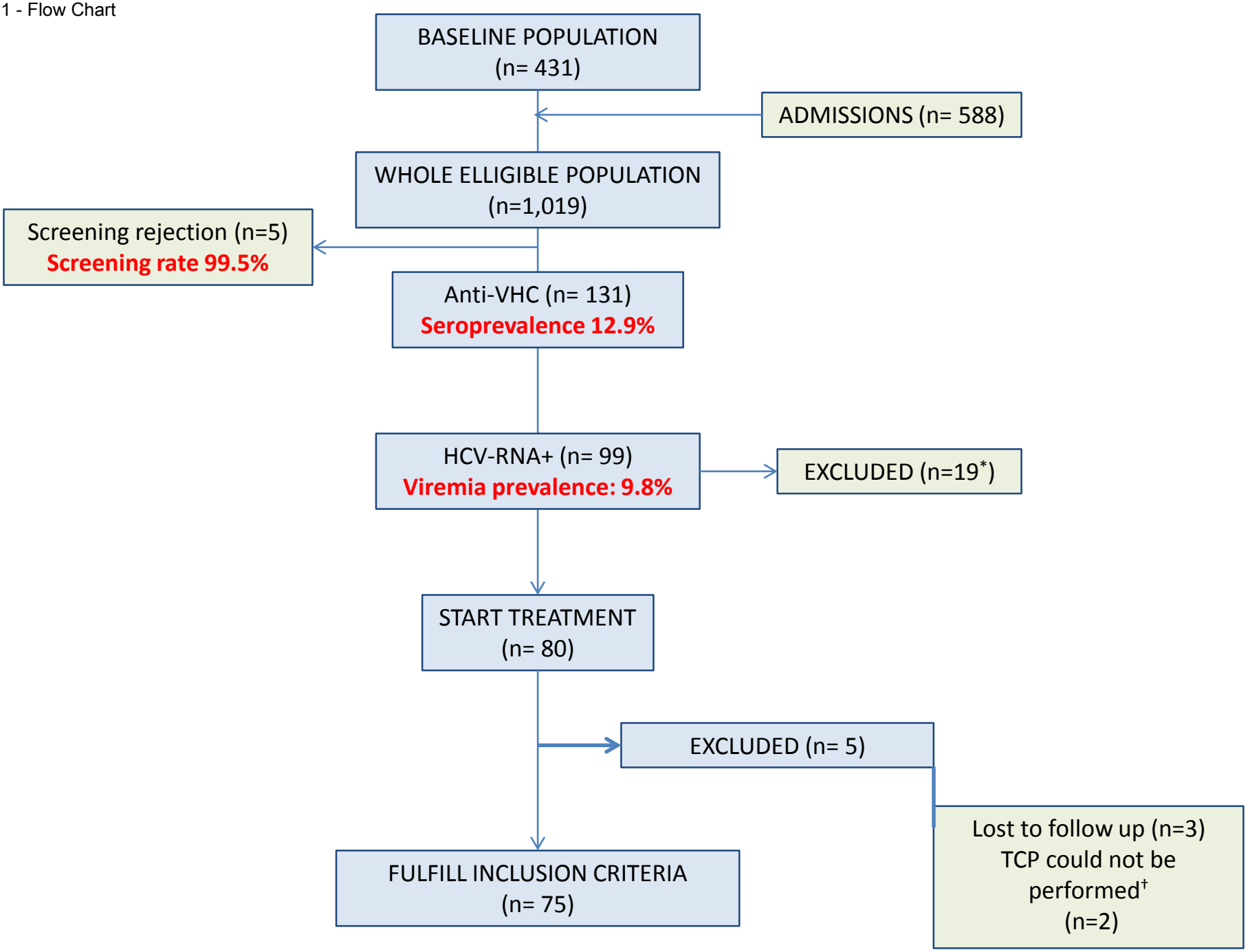

Profile
FFC†
TC 1§R
n=75
TE ≤ 20
n=58
TC 2||
TC 3¶
TC 4**R
PCR-
n=57
≤F2: Discharge
n=50
1
TE ≤ 20
n=7
2
>F2: FFC††
TC 5R
n=7
W/ OV
TC 6RP
FFC††
TC 7R
3
n=0
TE > 20
Gastro
W/O OV
TC 6R
FFC††
TC 7R
4
PCR+
n=1
≤F2: TC 5‡‡
n=1
TC 6||
TC 7¶
5
TE ≤ 20
TC 6||
TC 7¶
6
>F2: FFC†††‡‡
TC 5R
n=0
W/ OV
TC 6RP
TC 7||
TC 8¶
FFC††
TC 9R
7
TE > 20
Gastro
W/O OV
