THE MANAGEMENT OF PATIENT IN TELE-DIALYSIS: THE EXPERIENCE OF AZIENDA OSPEDALIERO-UNIVERSITARIA CONSORZIALE POLICLINICO, BARI (IT)

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Limitations

This report is based on information available when the searches were made and does not contain data on subsequent developments or improvements of the evaluated technology. The observations made on effectiveness, safety or cost-effectiveness of the technology evaluated in the report are to be considered current but may change as more evidence becomes available if an update of the document is commissioned.

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Declaration of Conflict of Interest

The authors declare that they will not receive either benefits or harms from the publication of this report. None of the authors have or have held shares, consultancies or personal relationships with any of the producers of the devices assessed in this document.

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Index

1. List of Abbreviations

APD	Automatic Peritoneal Dialysis
CAD	Centri territoriali per assistenza dialitica ad alta intensità (dialysis in high intensity satellite unit)
CAL	Centri territoriali per assistenza a media intensità (dialysis in medium intensity satellite unit)
CC	Cardiovascular complications
CCPD	Continuous cycling peritoneal dialysis
CG	Caregiver
CHHD	Conventional home haemodialysis
CKD	Chronic Kidney Disease
COPD	Continuous Outpatient Peritoneal Dialysis
COPE	Coping Orientation to Problems Experienced
CND	Medical Device Italian Classification
DES	Data Encryption Standard
ESRD	End-stage renal disease
GBD	Global Burden of Disease
GFR	Glomerular filtration rate
HD	Hemodialysis
HHD	Home HD
IOT	Internet of things
IPD	Intermittent Peritoneal Dialysis
LHA	Local Health Authority
MAST	Model for Assessment of Telemedicine
MAUDE	FDA Manufacturer and User Facility Device Experience
MPD	Manual Peritoneal Dialysis
PD	Peritoneal Dialysis
PB	Azienda Ospedaliero-Universitaria Consorziale Policlinico di Bari
RSA	Residenza sanitaria assistenziale
SHA	Secure Hash Algorithm
SDHD	Short-daily haemodialysis
SDHHD	Short-daily home haemodialysis
SQL	Structured Query Language
SSL	Secure Sockets Layer
SUTAQ	Service User Technology Acceptability Questionnaire
TD	Tele-dialysis
TDE	Transparent Data Encryption
TM	Telemedicine
TLS	Transport Layer Security
Ualb/Ucreat	Urinary albumin/creatinine concentration ratio
UF	Ultrafiltration profiling

2. Abstract

1.1. Background

Nell'ultimo decennio sono stati condotti numerosi studi volti a valutare la fattibilità e l'efficacia della telemedicina (TM), compresa la teledialisi (TD). TM include diverse applicazioni specifiche dei servizi sanitari a distanza, come il Tele-consulto, la Tele-conferenza, il Tele-monitoraggio e l'elenco è in rapida crescita. La dialisi consiste nella purificazione del sangue come sostituto della normale funzione del rene, e la Tele-dialisi consente a questa procedura di svolgersi fuori dagli ospedali o dagli ambulatori, grazie al monitoraggio da remoto. Dal 2010 sono state registrate molte esperienze TD in tutto il mondo inclusa l'Italia. TD può fornire emodialisi (HD) o dialisi peritoneale (PD). Di solito TD include tele-monitoraggio e visite di telemedicina per una migliore interazione tra medici e pazienti.

1.2. Obiettivi

Lo scopo di questo studio è valutare l'efficacia sperimentale, l'efficacia reale, i costi e la prospettiva dei pazienti sull'uso della Tele-dialisi domiciliare sulla base della primaria esperienza in corso presso l'Azienda Ospedaliero-Universitaria Consorziale Policlinico di Bari (PB), rispetto al trattamento di dialisi domiciliare senza il servizio di telemedicina.

Il prototipo di Tele-dialisi di PB è stato finanziato da UE e Regione Puglia (progetto Diadom, programma Smart Health 2.0) con lo scopo di validare il sistema di Home Care per pazienti con HD e PD in Regione Puglia. I dati raccolti dall'esperienza di cui sopra potrebbero essere utili per valutare se il trattamento TD domiciliare può prevenire eventi dannosi acuti e conseguenti ospedalizzazioni, e può essere vantaggioso per l'organizzazione dei servizi, in termini di costi, benessere del paziente e qualità della vita.

Nonostante l'esperienza PB rappresenti una fase iniziale di un progetto pilota, abbiamo scelto di adottare il rigoroso Modello per la Valutazione della Telemedicina (MAST), tradizionalmente adottato per mature esperienze di telemedicina, come toolkit per valutare l'impatto delle applicazioni di TD. Il MAST utilizza un approccio in tre fasi basato sui sette domini EUnetHTA, con l'obiettivo di fornire la base per il processo decisionale.

1.3. Metodologia di ricerca

Per studiare l'efficacia e la sicurezza delle esperienze di Tele-dialisi disponibili in letteratura, oltre all'esperienza del PB, abbiamo eseguito una ricerca sistematica nel database PubMed. La nostra ricerca è limitata ai testi integrali in lingua inglese pubblicati negli ultimi cinque anni e riguardanti la popolazione umana. Le informazioni tecniche sul dispositivo medico sono state ricercate consultando diverse fonti come: la banca dati/repertorio dei dispositivi medici nazionali italiani (BD/RDM) ed ECRI. Ulteriori e più dettagliate informazioni (come l'architettura ICT) sono state fornite da esperti clinici del PB che hanno risposto a un questionario strutturato ad hoc.

1.4. Criteri di selezione

La popolazione target identificata nell'esperienza pivotale del PB include pazienti sopra i 18 anni con insufficienza renale allo stadio finale, senza comorbilità, che necessitano di trattamento di dialisi o come trattamento a vita, o durante l'attesa di trapianto di rene.

1.5. Risultati principali

Finora non è ancora disponibile alcuna misura del risultato da parte di PB. Il basso numero di pazienti reclutati, la mancanza di risultati in termini di outcome e i setting non ben delineati non consentono di portare a conclusioni sulla sostenibilità o sulla costo-efficacia. Pertanto, utilizzando la strategia di ricerca riportata nell' Appendice 2, abbiamo riscontrato e analizzato una revisione sistematica da parte di Ramar et al. [Ramar 2017]. La revisione si focalizza sulla valutazione di scenari multipli, inclusa la dialisi domiciliare: 13 studi di emodialisi domiciliare, inclusi PD e HD comparati all'emodialisi ospedaliera, alla dialisi peritoneale e ai centri ambulatoriali territoriali (satelliti). Molti di questi 13 studi hanno anche incluso l'emodialisi notturna,

che ha dimostrato alla lunga di avere risultati migliori indipendentemente dalla ubicazione. Due dei 13 studi di emodialisi domiciliare analizzati hanno riportato sensibili miglioramenti negli outcome. I nostri criteri di selezione corrispondevano anche con quelli dello studio primario di Weinhandl e Collins [Weinhandl 2017].

Questo studio ha arruolato 606 pazienti e ha concluso che l'uso di una piattaforma di telesalute che consente una valutazione continua dei pazienti con HD domiciliare è stato associato a un minor rischio di abbandono per tutte le cause, a un minor rischio di guasti tecnici e una maggiore probabilità di finalizzazione dell'addestramento HD domiciliare (HHD). Saranno necessari ulteriori studi per identificare i meccanismi attraverso i quali l'uso di una piattaforma di telesalute possa migliorare gli esiti clinici e ridurre il carico sui pazienti. Il modello organizzativo del nuovo servizio di Tele-dialisi domiciliare consiste in un accurato monitoraggio del paziente. Il PB ha un ruolo fondamentale nel modello organizzativo per la TD. La sala di controllo si trova presso il PB e il personale è composto da 2 medici e 3 infermieri. Prima del loro reclutamento al protocollo di TD, i pazienti ricevono una formazione. Alcuni ostacoli all'introduzione della Tele-dialisi possono essere i pazienti stessi, le loro famiglie o le istituzioni.

Inoltre, abbiamo eseguito un'analisi economica confrontando il trattamento tradizionale senza assistenza video con il trattamento TD domiciliare. Abbiamo ottenuto 3 scenari di trattamento: Standard Care (non video-assistita), nuova introduzione (TD/Video - assistita) e scenari simulati (sia non video-assistiti che TD/video assistiti). I 3 scenari identificati sono stati analizzati sia per i setting di PD che di HD. Ma confrontando i costi della PD come trattamento standard con quelli del PD con l'approccio TD, questi ultimi sembrano grosso modo raddoppiare. Nello specifico, a partire da 17.539 euro di MPD self, si passa a 36.280 euro aggiungendo la video-assistenza; e il costo standard del trattamento self di APD/per paziente/per anno va da €28.819 a €47.560.
I dati suggeriscono alcune ottimizzazioni come: migliore utilizzo delle risorse umane (infermieri), attrezzature tecnologiche ausiliarie (es. POCT) e una migliore identificazione del tempo di utilizzo (es. Periodo di addestramento, condizione del paziente). Al contrario, in relazione al setting convenzionale HD domiciliare (CHHD), questo può essere considerato un approccio innovativo.
Il setting più costoso è risultato essere lo scenario simulato SDHHD con infermiere & Video-assistenza. L' esistenza contemporanea sia di video assistenza domiciliare complementare, sia di assistenza infermieristica sembra essere la meno conveniente.

1.6. Limiti

L'esperienza sui pazienti trattati in telemedicina da PB è in corso. Attualmente 30 pazienti sono arruolati nella PD e 2 nella HD. Non sono disponibili informazioni sia sui protocolli di studio, sia sui risultati. Ciò non consente di esprimere un giudizio definitivo sulla tecnologia valutata.

1.7. Conclusioni

La gestione remota dei pazienti può aiutare i medici ad eseguire il follow-up del paziente nella dialisi domiciliare piu frequentemente, prevenendo le complicanze ed evitando il peggioramento delle condizioni del paziente. Per il paziente in dialisi domiciliare i potenziali benefici potrebbero essere la riduzione delle visite al centro di dialisi (che nella maggior parte dei casi è rappresentato dall'ambulatorio di nefrologia) e la prevenzione dei gravi effetti collaterali del trattamento potenzialmente seguiti da ricoveri ospedalieri. Inoltre, la dialisi domiciliare potrebbe essere più vantaggiosa per il sistema sanitario, in termini di costi, benessere del paziente e qualità della vita.

Il progetto TD di PB è una esperienza prototipale di Tele-dialisi PD e HD. Attualmente, 30 pazienti sono arruolati alla PD video assistita e solo 2 in emodialisi domiciliare breve -giornaliera (SDHHD) con il supporto di un caregiver e Video-assistenza. Sfortunatamente, non sono disponibili dati in termini di outcome e costo-efficacia. Soprattutto per la dialisi SDHHD video-assistita in cui dovrebbero essere reclutati più pazienti per raccogliere dati affidabili.

In letteratura, i dati sulla telemedicina sembrano essere incoraggianti. Ma provengono da un'unica recensione sistematica di Ramar et al. [Ramar 2017] e da uno studio retrospettivo di coorte di Weinhandl

[Weinhandl 2017]. In quest'ultimo studio gli autori hanno dichiarato un conflitto di interessi e hanno scoperto che l'uso della Nx2me (un dispositivo utilizzato per eseguire l'HD domiciliare) era associato a un minor rischio di fallimento della tecnica dialitica, ma non al rischio di interruzione della dialisi. Tuttavia, il tasso aggregato di decesso e il fallimento della tecnica a causa dell'accesso vascolare o di problemi di salute era moderatamente più basso negli utenti Nx2me rispetto ai controlli associati.

Per la futura implementazione del progetto di teledialisi, si raccomanda una raccolta sistematica dei risultati e dei costi prima di attuare la teledialisi su scala più ampia. Successivamente, sarebbe opportuna un'implementazione modulare del servizio di tele-dialisi all'interno della rete regionale di nefrologia tra le Aziende Sanitarie Locali.

Il basso numero di pazienti arruolati, la carenza di risultati in termini di outcomes e i setting assistenziali non perfettamente definiti non consentono di formulare conclusioni sulla sostenibilità e sui risultati di costo-efficacia.

1.8. Indicazioni per futura ricerca

Per ampliare il progetto e prima di estendere il programma di tele-dialisi su una dimensione regionale, è necessario eseguire ulteriori studi per raccogliere maggiori informazioni sull'efficacia e sui costi.

3. Abstract

1.9. Background

Over the last decade, numerous studies aimed at assessing the feasibility and effectiveness of Telemedicine (TM) including Tele-dialysis (TD) have been run. TM contains several specific applications of health services at a distance as Tele-consultation, Tele-conference, Tele-monitoring, and the list is rapidly increasing. Dialysis consists in the clinical purification of blood as a substitute for the normal function of the kidney, and Tele-Dialysis allows this procedure to occur out of Hospitals or outpatients' clinics, thanks to remote monitoring. From 2010 many TD experiences were registered worldwide including Italy. TD can provide either haemodialysis (HD) or peritoneal dialysis (PD). Usually, TD includes Tele-monitoring and Telemedicine Visits for a better interaction between clinicians and patients.

1.10. Objectives

The aim of this study is to assess efficacy, effectiveness, costs and patients' perspective on the use of tele-dialysis at home based on the pivotal experience running at "Azienda Ospedaliero-Universitaria Consorziale Policlinico di Bari" (PB), compared to home dialysis treatment without the telemedicine service.

The Tele-dialysis prototype of PB was financed by EU and Regione Puglia (Diadom project, Smart Health 2.0 programme) with the purpose to validate the home care system for patients on HD and PD in Puglia Region. Data gathered by the above mentioned experience could be useful to evaluate whether home TD treatment can prevent acute harmful events and consequent hospitalizations, and can be advantageous for the healthcare organization, in terms of costs, patient's well-being and quality of life.

Despite the PB experience represents an early stage of a pilot project, we chose to adopt the rigorous Model for Assessment of Telemedicine (MAST), usually adopted for mature telemedicine experiences, as the toolkit to evaluate the impact of the TD applications. MAST uses a three-steps approach based on the seven EUnetHTA domains, with the aim to provide the basis for decision-making.

1.11. Search Methods

To investigate efficacy and safety about the tele-dialysis experiences available in the literature, besides the PB experience, we performed a systematic search in the PubMed database. Our search is limited to English language full texts published in the last five years and filtered by "humans". Technical information on medical device have been searched consulting different sources as: the Italian National Medical Device database (BD/RDM) and ECRI. Additional and more detailed information (as ICT architecture) were provided by PB clinical experts answering an ad hoc structured questionnaire.

1.12. Selection criteria

The target population identified in the PB pivotal experience includes patients above 18 years with end-stage renal failure, without comorbidity, who need dialysis treatment, either as life-time treatment or while waiting for kidney transplantation.

1.13. Main results

Up to date no measure of outcome is yet available from PB. The low number of patients' enrolled, the lack of results in terms of outcomes, and the not well-defined settings do not allow to bring conclusion on sustainability or cost-effectiveness. Thus, using the search strategy reported in Appendix 2, we found and analysed a systematic review by Ramar and al. [Ramar 2017]. The review focuses on the evaluation of multiple scenarios, including the home dialysis. 13 home haemodialysis studies, including both PD and HD compared to centre haemodialysis, peritoneal dialysis, and satellite centres. Many of these 13 studies also incorporated nocturnal haemodialysis, which has long been shown to have better outcomes regardless of location. Two out of the 13 analysed home haemodialysis studies reported dramatic improvements in outcomes. Our selection criteria matched also with the primary study by Weinhandl and Collins [Weinhandl

2017]. This study enrolled 606 patients and concluded that the use of a telehealth platform that enables ongoing assessment of Home HD patients was associated with lower risk of all-cause attrition, lower risk of technique failure, and higher likelihood of Home HD (HHD) training graduation. Further studies are needed to identify the mechanisms by which the use of a telehealth platform may improve clinical outcomes and reduce patient burden. The organizational model of the new Tele-dialysis home service consists of an accurate patient monitoring. PB has a pivotal role in the organization model for TD. The control room is located at PB and the staff is composed by 2 medical doctors and 3 nurses. Before their admission to the TD Protocol, patients receive a training. Some barriers to the introduction of tele-dialysis can be patients themselves, their families or Institutions.
Additionally, we performed an economic analysis comparing traditional treatment without video assistance with TD treatment at home. We obtained 3 treatment scenarios: Standard Care (non-video-assisted), new introduction (TD/Video Assisted) and simulated scenarios (both non-video-assisted and TD/video assisted). The 3 scenarios identified were analysed both for PD and HD settings. But comparing the costs of PD as standard care with those of PD with the TD approach, they seem roughly to double. Specifically, from **€17,539** of MPD self, it turns to **€36,280** adding the video-assistance; and the standard APD self-treatment cost/pt/year goes from **€28,819** to **€47,560**.
Data suggest some optimizations as: better use of human resources (nurses), ancillary technological equipment (eg. POCT) and a better identification of usage time (eg. Training period, patient condition). Conversely, in relation to the Conventional Home HD (CHHD), it can be considered an innovative approach.
The most expensive setting was the simulated scenario **SDHHD with Nursing & Video-Assistance**. The co-existence of both video assistance and supplementary home Nursing appear to be the less convenient.

1.14. Limitations

The experience on patients treated in telemedicine by PB is ongoing. Currently 30 patients are enrolled in PD and 2 in HD. No information on both study protocols and outcomes are available. This does not allow to state a definitive judgment on the evaluated technology.

1.15. Conclusions

Remote patient management can help clinicians to follow up patient in Home Dialysis more frequently, preventing complications and avoiding the worsening of the patient's condition. For patient in home dialysis potential benefits might be the reduction of visits to the dialysis centre (that in most case is represented by nephrology outpatient clinic), and preventing acute side effects of the treatment potentially followed by hospitalizations. Moreover, Home Dialysis could be more advantageous for the healthcare system, in terms of costs, patient's well-being and quality of life.

The TD project by PB is a prototype experience of PD and HD tele-dialysis. Currently, 30 patients are enrolled in Video assisted PD and only 2 in short-daily home haemodialysis (SDHHD) with the support of a Caregiver and Video-assistance. Unfortunately, no data are jet available in terms of outcomes and cost-effectiveness. Especially for video assisted SDHHD dialysis in which more patients should be recruited to gather reliable data.

In the literature, data on telemedicine seems to be encouraging. But they came from a single systematic review by Ramar et al. [Ramar 2017] and a retrospective cohort study by Weinhandl [Weinhandl 2017]. In the latter study authors declared a conflict of interest and found that the use of Nx2me (a machine use to perform HD at home) was associated with lower risk of technique failure, but not with risk of dialysis cessation. Nevertheless, the pooled rate of death and technique failure due to vascular access or health issues was modestly lower in Nx2me users vs. matched controls.

For the future implementation of the tele-dialysis project, a systematic collection of outcomes and costs is recommended before implementing teledialysis at a larger scale. Subsequently, a modular implementation of the tele-dialysis service within the regional nephrology network across local health authorities would be appropriate.

The low number of enrolled patients, the lack of results in terms of outcomes, and the not well-defined settings do not allow to bring conclusion on sustainability and cost-effectiveness.

1.16. Indication for research

To scale up the project, and before extending the tele-dialysis program on a regional dimension, it is necessary to perform further studies to gather more information on effectiveness and costs.

4. Introduction

Telemedicine, which literally means “healing at a distance” [Strehle 2006], signifies the use of ICT to improve patient outcomes by increasing access to care and medical information. The World Health Organization has adopted the following broad description: *the delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities* [WHO 1998]. According to the last Italian guidance approved by “Conferenza Stato Regioni” on 17.12.2020, *telemedicine represents an innovative approach to health practice allowing the provision of remote services through the use of digital devices, internet, software and telecommunications networks.* [CsR 2020].

Over the last decade, there have been numerous studies aimed at assessing the feasibility and effectiveness of telemedicine (TM) strategies applied to several therapeutic fields. This also applies to the number of published studies dealing with Telemedicine approaches for dialytic patients. Tele-dialysis is the branch of tele-health associated with dialysis -either haemo- (HD) or peritoneal-dialysis (PD). Dialysis consists in the clinical purification of blood as a substitute for the normal function of the kidney and it may comprise elements of tele monitoring and tele health that allows for the analysis of remote treatments using a platform that ensures the interaction between clinicians and patients and to connect to the automated peritoneal dialysis (APD) cycler or HD machine [Blinkhorn 2012].

Moreover, the last pandemic events associated to Covid-19 has highlighted the need to treat patients at home to avoiding travel to in-person care sites and reducing patient and clinicians moving [CSR 2020].

Hence, in order to create an evidence-base for the effectiveness of TD, we searched for the most updated systematic reviews and primary studies discussing its effectiveness for dialytic patients and we assessed the telemedicine platform in use at PB.

5. Domain: Health problem and description of the application

5.1. Health problem

According to the *National Health and Nutrition Examination Survey* III (NHANES III) [Coresh 2007], Chronic Kidney Disease (CKD) is defined as "a condition of impaired kidney function *that persists for more than 3 months*" and it is classified into 5 stages of severity. CKD is widespread and increasing globally. This phenomenon is observed uniformly worldwide, and it is estimated that about 10% of the population of both developed and developing Countries are affected by CKD, in most cases unrecognized [MoH 2014]. Most reasons of increasing are due to:

- the aging of the population that contributes to the emergence of an increasing number of subjects with reduced kidney function, even if only as a physiological consequence linked to "aging kidney"
- the increased prevalence in the general population of clinical conditions characterized by a high risk of renal damage (such as type II diabetes mellitus, metabolic syndrome, arterial hypertension, obesity, dyslipidemia) and increased patient survival
- the greater attention nowadays paid to the diagnosis of this pathology, facilitated by the availability of simple, reliable and low-cost diagnostic tools
- competitive mortality linked to the increase in average life and therapies that solve critical situations (eg: primary revascularization in myocardial infarction).

CKD is a dangerous clinical condition for two main reasons:

1. it can be the prelude to the development of End Stage Renal Disease (ESRD), that is the final stage of kidney disease where dialysis and transplantation are the first-choice treatments
2. amplifies the risk of cardiovascular complications (CC).

There is also increasing evidence of the close correlation of CKD in its earliest stages and the appearance of cardiovascular events.

The CKD patient has high/very high CC risk. This unfavourable risk profile is justified by the simultaneous presence of "traditional" CC risk factors (arterial hypertension, dyslipidaemia, type II diabetes mellitus, etc.), which represent themselves a frequent cause of CKD, and "peculiar" CC risk factors, more characteristic of the patient with CKD (endothelial dysfunction, increased oxidative stress, chronic inflammation, vascular calcifications, etc.).

5.1.1. Definition of target condition/disease, symptoms, consequences

The definition and staging of Chronic Kidney Disease were proposed by the National Kidney Foundation - Kidney Disease Outcomes Quality Initiative (NKF - KDOQI) of the United States of America in 2002, later modified from: Kidney Disease: Improving Global Outcomes (KDIGO) in 2004 [MoH 2014]. According to NKF – KDOQI proposal CKD is defined as the persistent condition for at least 3 months:

1) a reduction of the Glomerular Filtration Rate (GFR) that is below 60 ml/min/1.73 m^2 estimated with the MDRD or CKD-EPI formula, or
2) presence of renal damage, even in the absence of a GFR<60 ml/min/1.73 m^2. Kidney damage must be documented by a kidney biopsy, a history of kidney transplantation, or by the presence of blood or urinary markers of kidney damage, such as:
    a. proteinuria
    b. alterations of the urinary sediment (presence of microhematuria/macrohematuria not secondary to urological pathologies, blood, leukocyte or greasy cylinders, oval bodies, granular cylinders and tubular epithelial cells, etc.),
    c. kidney alterations diagnosed by imaging (ultrasound, CT scan, scintigraphy, MRI, etc. with polycystic kidney findings, hydronephrosis, scars, masses, renal artery stenosis, etc.).

CKD staging involves 5 progressive stages, assessed through GFR.

Patients with CKD stage 4 to 5 have a 2-4 times greater risk of mortality from cardiovascular disease than the general population, while patients with end-stage renal disease have an up to 20 times greater risk [MoH 2014].

Table 1 – CKD Classification (from DOCUMENTO DI INDIRIZZO PER LA MALATTIA RENALE CRONICA – MoH, adapted by Aress Puglia)

Stage of disease	Description of renal damage	GFR (ml/min/1,7m^2)
1	Normal and high	>90
2	Mild functional impairment	89-60
3a	Mild-moderate reduction	59-45
3b		44-30
4	Severe reduction	29-15
5	Kidney failure	<15 (or dialysis)

When patients with CKD have progressed to symptomatic end-stage renal disease (ESRD), their kidneys are no longer functioning adequately enough to filter waste products such as urea, albumin, and other small molecules from the body. Patient survival is dependent on renal replacement therapy, which may take the form of kidney transplantation or chronic dialysis. Use of kidney transplantation is limited by the availability of donor organs, tissue matching, and the high cost of the procedure, thus chronic dialysis is the primary treatment modality.