TC 6R
TC 7||
TC 8¶
FFC††
TC 9R
8
TE > 20
n=17
Gastro
W/ OV
n=5
TC 2||P
TC 3¶
TC 4**R
PCR-
n=4
FFC††
TC 5R
9
n=1
PCR+
TC 5‡‡
TC 6||
TC 7¶
FFC††
TC 8R
10
n=12
W/O OV
TC 2||
TC 3¶
TC 4**R
PCR-
n=10
FFC††
TC 5R
11
n=2†
PCR+
TC 5‡‡
TC 6||
TC 7¶
FFC††
TC 8R
12

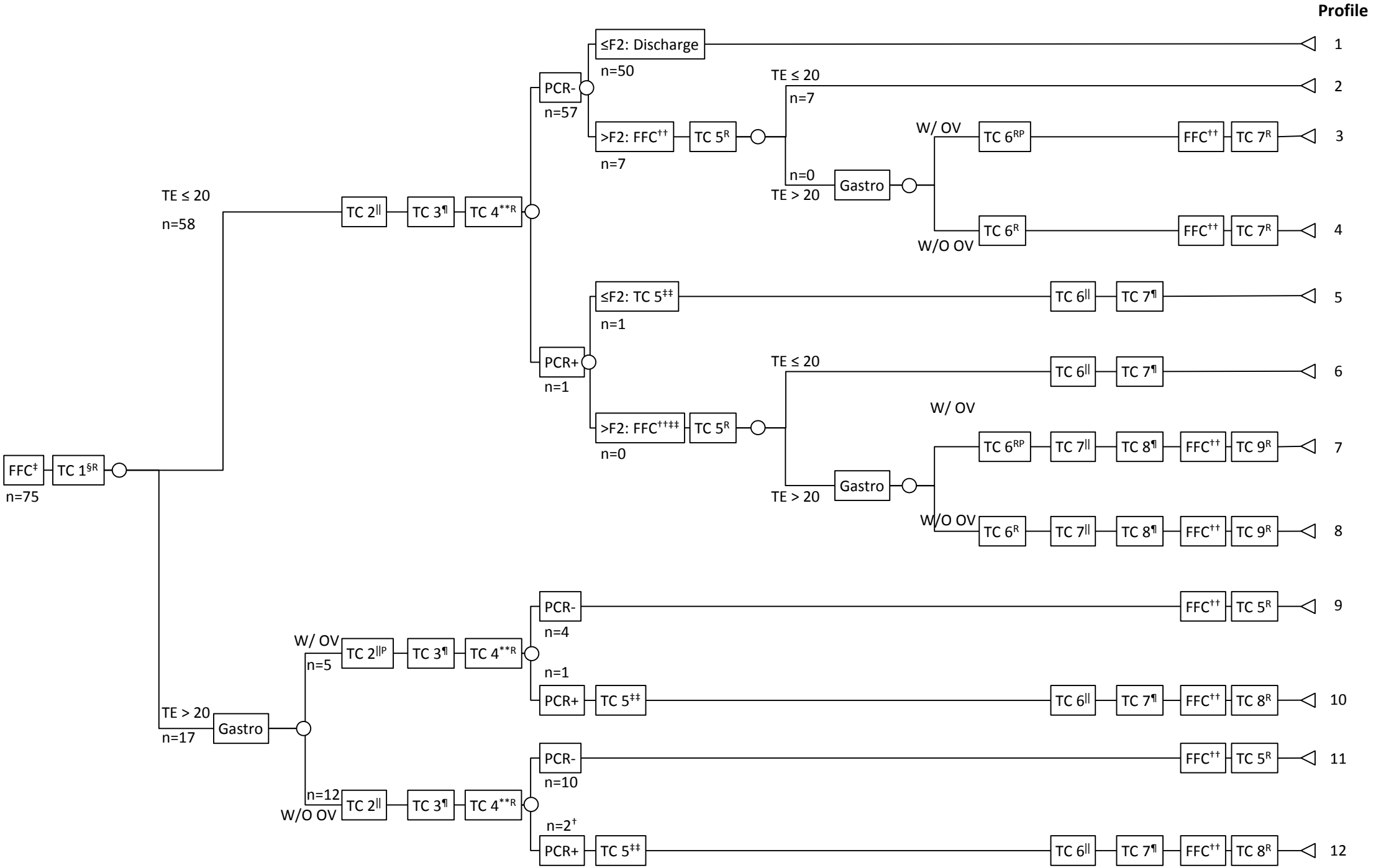
Figure 2. Decision tree of the cohort with the telemedicine strategy followed for 52 weeks[*].