5.1.2. Number of patients (epidemiology)

The world prevalence of chronic diseases has grown significantly in the last few years. Currently, they are the leading cause of death in many countries.

Kidney disease has numerous complex causes, even if it is often considered a comorbidity of diabetes or hypertension. Essentially, such disease has an indirect impact on global morbidity and mortality by increasing the risks associated with at least five other major diseases: cardiovascular diseases, diabetes, hypertension, infection with human immunodeficiency virus (HIV) and malaria [WHO 2018].

The Global Burden of Disease (GBD) study estimated that, in 2015, 1.2 million people died from kidney failure, an increase of 32% since 2005. In 2010, it was estimated that 2.3–7.1 million people with end-stage kidney disease died without access to chronic dialysis. Additionally, each year, around 1.7 million people are supposed to die from acute kidney injury [WHO 2018].

The Census study commissioned by the Italian Society of Nephrology (SIN) in 2014 and the CHARES study [De Nicola 2011] recorded 2.2 million nephropathies in Italy (6.3% of the population aged 35-80 years), of which about 2 million followed outpatient, about 25,000 transplanted and 50,000 undergoing dialysis treatment. Acute patients should be added to these numbers. Moreover, about 140,000 haemodialysis treatments are performed in Italy for acute cases and, of these, 11,800 are performed in Intensive Care setting.

From those studies CKD prevalence (GFR <60 and/or Ualb/Ucreat ≥30 mg/g) was respectively 7.5% in men and 6.5% in women with a greater prevalence of early stage (~60%) 1 and 2 of CKD, compared to stages 3-5 with CKD (equal to 40%) [MoH 2014].

According to a clinical study carried out in Puglia (NEFRO study) [RIDT 2010] the clinical characteristics of patients needing dialysis treatment have changed in recent years. In particular, the average age of patients has increased, now approaching 70 years. “Complex” patients have become increasingly numerous, with comorbidities, such as cardiovascular diseases and diabetes [RIDT 2010]. The patient’s complexity is linked to a high consumption of both services and economic resources, as well as a wider involvement of families and social services.

According to the Dialysis Registry of the Puglia Region 3,659 are patient in dialysis (until 31.12.2015) [DGR Puglia n.1679/2018].

In 2011, from data analysis of the Dialysis Registry of the Puglia, 730 patients were treated with PD, of which 73 patients (10% of PD patients) chose home dialysis therapy with PD treatment.

Peritoneal dialysis is a minimally invasive approach, since it does not involve the use of an extracorporeal circulation, and it is easy to learn and manage due to the use of simple technology. In most cases, it does not require the help of a care giver. However, the percentage of prevalent patients in home therapy (peritoneal dialysis only) is comparable to the national average value (10%) [RIDT 2010] and even lower compared to the European average (15%).

Currently, in Puglia, nephropathic outpatients are followed up both in the hospital units of Nephrology/Dialysis and in the HD Centres with Decentralized Assistance (CAD). The total nephrological hospitalizations were 80,264 (2014) with a higher distribution in the three 'Vast Areas': North (including the Provinces of Foggia and BAT), Centre (including the Metropolitan Area of Bari) and South (including the Provinces of Brindisi, Lecce and Taranto). [DGR Puglia n.1679/2018]

The Nephrology Department of PB selection criteria for the TD Project include patients above 18 years with end-stage renal failure, no comorbidity, candidates to dialysis treatment as destination therapy or before kidney transplantation. According to PB clinicians, 125 new patient are candidate to home treatment (both PD and HD) with telemedicine.

5.1.3. Burden of disease, resource used

Currently, the treatment of end-stage CKD involves significant costs for National and Regional Health Care System. Direct annual cost for treating a patient in dialysis is estimated ranging from a minimum of € 29,800 (peritoneal dialysis) to a maximum of € 43,800 (haemodialysis). Moreover, health and social costs should be added. On the other hand, the costs of the transplant are estimated € 52,000 for the first year and € 15,000 for each subsequent year [Delibera FVG n.1539 del 31 luglio 2015].

5.1.4. Current management of the health condition

As it stands, in Puglia, most patients are treated in hospital with great consumption of resources. According to data shared by the Nephrology Department of PB no more than 10% of PD patients in Puglia are treated at home, anyway this percentage is expected to increase to 15% (European average).

5.1.5. Relations to other conditions or treatments

The telemedicine platform, used within the pilot project of TD at PB, has been designed exclusively for patient in HD and PD. The feasibility to expand the platform to treatments other than dialysis is currently unknown.

5.2. Description of the health technology

As mentioned before two different dialysis approaches do exist: haemodialysis (HD) and peritoneal dialysis (PD). In haemodialysis the circulating blood is filtered through a semipermeable membrane in a device which removes waste products and water from the blood. In peritoneal dialysis the patient's own peritoneal membrane inside the abdominal cavity is used as the dialysis membrane [Pike 2013]. Haemodialysis can be performed in hospitals, in different medical institutions or at home, whereas peritoneal dialysis (PD) is a home-based dialysis. HD is usually performed for 3-5 hours, 3 times a week [Pike 2013], whereas PD at home is continuously performed with change of fluid 4 times per 24 hours (CAPD) or by use of a machine that exchanges the fluid during the night (APD). Telemedicine Service can support both home-based HD and PD.

5.3. Technical characteristics

The following description of a tele-dialysis system is referred to the one currently used at PB.

The remote dialysis system is an integrated platform intended as a set of infrastructural components, software application components and hardware devices that are globally functional for monitoring home and/or hospital dialysis treatments.

The platform consists of three levels:

- **Home Level (more details at paragraph 3.3.1):** software modules, apps and hardware devices are used for the detection of vital signs, the acquisition of data from dialysis machines and to perform specific blood in vitro tests and activate an audio/video channel for doctor-patient interaction. The collection of vital parameters is achieved via Bluetooth Low energy 4.0 using an App, installed on a tablet (or a smartphone), which works as a vital parameters HUB. The task of the App is to collect the output from the devices and send them encrypted to the central system in the Cloud.
  Equipment at patient home includes also:
    - **POCT** (Point of Care Testing): allows to carry out specific blood chemistry near patient testing. The test response, after a qualitatively validation, is transmitted to the control room in real time. The POCT uses cartridges for the analysis of different haematochemical parameters (sodium, potassium, chlorine, TCo2, Anion Gap, ionized calcium, glucose, urea, Urea Nitrogen (BUN) / Urea, creatinine, haematocrit, haemoglobin, lactate, blood gas analysis, etc.).
    - **Hub** for detecting data from dialysis machines.
    - **Robotic high-definition camera** that allows an audio-visual connection by means of which the patient can relate, in real time, during the entire dialysis session, with the medical staff and nursing. The camera is also used to examine the conditions of the patient's vascular access (arteriovenous fistula or central venous catheter) and to verify the correctness of the relative dialysis manoeuvres by the patient.
    - **Device Pack** including oximeter, ECG, glucometer, thermometer, sphygmomanometer and a scale.
    - **Armchair** integrating the device pack and a tablet (used as hub to connect all medical device with the control room).

Figure 1 - Robotic high-definition camera

- **Cloud Level:** where the parameters coming from the patient's empowerment devices and / or apps are collected pseudo-anonymized. All clinical data acquired at home, are collected in the central Cloud system and they are available to application clients through reading interfaces. The cloud solution includes the ISO standard protocol for instant messaging: Message Queue Telemetry

Transport (MQTT) manager for the creation of a data distribution queue, a series of services for the acquisition of the collected parameters, a database for the distribution of the configuration and the temporary collection of the parameters, a service for management of the audio / video channel.

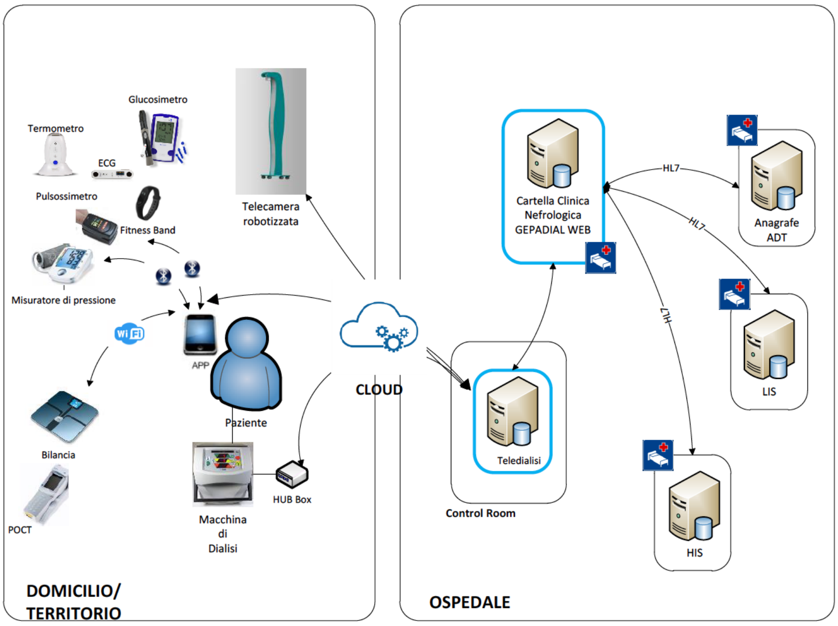
- **Hospital Level:** where a Control Room is set up to accommodate qualified health professionals who use special web application interfaces for the management of home Tele-dialysis patients.
  - The application interfaces includes:
    - tools for interfacing with local medical records and nursing records.
    - **monitoring dashboards** to interact with the patient through an audio/video channel and to characterize the clinical progression, the monitored vital parameters, the outcome of blood chemistry tests performed at home, the evolvement of dialysis therapy, potential alert situations.

    Patients undergo dialysis treatments in time slots agreed with the operating unit. Each detected parameter can determine two alarm conditions: **Yellow Alarm** (intermediate severity), **Red Alarm** (greater severity). Alarms are visually and acoustically perceived by the patient and the care-giver and simultaneously transmitted to the control room. The patient and the care-giver operate as learned during the training period, under video surveillance of the control room operators. Intradialytic clinical emergencies that cannot be resolved at home are dealt with according to the protocols of the Emergency Number 118.

    Alarms are concerned to:
    - ***Body Weight****:* The optimal percentage increase in the patient's body weight, at the time of attachment, should be between 2% and 2.5% of the dead weight of the previous dialysis in the short interval, between 2.5% and 3% in the long interval.
    - ***Blood pressure****:* optimal values between 110/75 mmHg and 130/85 mmHg or PAM (mmHg) between 87 (min) and 100 (max).
    - ***Heart rate****:* optimal value between 64 (min) and 82 (max) beats per minute.
    - ***Acid-Base Balance Measurement****:* optimal value of standard plasma bicarbonates at the time of attack in the long range between 21 mEq/l (min) and 24 mEq/l (max) and lactacidemia between 3 and 5 mmol/L.
    - ***Measurement of potassium***: optimal potassium value at the time of attack in the long range between 4 and 5 mEq/l.
    - ***Blood glucose measurement***: Fasting and pre-prandial blood glucose between 70 and 130 mg / dl, post-prandial blood glucose at 60 m '<180 mg/dl.

    The detection of the parameters listed above allows clinicians to define the haemodialysis program in terms of Ultrafiltration profiling (UF), duration of the session and the type of dialysis fluid to be used. [Information provided by PB]

Figure 2 - Tele-dialysis platform currently used at PB



5.3.1. TM platform

The telemedicine platform is made up of the following main components:

- SMARTDIAL BOX HUB: HUB for connecting all associated devices with a single access/data transmission point:
  - HD dialysis equipment (NxStage);
  - PD equipment (Home Choice, SleepSafe);
  - Point of Care Testing (POCT);
  - Digital scale; Digital sphygmomanometer for measuring blood pressure and heart rate; Blood glucose; One-lead electrocardiograph; Pedometer.
- SMARTDIAL 2.0: Vertical SW monitoring module with the following functions
  - research patient starting from his surname, name, date of birth and dialysis date
  - display of main patient data, including anagraphic, anthropometric and contact data
  - allergy evaluation
  - medical history data
  - laboratory test
  - summary of dialysis sessions
  - consulting and modifying therapies
  - pre, intra and post dialysis complications
  - Computer-aided Diagnosis (CAD-Nephro) visualization
- SMARTDIAL platform includes a software as a medical device TELEDIAL (manufactured by Cooperativa EDP LA TRACCIA) for managing clinical data. The software is classified according to the Classificazione Nazionale dei Dispositivi Medici (CND) under the class “Z12099082 - STRUMENTAZIONE VARIA PER NEFROLOGIA ED EMODIALISI - COMPONENTI ACCESSORI SOFTWARE” and registered within the Italian National medical device database (BD/RDM) with the number 1242117. TELEDIAL is in IIa risk class.
- App Mobile Smartdial Remote: allows physician to collect real-time feedback on the physical condition of the patient undergoing dialysis treatment.
- NEPHROCAD: a Computer-aided Diagnosis (CAD) tool, specific for patients with chronic uraemia which allows the identification of significant and useful parameters for the description of the clinical assessment of each patient, identifying critical situations with consequent warning signals.
- Platform for system management, Social networking, e-learning.