[*]In usual clinical practice (UCP) telemedicine consultations (TC) are substituted by face-to-face (FFC) consultations with the hepatologist at the hospital. The rest of the decision tree is identical for both strategies. n = number of patients; [†]One patient belonging to profile 12 refused to undergo gastroscopy; Gastro = gastroscopy; PCR = HCV-RNA determined by PCR (positive means detectable, and negative undetectable); TE = transient elastography by Fibroscan® (expressed in kilopascals [kPa]); OEV = oesophageal varices; W/ OV = With oesophageal varices; W/O OV = Without oesophageal varices; [‡]First FFC common for all patients included the following procedures: a complete medical history, a conventional blood test (CBT) that includes a complete blood cell count and biochemistry, and liver function tests (LFTs), TE, and abdominal ultrasound; TC = telemedicine consultations are numbered consecutively by Arabic numbers as they occur; in addition, every TC is marked with a superindexed letter that indicates the purpose of it. TCs where some kind of results are communicated are additionally marked with a 'R' superindex whereas those where a specific medical treatment is directed to treat portal hypertension are super indexed with a 'P'; [§]the treatment was started after communicating the results; [‖]middle treatment TC with a medical review and CBT; [¶]End of treatment TC with the following procedures: medical review, CBT, LFTs, PCR; [**]TC twelve weeks post- treatment with the following procedures: medical review, CBT, LFTs, PCR, and communication of results (R); [††]FFC post-treatment where a new abdominal ultrasound and TE (by Fibroscan®) are performed to guide future actions; [‡‡]Start of an anti-HCV salvage regimen.

Figure 1 - Flow Chart



Figure(s)


Profile
FFC‡
TC 1§R
n=75
TE ≤ 20
n=58
TC 2‖
TC 3¶
TC 4**R
PCR-
n=57
≤F2: Discharge
n=50
1
TE ≤ 20
n=7
2
>F2: FFC††
n=7
TC 5R
W/ OV
TC 6RP
FFC††
TC 7R
3
n=0
TE > 20
Gastro
W/O OV
TC 6R
FFC††
TC 7R
4
PCR+
n=1
≤F2: TC 5‡‡
n=1
TC 6‖
TC 7¶
5
TE ≤ 20
TC 6‖
TC 7¶
6
>F2: FFC†††‡
n=0
TC 5R
W/ OV
TC 6RP
TC 7‖
TC 8¶
FFC††
TC 9R
7
TE > 20
Gastro
W/O OV
TC 6R
TC 7‖
TC 8¶
FFC††
TC 9R
8
TE > 20
n=17
Gastro
W/ OV
n=5
TC 2‖P
TC 3¶
TC 4**R
PCR-
n=4
FFC††
TC 5R
9
n=1
PCR+
TC 5‡‡
TC 6‖
TC 7¶
FFC††
TC 8R
10
n=12
W/O OV
TC 2‖
TC 3¶
TC 4**R
PCR-
n=10
FFC††
TC 5R
11
n=2†
PCR+
TC 5‡‡
TC 6‖
TC 7¶
FFC††
TC 8R
12