5.3.2. Technologies for HD treatment

Haemodialysis uses a dialysis machine and special filters to create an artificial kidney. Vascular access is required to allow blood to flow through dialysis tubes to the machine. Minor surgery is used to create a fistula joining an artery and vein in the arm, a graft using a tube to join an artery and vein in the arm, or a catheter placed in a large vein of the neck. For a fistula or a graft, two needles are placed into the access before the start of treatment. Blood travels to the machine through one tube to be cleaned and then returns through the other tube. Fistulas generally last longer and have fewer problems with infections and clotting. Haemodialysis filters do not allow blood cells, protein, and other larger blood components to pass through them. These components are retained in the blood. Smaller components, such as urea, creatinine, potassium, and extra fluid, pass through the membrane and are washed away by the machine. Haemodialysis is typically performed in a hospital, a specialized dialysis centre, or at home. At a dialysis centre, treatments may be three times a week, each lasting four hours. Home treatments are usually more frequent — from four to seven times a week—but for shorter periods. [ECRI 2017].

The systems for HD used in the PB Project are described below:

NxStage® System One™ (NxStage Medical, Inc., Fresenius Medical Care)

The NxStage System One consists of the NxStage Cycler, an electromechanical control unit, and the NxStage Cartridge, a sterile, single-use extracorporeal blood and fluid management circuit (with or without a preattached high permeability filter) that mounts integrally within the NxStage Cycler [ECRI 2017].
NxStage® System One™ is indicated to be used in a healthcare setting for the treatment of acute and chronic forms of kidney failure or fluid overload. NxStage® uses the hemofiltration techniques, haemodialysis and/or ultrafiltration. The system is also indicated for haemodialysis with or without ultrafiltration at home [System One™ IFU]. All treatments must be administered under a physician's prescription and must be observed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician [ECRI 2017].

NxStage® System One, moreover, is available in two configurations: home setup and travel setup because it's small enough to be portable and it's equipped with dialysate bags and warmer. At home System One is used with NxStage Cartridge and is arranged onto a support (PureFlow SL) equipped with a dialysate preparation system capable to purify tap water and then to combine it with concentrate, to create dialysate [NxStage web].

NxStage System One received the CE mark during 2012 and the first FDA 510(k) clearance in July 2003. In Italy, NxStage System One is classified according to the Classificazione Nazionale dei Dispositivi Medici (CND) under the class "CND: Z12090201 - APPARECCHIATURE PER EMODIALISI" and registered within the Italian National medical device database (BD/RDM) with the number 512348. NxStage System One is in IIb risk class.

5.3.3. Technologies for PD treatment

PD units treat renal failure, partially replacing kidney function by removing metabolic wastes through selective diffusion across the peritoneum that is the abdominal internal lining. These devices automatically control the flow of dialysate (a solution formulated to promote selective diffusion through passive equilibration) into and out of the abdominal cavity.

Although haemodialysis is the predominant therapy used to treat patients with end-stage renal disease (ESRD), PD is currently used for a lower percentage of dialysis patients.

PD therapy relies on diffusion of waste products across the peritoneum as the PD system infuses and removes dialysate by means of a catheter and a sterile disposable tubing system. Usually, a permanently implanted abdominal catheter provides access to the peritoneal cavity for a series of dialysis sessions. Diffusion of metabolic wastes from the blood occurs within the abdominal cavity through the pores and intercellular channels of the peritoneum.

PD is based on the principles of diffusion and osmosis. Through diffusion, solutes (e.g., toxic metabolic wastes, electrolytes) move readily from an area of higher concentration to one of lower concentration until equilibrium is reached. Through osmosis, solvents (e.g., water) move across the peritoneum, a semipermeable membrane, from an area of lesser solute concentration to one of greater solute concentration.

A typical dialysis cycle consists of filling the peritoneal cavity with a volume of dialysate, letting the dialysate remain within the cavity for a selected period of time ("dwell time") while diffusion and osmosis occur, and draining the spent dialysate (dialysate containing metabolic wastes and water diffused from the blood) from the peritoneal cavity. The dialysate volume in the peritoneal cavity is smaller than the total blood volume, and since diffusion and osmosis achieve near-equal concentrations of metabolic wastes and water between the blood and dialysate, one dialysate infusion cycle does not remove all the toxic metabolic wastes and excess of water from the blood. Therefore, several dialysis cycles are necessary. The effectiveness of dialysis increases when several dialysis cycles with short dwell times (e.g., 20 to 30 minutes) are performed [ECRI 2020].

5.3.3.1. Types of Peritoneal Dialysis

The three main types of PD therapy are Continuous Outpatient Peritoneal Dialysis (COPD), Intermittent Peritoneal Dialysis (IPD), and Continuous cycling peritoneal dialysis (CCPD). The most commonly used type of therapy is COPD, in which the patient manually infuses dialysate from a portable plastic bag that is usually worn until the dialysate is drained several hours later.

CCPD is an automatic technique designed to take place while the patient sleeps, often in their own home. In CCPD, there are usually three or four dialysis cycles each night with a two- to three-hour dwell time for each cycle. A final infusion of one to two litres is left in the peritoneal cavity during the day (diurnal cycle) and is drained by the next set of exchanges the following night.

IPD was originally used to treat acute renal failure, but more recently has been used in long-term treatment of some people with chronic renal failures. The therapy uses the same type of machine as CCPD to add and drain the dialysate. IPD is performed several times a week and each session can take up to 24 hours.

TPD (Tidal Peritoneal Dialysis) is similar to CCPD because consists of a number of dialysis cycles throughout the night. TPD, however, includes more cycles, with a shortened dwell time for each; the cavity is only partially drained during each cycle, leaving a reserve volume in the cavity. A tidal inflow equal to the volume drained is infused and mixes with the reserve volume. At the end of TPD, the entire cavity is drained. TPD has a shorter dialysis time (8 hours, compared to 10 hours using CCPD) and a similar number of reported complications.

Another variation of this treatment is the Nocturnal Intermittent Peritoneal Dialysis (NIPD). In this treatment, the patient does not have an exchange during the day; the abdomen is left dry after the last nightly cycle. However, there are more exchanges during the night (six or more). This treatment is generally used for patients with better kidney function. [ECRI 2020]

The systems for PD used in the PB Project are described below:

Table 2 – Medical device system for peritoneal dialysis

Product name (Manufacturer)	Main characteristics	Regulatory aspects
HomeChoice (Baxter HEALTHCARE)	HomeChoice automated peritoneal dialysis systems (automated peritoneal dialysis - APD) provides automatic control of exchanges of dialysis solutions in the peritoneal dialysis treatment of pediatric and adult nephropathic patients.	HomeChoice received the CE mark during 2010 and the first FDA 510(k) clearance in May 2003. In Italy, HomeChoice is classified according to the Classificazione Nazionale dei Dispositivi Medici (CND) under the class "CND: Z12090101 - APPARECCHIATURE PER DIALISI PERITONEALE" and registered within the Italian National medical device database (BD/RDM) with the number 305823. HomeChoice is in IIb risk class.
SleepSafe (Fresenius Medical Care)	The SleepSafe has been designed for the peritoneal dialysis in hospital or at home. It offers the possibility of performing CCPD, IPD, NIPD, Tidal Dialysis or PD-Plus therapies. In the Sleep Safe system, the automatic connection of the dialysis solution bags allows to minimize the risk of contact contamination; the only operation that the patient must perform is that of the catheter connection before starting the treatment. The dialysis solution bags are immediately identified by the system thanks to an internal laser reader that reads the bar code placed on the solution bag connector. Automatic bag recognition eliminates the possibility of patient error and ensures that prescribed bags are actually used	SleepSafe received the CE mark during 2008. None FDA approval. In Italy, SleepSafe System One is classified according to the Classificazione Nazionale dei Dispositivi Medici (CND) under the class "CND: Z12090101 - APPARECCHIATURE PER DIALISI PERITONEALE" and registered within the Italian National medical device database (BD/RDM) with the number 15196. SleepSafe is in IIb risk class.

5.4. Infrastructural characteristics

The infrastructural and communication requirements that characterize the home Tele-dialysis application solution are listed below:

Table 3 - Architectural infrastructure of tele dialysis platform

Architectural level	Infrastructural and communication characteristics
Home	1. ADSL Flat connection or, alternatively, a SIM with data traffic, in 4G / LTE mode, not limited (at least for the number of monthly processing hours provided) 2. Router: ● Router ADSL Dual-SIM 4G/LTE and Wi-Fi. ● VPN communication with support for OpenVPN/PPTP/IPSEC 3. Bluetooth Low energy 4.0

	4. Robotic camera.
Cloud	1. Server Windows 2019 2 core, 6 GB RAM, 100 GB HD, Microsoft SQL Server 2019 Ed. Standard for archive encryption and IIS; 2. Server Linux 2core, 6 GB RAM, 100 GB HD, protocol ISO standard (ISO/IEC PRF 20922) MQTT for the management of the data transport component.
Hospital	PC: - 4 GB RAM, 50 GB HD, Monitor (minimum resolution 1280x800), Network card 10/1000, Sound card with speakers and microphone - SO Microsoft Windows 10 Professional - Browser Google, Chrome, Mozilla Firefox Server with VPN: - 2 core, SO Microsoft Windows Server 2012, 6 GB RAM, 100 GB HD - SQL Server 2008 or higher reachable from the public network configured for internal routing to the hospital network (towards the ward PC/s on which the hospital component of the Tele-dialysis system is installed) with OpenVPN / PPTP / IPSEC support.

5.5. Interoperability: Integration needs (EPR, devices, with current applications, technical standards etc.)

The system exposes RESTful Web APIs, software interfaces that follow the Representational State Transfer (REST) architectural style for:

- Sharing of users / operators
- Sharing of personal data
- Sharing of enrolment parameters
- Reading of vital parameters
- Technical support
- Technical environment
- Standard situation
- User support
- Back-up systems and procedures

The ICT platform is interoperable by design with other external regional systems as EDOTTO[1].

The standards are reported in the Annex 1

[1] Edotto is the Health Information System of the Puglia Region, in use since 2012 as an essential tool for the governance of the regional health service. The system, based on the most innovative ICT tools, facilitates the widest interaction between the subjects operating at the various levels of the health organization (Department of Welfare, Regional Health Agency, local health authorities, GPs and paediatricians, pharmacies, etc.) with the aims of satisfying the growing needs for healthcare and monitoring the health services provided in Puglia. It is structured in many modules to manage different health and administrative data flows.

6. Domain: Safety

6.1. Clinical safety (patients and staff)

We are not aware of technical recall related to the home treatments of patients involved in the U.O.C. NEFROLOGIA, DIALISI E TRAPIANTO of AZIENDA OSPEDALIERO-UNIVERSITARIA CONSORZIALE “POLICLINICO DI BARI” TD project.

Specific recall concerns with dialysis machines; as reported by ECRI [ECRI 2017] throughout the FDA Manufacturer and User Facility Device Experience MAUDE Database we identified 9 Health Devices Alerts and 176 (MAUDE) reports (submitted between January 1, 2014, and May 25, 2017): 25 deaths, 114 injuries, and 37 malfunctions related to NxStage System (home or hospital treatments aggregated data). The alerts referred to electrolyte imbalances when using multiple premixed bags, software errors, excessive aluminium levels in dialysate concentrate, mislabelled dialysate, and dialysate sacks with excess concentrate.
Among the 25 (MAUDE) death reports 15 were not related to the device, 6 patients died from significant blood loss, 3 patients died from user error, and 1 patient died of an air embolism.
We reviewed the first 25 of the 114 MAUDE injury reports. The most common events were allergic reaction and shortness of breath (6), hypotension (6), blood loss (4), and reduced platelet count (4). As regards to the first 25 of the 37 malfunction reports, most were connector or tip breaks (16). Three reports involved the fluid warmer catching fire. [ECRI 2017]

6.2. Technical safety (technical reliability) and privacy assurance mechanism

The first step to activate the teledialysis system consists of a configuration phase characterized by the census of operators/users, devices and subscribers, followed by the enrolment of the patients treated with the home therapy.
The inclusion of a patient is a multilevel-step that is described below:

1. Patient enrolment phase at the hospital.
2. Data acquisition phase at patient's home.
3. Transformation, normalization and standardization phase at the Cloud infrastructure level.
4. Patient Monitoring Phase at the Monitoring Control Room in the hospital.

Steps 2 and 3 are managed by the external service provider of telemedicine and ICT services.
Among the services offered by the provider there is the general maintenance and assistance articulated as follows:

- **Dedicated Help Line**: A mobile number will be available for any user’s necessity. Users can report malfunctions, request clarifications on the tele-dialysis system or request assistance on their use. Requests by the Users will be processed in real time: the service will be available every day from Monday to Friday at 9.00 / 13.30 and 15.00 / 18.00 and on Saturdays from 8.00 to 14.00. The resource, in case of receiving a call from a user, will be able to support him in his activity and / or in the event of a "serious" and / or "blocking" problem will immediately begin to take action towards the solution of the problem.
- **Access to the “Ticket Management Site”**: this allows the IT Service user to communicate new requests, anomalies found, etc. Once the request has been sent, an email will reach each member of the tele-dialysis technology Provider Team. The IT Service staff will be able to follow the progress of each request if approved by the external service provider in agreement with the user.
- **Tele-assistance Service**: carried out in a telematic mode agreed with IT referents, provides an unlimited number of interventions. Direct access to the system by specialized technicians reduces the telephone time required for identifying, analyzing and solving problems in real time: the service will be available with the same coverage as the Dedicated Helpline.

Specifically, maintenance and updating services for the software include all the necessary interventions to ensure continuous functioning of the application environment and support for full operation of health professionals. The services included in the ordinary maintenance are the following:

- *Preventive Maintenance*: periodic testing and monitoring activities aimed at identifying and promptly communicating and implementing the measures necessary to prevent critical situations.
- *Corrective Maintenance*: the implementation of all the necessary changes to allow the correct applications' operation, and to overcome the causes of system block, the correction of errors and applications' malfunctions etc. In order to define the Service Levels (SLA), the anomalies detectable on the tele-dialysis system are classified in three different levels according to criteria of severity and urgency.
- *Regulatory Maintenance*: changes to software applications that may derive from new national, regional or European regulations or laws, that do not significantly change the functionality of the application system.

The assistance services can be provided either through an electronic connection (remote assistance) or, if foreseen or requested, through interventions in hospitals.

External service provider (of telemedicine service and ICT) tasks are:

1. To guarantee adequacy of the procedure: monitoring of the nephrology and dialysis operating unit, through periodical check of the adequacy of what is installed as compared to the clients' needs.
2. To provide periodic updates: execution of telematic updates (usually quarterly), to release specific patches concerning the resolution of anomalies reported by clients' requests through the assistance tickets. The updates will cover clinical, administrative and organizational aspects.
3. To ensure continuous training: telematic training sessions to align operators to the new released software features. In accordance with the best practices, as mentioned in Annex 1, the tele-dialysis system is compliant with the privacy legislation. In addition, the tele-dialysis system requires the patient to provide privacy consent after being adequately informed through the privacy policy.

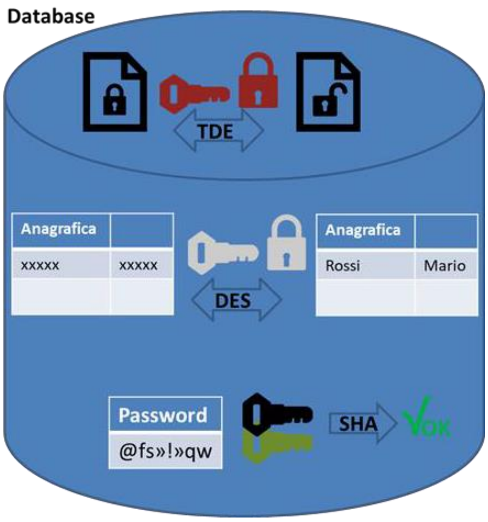
From a quality management point of view, the tele-dialysis system checks incoming data normalizing them properly, verifying that they fall within an allowed range of values, reporting inconsistencies and limiting human error through the use of drop-down lists.

6.3. ICT safety and cyber security

The TD remote monitoring application includes encrypted backup-restore services as specific task under the host Administration's liability, which plans, executes and verify the execution of backups. Moreover it performs both the restore of data in case of need and the restore tests, according to the policies and SLAs (Service Level Agreement) of the Administration (backup retention time, periodicity of restore tests, etc.).

The included cryptography system is based on three security levels as shown in Figure 3

Figure 3 – Three levels cryptography system



1. **Structured Query Language (SQL) data file encryption using Transparent Data Encryption (TDE):** SQL Server feature enables encryption of data, log, and backup files. Encryption uses a self-generated certificate, with private and public keys.
2. **Encryption of personal data using the Triple Data Encryption Standard (DES) system**: in addition to the TDE, the encryption of patient personal data (surname, name, date of birth, social security number, telephone numbers, e-mail addresses, ...) is implemented using the Triple algorithm DES, with a key known only to the management software. This feature prevents the clear reading of personal data even for those who have data logging account to the DB and can query the data.
3. **Encryption of access passwords using the Secure Hash Algorithm (SHA) system**: The passwords for accessing the system are encrypted with an additional algorithm called SHA, which guarantees the non-reversibility of the encryption. Starting from the encrypted password it is not possible to obtain the password in clear text. The system only allows a comparison between the entered password and the memorized one to verify correspondence.

Furthermore, the Tele-dialysis system adopts Secure Sockets Layer (SSL) and Transport Layer Security (TLS) encryption protocols for data exchange between clients and web services.

7. Domain: Clinical effectiveness

The pivotal experience running at PB on patients treated at home with the support of a Telemedicine Service is still ongoing. Currently 30 patients in PD (10 in self PD and 20 PD with the caregiver assistance) and 2 patients in HD (in particular in Short-daily haemodialysis - SDHD) are enrolled, but no experimental protocol has been planned and developed. The results of the PB's experience are not yet available. Clinical effectiveness of the technology under evaluation has been assessed on the basis of the data available in literature only.

7.1. Methods

In order to identify the most recent studies and systematic reviews we designed the following PICO:

Population	Patients on PD or HD
Intervention	Home management of patients assisted by a caregiver with Telemedicine
Comparator	Home management of patients assisted by a caregiver without Telemedicine
Outcomes	Effectiveness ***Primary outcomes:*** Mortality, hospital admissions, visits, first aid. ***Secondary outcomes:*** intradialytic complications, safety, technological reliability, technical and service problems, Quality of Life, adherence to therapy
Study design	Systematic reviews, primary studies
Publication Period	2016-2020
Language	Italian, English

The AMSTAR 1 Checklist [Shea, 2007] has been used to score the systematic reviews.

7.2. Search strategy

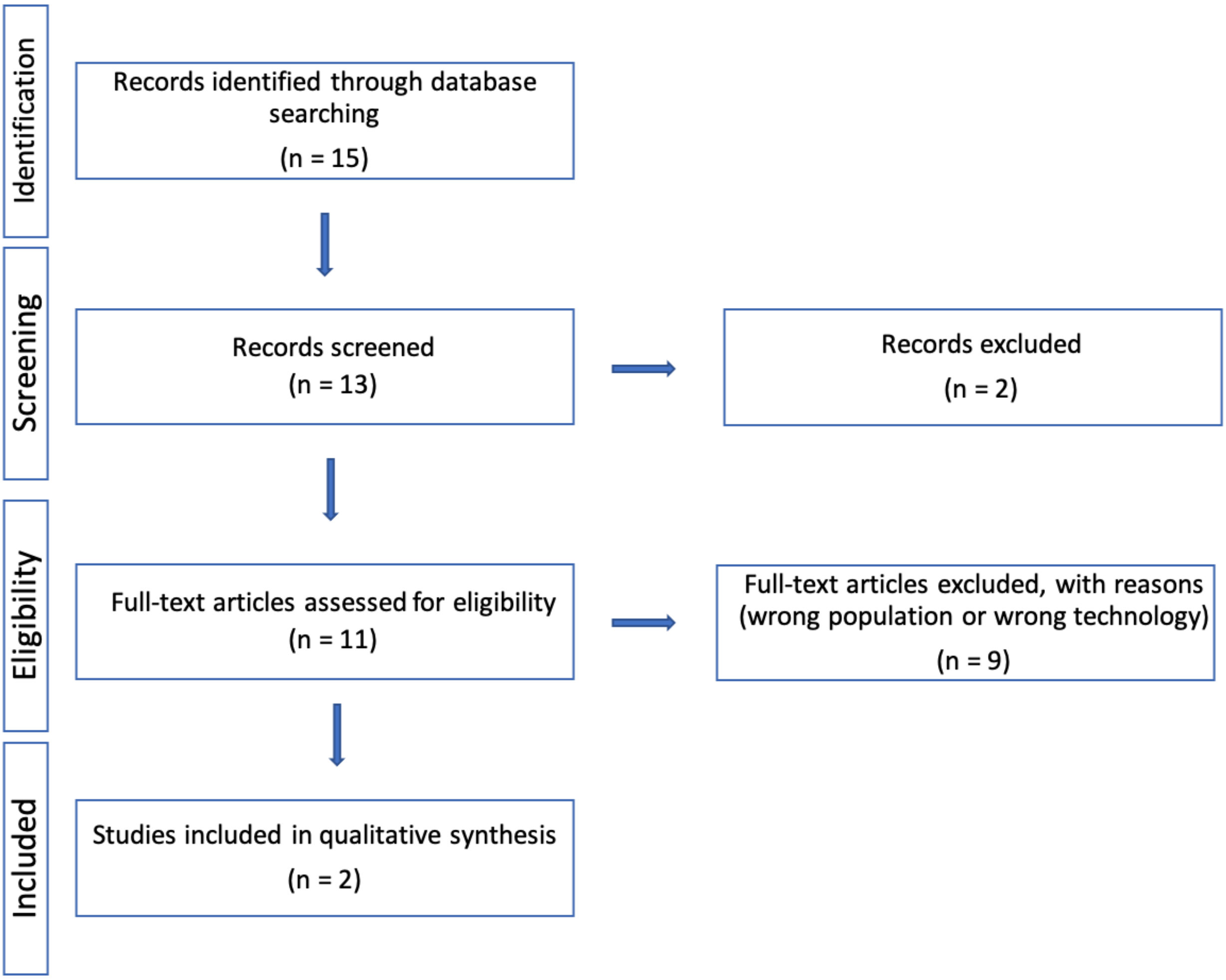
The systematic search was performed on 19th March 2020 in the PubMed database using the search strategy reported in Annex 2 and retrieved 15 articles having limited to English language in the last five years and filtered by "humans" (Annex 2).

Then, according to the title, we removed all articles dealing with the use of mobile technologies (including smartphone) or focused on education; we obtained 13 articles. Finally, titles and abstracts were independently screened by 2 readers (BF, CE) to exclude obviously irrelevant articles. Discordant classifications between the 2 readers were resolved through discussion.

7.3. Flow chart of study selection

Overall, 15 hits were identified. The references were screened by two independent researchers (FB, EC) and in case of disagreement a third researcher (EG) was involved to solve the disputes. After selection two articles only were included. The selection process is showed in Figure 4

Figure 4 - Flow chart of study selection (PRISMA Flow Diagram)



7.4. Analysis

After the full-text review, a systematic review [Ramar 2017] and a primary study [Weinhandl 2017] were identified to be relevant. The "Assessing the Methodological Quality of Systematic Reviews" (AMSTAR) Checklist [Shea 2007] was used as assessing quality tool for the systematic review by the two researchers EC and FB and reported in Annex 4. Ramar et al. AMSTAR score was 9/11.

7.5. Results

<u>Results from Ramar et al systematic review</u>

Ramar et al' systematic review (SR) entitled "Effects of Different Models of Dialysis Care on Patient-Important Outcomes: A Systematic Review and Meta-Analysis" and published in 2017, included comparative randomized controlled trials or observational studies with no restriction on language, published from 2000 to 2014, involving at least 5 adult dialysis patients who received a minimum of 6 months of follow-up. A total amount of 25 studies, 4 RCTs and 21 cohort studies (Six retrospective cohort 15 prospective cohort studies), with a total amount of 74,833 maintenance dialysis patients, were selected to be in depth analysed. The

effect size was pooled and stratified by intervention strategy (multidisciplinary care [MDC], home dialysis, alternate dialysis settings, and electronic health record implementation).
Four primary intervention strategies were examined and described. These include (1) Multidisciplinary Care (MDC) - 7 international studies, (2) home dialysis - 13 studies, (3) alternate dialysis settings, and (4) Electronic Health Records (EHR) implementation. We focused on the analysis of the homedialysis as primary intervention strategy. Ramar et al' SR analized together PD and HD at home compared to centre haemodialysis/peritoneal dialysis, and satellite centres. The 13 home haemodialysis studies discussed in Ramar et al' SR showed better outcomes, but no measure was reported. Moreover, authors reported that 13 studies also incorporated nocturnal haemodialysis, which has long been shown to have better outcomes regardless of location. Two home haemodialysis studies, only, [Berman 2011 and Gallar 2007], included telemedicine, or remote monitoring, and, despite no numeric data has been explicitly reported, both showed dramatic improvements in the following outcomes: hospitalization and frequency of pts and nurse contacts for clinical issues.

Ramar discussed Berman et al study's concluding that *the addition of a nurse-clinician to remotely monitor the health status of high-risk home haemodialysis patients reduced the number of hospitalizations by more than half compared to high-risk home haemodialysis patients who did not have nurse-clinician oversight of their care. They also noted a decrease in frequency of patient and nurse contacts for clinical issues over time, suggesting patient empowerment and stronger self-management resulting from remote therapy, combined with clinical oversight and ongoing communication with the nurse-clinician.* Commenting Gallar's study [Gallar 2007], Ramar's SR *reported that home haemodialysis patients with telemedicine visits had a hospitalization rate that was half that of home haemodialysis patients without telemedicine visits*. *They also described the additional benefit of added surveillance as error avoidance, and an increase in focused attention from nurses with teleconsultation difficult to achieve in a busy multiple-bed hospital setting. In the Gallar et al. study [Gallar 2007] patients and providers reported that telemedicine successfully replaced clinic consultation more than 90% of the time, resulting in significantly lower hospitalization rate*. Ramar et al. found similar result in the study by Whitten [Whitten 2008] where was reported that telemedicine increased access to health care with successful maintenance of the patient-provider relationship.

The most important limitations declared in Ramar et al' SR were

1. The study team chose to focus on Hospitalizations and Mortality as the patient-important outcomes of interest. The team was unable to assess other valid patient-important outcomes, such as infection and emergency department visits, because of the limited scope of the included studies.
2. High heterogeneity caused by the pooling of observational studies having a wide variation in populations, treatment settings, providers, mode of dialysis, and intervention strategies, which determine the need to interpret results with caution.
3. No comparative effectiveness studies were discussed in terms of quality, safety, and costs of tele dialysis.

<u>Results from Weinhandl and Collins's primary study</u>

We analysed also a primary study, entitled "*Relative risk of home haemodialysis attrition in patients using a telehealth platform*" by Weinhandl and Collins [Weinhandl 2017] (the two authors declared a conflict of interest as employed in NxStage Medical).

The Weinhandl and Collins's retrospective cohort study [Weinhandl 2017] discusses on Home haemodialysis (HHD) performed with NxStage devices (discussed in paragraph 5.3.2 and adopted in PB experience) and Nx2me Connected Health. Nx2me Connected Health is a telehealth platform that enables ongoing assessment of HHD patients using NxStage equipment, and that, according to the authors, may reduce patient burden. Authors compared risks of all-cause and cause-specific HHD attrition in Nx2me users and matched control patient. Data from 606 Nx2me users has been analysed. Authors found that "*Nx2me users had 20% lower adjusted risk of HHD attrition, due to 29% lower risk of technique failure, and that patients who initiated use of Nx2me within roughly 3 months of HHD training initiation had 29% lower adjusted risk* *of attrition, due to 34% lower risk of technique failure. Furthermore, we found that patients who initiated use of Nx2me during HHD training were more likely to complete training and begin dialysis at home. These results suggest that use of Nx2me may greatly improve retention during the early course of HHD, an interval that is characterized by relatively high risk of attrition*."

In 286 patients who underwent intensive haemodialysis, with >95% in the home setting, each 1-session increment in weekly treatment frequency was associated with increased risk of a vascular access event, and both incremental treatment frequency and occurrence of a vascular access event were associated with increased risk of technique failure. Weinhandl found that use of Nx2me was associated with lower risk of technique failure, but not with risk of dialysis cessation. Nevertheless, the pooled rate of death and technique failure due to vascular access or health issues was modestly lower in Nx2me users vs. matched controls (with attrition events per 100 patient-years at 15.2 vs. 16.7, respectively).

Authors underlined the need of further studies to identify the mechanisms by which use of a telehealth platform may improve clinical outcomes and reduce patient burden.

7.6. Effects on health-related quality of life (HRQoL)

In Weinhandl's study [Weinhandl 2018] authors highlight that a better communication between patient and provider on a telehealth platform may improve the quality of care, thereby reducing the risk of technique failure and ultimately improving HHD retention.

7.7. Transferability issues

No data about the transferability of the organizational model has been found checking throughout literature. Data that are going to be provided by PB would be essential in order to gather information by external validity on effectiveness rather than efficacy of the TD model. The data collection and analysis concerning the effectiveness of PB approach are necessary to be able to discuss its transferability in other similar contexts. An experimental protocol is required.

8. Domain: Patient perspectives

In Weinhandl's retrospective cohort study it is mentioned that Nx2me app, displaying intradialytic parameters and offering real time troubleshooting of cycler alarms, along with anecdotal evidence included in online supplemental material, suggest several mechanisms by which the use of Nx2me may alter the course of a traditional HHD management.
Elimination of paper flowsheets, online troubleshooting of alarms, and the mere knowledge of provider monitoring may increase patient confidence. Interviews of 19 HHD patients in the United Kingdom, in fact, revealed that most patients felt scared or worried during the early course of HHD, and that patients and nurses found paper manuals to be impractical tools for troubleshooting.
Interviews revealed that remote monitoring serves as surrogate nursing care, thereby alleviating caregiver stress.
However, any monitoring tool can offer disadvantages. Patients may have difficulty with a tablet or consider monitoring to be intrusive, while providers may find that reviewing data inefficiently consumes nursing hours.
In order to go through the evaluation of the Patients Perspective dimension of the PB cohort, which has not been deepened in the selected studies, a specific literature reviewing scanning, focused on the existent tools to measure patients' beliefs and acceptability of TH, has been run by CReHTA Researchers.

The aim was to find out a specific available tool to be validated and administered to patients involved in the TD Project of PB and to directly collect patient perspectives data.

After the literature revision, the "Service User Technology Acceptability Questionnaire" (SUTAQ) has been selected as the most suitable implement to test patients' perception and acceptability of TD, assessing, at the same time, the performance of the own measure with regards to its internal reliability and validity.

Previously available tools, in fact, focused only on the predictions of technology acceptance and the effects that acceptance of technology may have on other outcomes such as intentions and actual behaviour resulting from acceptance. The SUTAQ, instead, aims for a more detailed investigation of the specific construct of technology acceptance rather than the precedents or consequences of the acceptance.

The SUTAQ consists of 22 statements with both negatively and positively worded items about six important dimensions of TH user acceptability taken as a definition of TH acceptability, each with satisfactory internal reliability [Hirani 2017].

The six elements under evaluation to assess users' acceptability are defined as "subscales", and identify 6 "packages" of questions to be analyzed differently. They are listed and well defined below:

Table 4 - The six elements under evaluation to assess users' acceptability

"Enhanced care"	involves items regarding patients' concerns about health status, their perception of active involvement, recommendations to people in a similar condition, and perceptions of enhanced care;
"Increased accessibility"	subscale includes questions about patients' perception of time saving, of increased access to care, of health improvement and of easier contact with professionals;
"Privacy and discomfort"	subscale consists of items regarding patients' concerns about privacy and their perception of discomfort;
"Care personnel concerns"	subscale includes questions about patients' perception of continuity of care and concerns related to personnel involved in the service;
"Kit as substitution"	subscale includes items regarding patients' concerns about health status and their perception of the service as a substitute for regular care and face-to-face consultations;
"Satisfaction"	involves questions about patients' satisfaction and their understanding of telemedicine services.

To check for SUTAQ copyrights and for the availability of a validated IT translation, CReHTA Researchers contacted both the UK creator, validator and first user of the SUTAQ, Prof. Stanton Newman, with his team of Researchers from the Centre for Health Services Research (CHSR), City University London.

CReHTA Researchers prepared and internally validated the IT version of SUTAQ to be addressed to Patients undergoing Telemedicine experience in Puglia, that has been presented and shared with Prof. L. Gesualdo of PB (Annex 6).

In addition, an ad hoc information document on the processing of personal data for patients' satisfaction survey in the use of tele-dialysis technologies at home and the related consent form has been prepared under the supervision of AReSS Puglia DPO and forwarded to PB.

The adoption of the SUTAQ for a Telemedicine Service would be the very first experience in Puglia Region, and the second experience in Italy, in fact an Italian version adapted to their specific context has already been used in Veneto, within the Renewing Health Project [Dario, 2016].

Thus, CReHTA Researchers agreed with CHSR Researchers to consider the usage of the version within the cohort of TD apulian users, as a sort of external validation of the abovementioned tool in the apulian setting and would be the occasion to check how to approach the data analysis phase in collaboration with CHSR Researchers.

PB cohort in fact would be perfect in the view of the very small number of patients involved and will represent the greenlight to adopt SUTAQ in larger cohort of patients involved in different experimental usages of Telemedicine services in Puglia.

The signed Information Consent Forms collection is still ongoing at PB and the SUTAQ administration to TD Patients hasn't taken off yet, unfortunately.

All data from collected questionnaires, if timely made available, would have contributed to set up the first results on the patient perspective aspect, and created the basis for a larger scale study.

Further updating about the Patients Perspective concerning TD, are highly recommended to fill this specific lack of knowledge in our local context.

9. Domain: Organisational aspects

The following information were directly provided by PB's staff by completing an *ad hoc*-structured questionnaire (Annex 8).

Currently, 80% of all dialytic patients treated at PB have been introduced to the dialytic therapy throughout the hospital specialist suggestion, 3% through GPs, 2% thanks to local health district professionals and 15% throughout the local emergency room physicians.

First of all we can state that, considering the two approaches under evaluation: Home Traditional Treatments (both HD and PD) and Home Teledialysis Treatments there is no difference between them, in terms of both HD and PD treatments' frequency (Table below).

Table 3 - Frequency of dialytic treatment

	Traditional home dialysis	**Tele dialysis**
Manual PD (MPD)	4-5 treatments every day	4-5 treatments every day
Automatic PD (APD)	1 night treatment (12 hours) every day	1 night treatment (12 hours) every day
Short-daily home haemodialysis (SDHHD)	5 treatments per week without a nurse	5 treatments per week without any nurse

Within the two macro treatment categories of Traditional Home Dialysis and Teledialysis, PB Project Representatives presented several home care possible scenarios.

Some of them represents the traditional home care setting: Manual PD (MPD) self, Automatic PD (APD) self and Short-Daily Home Haemodialysis SDHHD; some other refers to TM settings: video-assisted MPD, APD and SDHHD.

Moreover, PB staff conceived future possible scenarios which might be activated: Traditional home MPD, home APD, SDHHD and Conventional HHD (CHHD) with nursing support; SDHHD with both nursing and video assisted support. Table 4 summarizes the above-mentioned settings specifying which support has been foreseen: none, internal (caregiver) or external (home nursing/video-assistance), and their current activation status. The same patient management path (flow chart) was reported in Fig.5 as described in DGR Puglia 1961/2020.

Table 4 – Current status, external support and position in patient management for each type of home dialysis

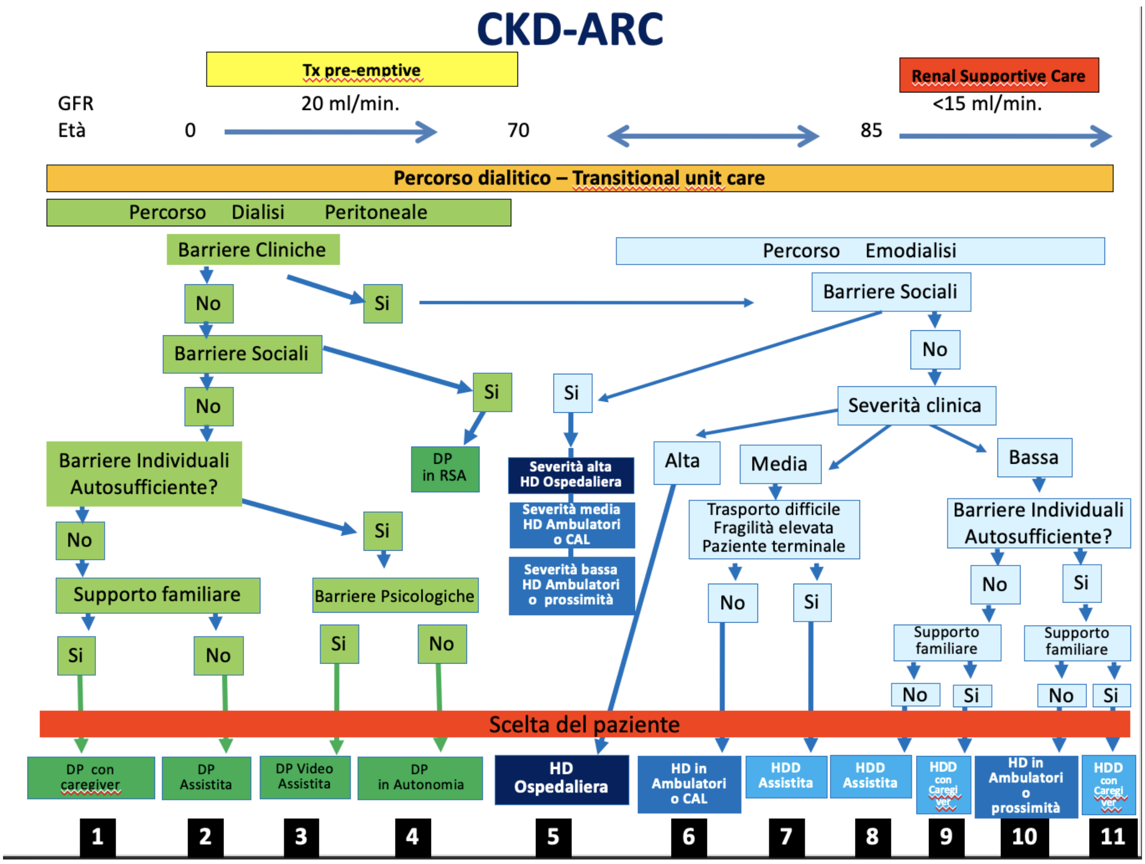
Types of Dialysis (**)		**Patient support**	**Current status**	**Patient managemet as described in DGR 1961/2020 (***)**	**Pts Enrolled (nr)**
PD	MPD self	None (self)	Standard of care	"DP IN AUTONOMIA" (position 4, Fig. 5)	10
	APD self				15
	MPD	Care Giver (CG)		"DP CON CAREGIVER" (position 1, Fig. 5)	20
	APD				30
	Video-assisted MPD	Self /CG + Control Room	New introduction (in TD)	"DP VIDEO ASSISTITA" (position 3, Fig. 5)	12
	Video-assisted APD				18
	MPD	Nursing	Possible future setting *(simulated scenario)*	"DP ASSISTITA" (position 2, Fig. 5)	-
	APD				-
HD	SDHHD	CG	Standard of care	"HDD con CAREGIVER" (position 9 and 11, Fig. 5)	5

	Video-assisted SDHHD	CG + Control Room	New introduction (in TD)	no ref.	2
	Video-assisted SDHHD	Nursing + Control Room	Possible future setting *(simulated scenario)*		-
	SDHHD (self /CG)	Nursing	Possible future setting *(simulated scenario)*	"HDD ASSISTITA" (position 7 and 8, Fig. 5)	-
	CHHD (self /CG)(*)				-

(*) To be defined according to DGR 1679/2018.
(**) PD can by manual (provides up to 5 exchanges/day) and automatic (provides for a single night exchange).
(***) Patient management path (flow chart) as in DGR 1961/2020 (Fig.5).

The corresponding patient management path (flow chart) of DGR 1961/2020 is reported in Fig.5.

Figure 5 - Patient management path (flow chart) (DGR 1961/2020)



Having a look at both Tab.3 and Fig. 5, two video-assisted macro home-settings can be defined: PD setting, (divided into Manual (MPD) or Automatic (APD)), and HD setting.

They differ in timing, methods and organization, and further important difference consists in the type of support, if available to patients (caregiver, nursing, control room) or not (self).

In Fig. 5 additional outpatients services are shown, they are represented by medical day dialytic treatment centre (CAL, CAD) or nursing home (RSA) but we won't take them into account in our analysis.

Moreover in Fig. 5 the "Video-assisted MPD" is reported without any caregiver, while the experimental PB project adds the Video support (Video-assisted PD) to the Caregiver support. Anyway, for economic evaluation purposes, no substantial difference in terms of costs between the video assisted MPD/APD with or without caregiver is detectable.

When a specific setting provides for, the home nursing service can be foreseen within the home management of the patient either for the entire home dialysis process, or in the main moments of his/her dialysis activity only, according to patient’s need.

Furthermore, the presence of the nurse at patients’ home varies according to the weekly frequency of the procedure and each type of home dialysis (automatic peritoneal, manual peritoneal, haemodialysis) is different in terms of weekly use and time of day dedicated.

The organizational model of the new Tele-dialysis home service consists of an accurate patient monitoring, performed by specialized staff, in a control room located in the PB’s dialysis department. PB has a pivotal role in the organization model for TD as described below.

The **control room** service is currently available from Monday to Saturday with two shifts (8.00-14.00 and 14.00-20.00). On holidays and at night time, staff ensures service continuity according to patient needs using a tablet with the same control room functionality. The support service is expected to be extended up to 18 hours per day (from 6 to 24) including holidays. Every control room will follow a maximum of 50 patients employing 9 nurses and 2 nephrologists.

The **staff** is currently composed by 2 medical doctors and 3 nurses (2 in morning time and 1 in the afternoon/evening). In the next future nurses’ visits at patient's home would be foreseen according to the number of patients and the type of dialysis (HD or PD).

Before their admission to the TD Protocol, patients receive a **training**. Training on the chosen dialysis technique (manual and automated peritoneo-dialysis or haemodialysis) is divided into two parts. The first session takes place in hospital with learning courses structured in modules and subsequent steps, which provide for the suitability for a module before moving forward, and for a final assessment of suitability for beginning the home treatment. The courses are carried out by nurses and the nephrologist and addressed to patients and caregivers. The hospital training has to be completed with a home-based training period including tele-monitoring services to ascertain the ability to communicate with the control room and transmit vital data and any other useful information for remote management of the session. Alternatively, for not trasportable patients or for particular social or temporary conditions (eg. COVID-19 pandemic), the whole training on the theoretical and practical dialysis technique and data transmission, both hospital- and home-based sessions can be managed completely remotely with the support of tele-monitoring.

The daily training activity carried out by the nurse includes:

- for manual peritoneal dialysis (MPD): about 1 hour for 10 days
- for automated peritoneal dialysis (APD): about 1 hour for 5 days to be performed after learning about manual peritoneal dialysis
- for short and frequent home haemodialysis (SDHHD): about 3 hours for 20 days (dialysis sessions)

The daily training activity carried out by the nephrologist includes:

- for manual and automated peritoneal dialysis (MPD/APD): about 1 hour for 2 days
- for short and frequent home haemodialysis (SDHHD): about 30 minutes for 20 days (dialysis sessions). The successful completion of the module is verified by check lists. Critical conditions of the dialysis session are also simulated, such as the management of alarms generated by dialysis equipment, or non-routine clinical conditions to be corrected with dialysis treatment. Only after assessing the patient's and/or caregiver's ability to deal with any kind of problems, both routine and urgent, the eligibility for home dialysis treatment is confirmed.

Some **barriers** to the introduction of tele-dialysis can be patients themselves, their families or Institutions as analyzed below:

Patient

The demographic transition, which took place in the last forty years, associated with the better survival of patients with extrarenal pathology, potentially complicated by chronic uraemia, has changed the personal and clinical characteristics of new patients who require dialysis assistance, whose average age has grown close to 70 years.

There are more "complex" patients suffering from clinically severe comorbid diseases, such as cardiovascular diseases and diabetes. Therefore, the Comorbidity Charlson Index (CCI) as a proxy indicator of general clinical conditions, can be appropriate to define criteria for inclusion and exclusion patients for home dialysis treatment.

In addition, the percentage of patients who arrive late for the observation of nephrologists is increasing, they are known as "late referral" (time interval, less than 90 days, between the first contact with the nephrological structure and the start of dialysis). Late referral can't receive adequate and timely information about training and therapeutic options. Usually, patient should be informed about the different treatments option as haemodialysis, peritoneal dialysis, transplantation and the different settings where they can be treated: hospital, Centres with Decentralized Assistance, home dialysis.

The barriers directly deriving from the patient's "personality" should be considered, the unwillingness to dedicate part of their time to the direct treatment of their disease, the phobia for self-stinging, fear of social isolation, as well as the personal level of "technological ability" and "empowerment" and the level of education. These aspects can be correctly assessed through the Coping Orientation to Problems Experienced (COPE) - New Italian Version (NVI), which measures people's ability to positively deal with the discomfort induced by the disease.

Family

Family problems related to home care can be:

- unsuitability of housing: this condition is rarely fulfilled. However, some minimum requirements must be checked:
    - title of possession or rent of the house;
    - possible presence of a lift;
    - suitable accessibility to the home for medical vehicles;
    - door width> 0.9 m, required for the passage of stretchers
    - room or space suitable for the allocation of instrumentation, dialysis material and bed/ armchair equipped with the medical device kit.

The patient can experience the change in the organization of his/her home as a sort of "intrusion and shelter".

- Inadequate family support: the inadequate relationship between family members, the unavailability of cohabiting family members and / or the absence of any external support (caregiver, family assistant, foster carer, volunteer) constitute a difficult barrier, especially for non-autonomous patients to pass for the implementation of the home dialysis program. Often, home care is interrupted due to new family conditions (illness of other family members), working conditions (moving to another city, new organization of work, etc.), emotional (burnout), social (separation / divorce, economic hardship). Furthermore, the fragility of the patient and the consequent low level of functional autonomy on the one hand, and the caregiver's commitment, onerous and additional to the daily commitments on the other, can lead to a failure to comply with the prescriptions of frequency and duration of the haemodialysis sessions. It cannot be excluded that the reduced compliance may contribute to the "discomfort" that the caregiver can experience, already after a few months from the start of home treatment, for each dimension examined by the "Caregiver Burden Inventory", (restriction of the availability of one's own time, physical and somatic stress, conflict in the family and in the workplace, negative feelings towards the relative to be assisted).

Public institutions

The implementation of the program requires an "IT competence" of health professionals for the correct management of procedures; moreover, integration takes place in the construction of the specific assistance network for the implementation of the home dialysis and / or proximity care program. Additionally, the program, how to participate in the program, as well as the type and level of intervention have to be shared with the local health districts, with the GPs and local emergency network.

10.Domain: Economic aspects

A comparative economic evaluation needs the right identification of the main features for each type of dialysis. The table below (Table 5) summarizes the main features of the above-described organizational settings (Home Standard Care, New video-assisted Care and Simulated scenarios).

Our economic analysis included also future scenarios not yet active. We reported in Tab 5 the simulated scenarios: MPD with Nursing support, APD with Nursing support, SDHHD with nursing + Video-assistance, to provide provisional information on their predictable costs. Specifically, the second column of Table 5 shows the number of patients recruited.

30 patients are treated in PD at home (10 of them are in PD-self and 20 are in PD supported by a caregiver). According to PB clinicians 60% of patients are in APD and 40% in MPD. We used the same proportions (40% in APD and 60% in MPD) to perform economic analysis in the simulated scenarios (in grey in Table 5).

Table 5 - Synthesis of the main characteristics of the home patient management in dialysis

	Number of patients and treatment frequency			Nursing support			Patient IOTs					CONTROL ROOM
Types of dialysis	**Number of patients**	**Number of patients in sub setting**	**weekly treatment frequency**	**Weekly visits for nursing support**	**Time per session (h)**	**total hours per year**	**Robotic Camera**	**Device pack**	**POCT**	**POCT (exames per mounth)**	**Integrated dialysis armchair**	**TD**
MPD self (standard care)	***25***	***10*** *(*)*	*7*	*0*	*1*	*0*	*0*	*0*	*0*	*1 - 2*	*0*	0
APD self (standard care)		***15*** *(*)*	*7*	*0*	*1*	*0*	*0*	*0*	*0*	*1 - 2*	*0*	0
MPD (CG support) (standard care)	***50***	***20*** *(*)*	*7*	*0*	*1*	*0*	*0*	*0*	*0*	*1 - 2*	*0*	0
APD (CG support) (standard care)		***30*** *(*)*	*7*	*0*	*1*	*0*	*0*	*0*	*0*	*1 - 2*	*0*	0
Video-assisted MPD (New introduction)	**12**	**12** *(*)*	**7**	**0**	**1**	***0***	**1**	**1**	**1**	**1 - 2**	**1**	**1**
Video-assisted APD (New introduction)	**18**	**18** *(*)*	**7**	**0**	**1**	***0***	**1**	**1**	**1**	**1 - 2**	**0**	**0**
MPD with Nursing support (simulated scenario)	*0*		*7*	*7*	*1*	*364*	0	0	0	*1 - 2*	*0*	0
APD with Nursing support (simulated scenario)	*0*		*7*	*7*	*1*	*364*	0	0	0	*1 - 2*	*0*	0
SDHHD with CG support (standard of care)	***5***		*5*	*0*	*3*	*0*	*0*	*0*	*0*	*2*	*0*	0
SDHHD with CG + Video-assistance (New introduction in TD)	***2***		***5***	***0***	***3***	***0***	**1**	**1**	**1**	***2***	***1***	**1**
SDHHD with nursing + Video-assistance (simulated scenario)	***0***		*5*	*5*	*3*	*780*	1	1	1	*2*	*1*	1
SDHHD (self/CG and nursing support) (simulated scenario)	*0*		*5*	*5*	*3*	*780*	*0*	*0*	*0*	*2*	*0*	0
CHHD (self/CG and nursing support) (simulated scenario) (**)	*0*		***3***	*3*	*5*	*780*	*0*	*0*	*0*	*2*	*0*	0

(*) estimation of patient in APD and MPD
(**) to be defined according to DGR 1679/2018

As mentioned in the "Domain: Organizational aspects" (Section 8), the main organizational characteristics that have considerable impact on costs and on the consumption of resources are:

- the frequency of dialysis: takes place in several daily phases as part of a single cycle;
- the frequency of nurse access: i.e. the presence may (or not) coincide with the frequency of dialysis in case of occasional nursing presence;
- the length of stay of the nurse at the patient's home.

Consequently, in our analysis it was important to investigate the need and the frequency of use of technological resources (medical devices and ICT platform for remote control patient) as well as the use of robotic camera, Device Pack (consisting of weighing scale, sphygmo-manometer, oximeter, Glucometer, ECG, Thermometer), POCT device for clinical analysis (and the relative monthly average frequency of examinations), and the dialytic armchair (with integrated controls). Unfortunately, it was difficult to identify when and which technology was more used by patients. The present analysis considers only direct cost.

Starting from the costs of the equipment, treatments, ICT platform, etc provided by PB and reported in Annex 9, economic data have been elaborated and summarized in the following table (Table 6).

Table 6 - Distribution of detected costs

Distribution of detected costs	Costs (€)
HD treatment per patient (disposable materials and rental of the dialysis equipment)	101,00
MPD treatment per patient (disposable materials and rental of the dialysis equipment)	46,48
APD treatment per patient (disposable materials and rental of the dialysis equipment)	77,47
Robotic camera (annual cost per patient)	3.079,00
"Device Pack" (scale, sphygmomanometer, pulse oximeter, glucometer, ECG, thermometer, router, tablet) (annual cost per patient)	2.691,67
POCT in service (exams/year < 200) (annual cost per patient) (*)	4.000,00
Dialytic armchair Cost/year/patient	900,90

(*) Estimation based on market evidence by CReHTA

Successively, we estimated the costs for each single treatment, including the rental of the dialysis machine, the disposable materials (cycle of use), differentiating agree with the type of dialytic approach: home haemodialysis, and manual and automatic home peritoneal.

Dialysis devices in use within PB Project are divided by type as follows:

Table 7 – Dialysis devices used in PB project

Types of dialysis	Producer	Model
MPD	Fresenius	Harmony SleepSafe
APD	Baxter	HomeChoice
HD	Fresenius	NXStage - System One

Moreover, we calculated the annual rental costs (per patient) of all the IOT devices delivered to the patient and related to Robotic camera, Device Pack, Router, Tablet for command and communication) and, in addition, the annual cost (per patient) of the dialytic armchair (ad hoc solution for this project).

With data provided by PB, it was possible to calculate the annual cost per patient according to the different clinical settings. The results refer to an annual cost projection per single patient (Table 8).

We estimated €16,919 for Video-assisted MPD self and €15,756 for CHHD (the less expensive treatments and €28,199 for APD and €26,260 SDHHD (the most expensive treatments).

Table 8 – total annual costs per patient for dialysis machine and disposable in different type of dialysis

Types of dialysis	Total annual costs per patient for dialysis machine and disposable
Video-assisted MPD self (New introduction in TD)	€ 16,919
Video-assisted APD self (New introduction in TD)	€ 28,199
MPD self (standard care)	€ 16,919
APD self (standard care)	€ 28,199
MPD with Caregiver support (standard care)	€ 16,919
APD with Caregiver support (standard care)	€ 28,199
MPD with Nursing support (simulated scenario)	€ 16,919
APD with Nursing support (simulated scenario)	€ 28,199
SDHHD with CG + Video-assistance (New introduction in TD)	€ 26,260
SDHHD with nursing + Video-assistance (simulated scenario)	€ 26,260
SDHHD with CG support (standard of care)	€ 26,260
SDHHD (self/CG and nursing support) (simulated scenario)	€ 26,260
CHHD (self/CG and nursing support) (simulated scenario)	€ 15,756

Although the costs for caregiver are relevant, they were not considered in the cost analysis due to the regional health system perspective.

To identify the costs related to nursing staff, the home nurse's assistance has been estimated considering the involvement of outsourced personnel, with hourly commitment (See table 5, "nursing support" column). A cost range of € 20-25 / hour is also comparable to standard salary of a Nurse employed in Public Health Service [€ 35,000 / year approximately].

Currently, nurses are not employed for home dialysis services but as declared by PB clinicians they are supposed to be employed in the future (simulated scenario).

The details of the future costs, related to the nursing service are described in following Table 9.

Table 9 - future costs related to the nursing service involvement

Types of dialysis	Nursing costs (€/year per patient)
Video-assisted MPD self (New introduction in TD)	€ 0
Video-assisted APD self (New introduction in TD)	€ 0
MPD self (standard care)	€ 0
APD self (standard care)	€ 0
MPD with Caregiver support (standard care)	€ 0
APD with Caregiver support (standard care)	€ 0
MPD with Nursing support (simulated scenario)	€ 9.100
APD with Nursing support (simulated scenario)	€ 9.100
SDHHD with CG + Video-assistance (New introduction in TD)	€ 0
SDHHD with nursing + Video-assistance (simulated scenario)	€ 9.100
SDHHD with CG support (standard of care)	€ 0
SDHHD (self/CG and nursing support) (simulated scenario)	€ 9.100

CHHD (self/CG and nursing support) (simulated scenario)	€ 9.100

As previously mentioned, it was difficult to identify when and which technology was more used by patients, so we assumed that all medical devices included in the device pack were provided to the patients. Specifically, we estimated the annual operating lease amount per patient and the total costs, to be incurred, depending on the specific type of dialytic treatment required (Table 10).

Table 10 - Costs of technologies

Types of dialysis	***Robotic camera (year costs)***	***Device Pack (year costs)***	***POCT (year costs) (*)***	***Dialytic armchair (year costs)***	***ICT (Total cost per patient/year)***
Video-assisted MPD self (New introduction in TD)	€ 3,079	€ 2,692	€ 4,000	€ 901	**€ 10,672**
Video-assisted APD self (New introduction in TD)	€ 3,079	€ 2,692	€ 4,000	€ 901	**€ 10,672**
SDHHD with CG + Video-assistance (New introduction in TD)	€ 3,079	€ 2,692	€ 4,000	€ 901	**€ 10,672**
SDHHD with nursing + Video-assistance (simulated scenario)	€ 3,079	€ 2,692	€ 4,000	€ 901	**€ 10,672**

We also considered the reimbursement, by the Local Health Authority (LHA), for the electric energy cost sustained by patients (Table 11). The reimbursements costs were calculated per patient annually.

Table 11 - LHA reimbursements values for electric energy consumption (Det. N° 12/27 del feb.2021 – ASL BR)

Macro setting	**Reimbursement of electric energy costs/month**	**Total reimbursement per patient/year**
MPD	€ 51,65	~ € 620
HD	€ 77,47	~ € 930

Thus, Direct Costs (costs directly imputable to the single patient and proportional to the total number of patients) may result including the four cost items previously analyzed:

1. Dialysis machine and disposable (Table 6),
2. Personnel costs (Nursing) (Table 9),
3. Costs for technologies (Table 8)
4. Reimbursement for electricity costs (Table 11)

The Direct Costs assessment, as showed in Table 12, expresses the total annual expenditure in each dialytic setting per patient, except for the Control Room costs.

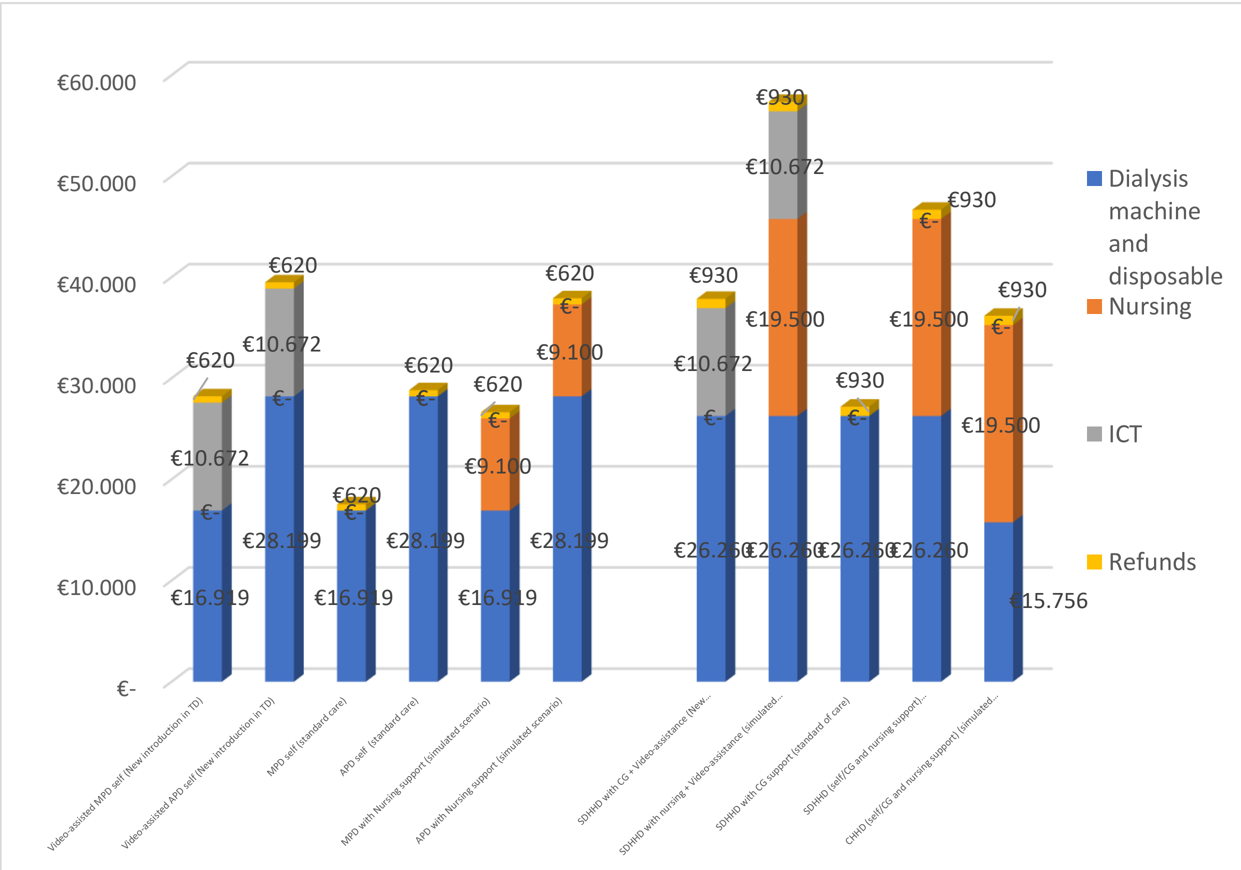
Table 12 – Direct costs per patient year

Types of dialysis	**Dialysis machine and disposable**	**Nursing**	**ICT**	**Reimbursement**	**Direct Costs**
Video-assisted MPD self (New introduction in TD)	€ 16,919		€ 10,672	€ 620	**€ 28,210**
Video-assisted APD self (New introduction in TD)	€ 28,199		€ 10,672	€ 620	**€ 39,490**
MPD Self (standard care)	€ 16,919			€ 620	**€ 17,539**
APD Self (standard care)	€ 28,199			€ 620	**€ 28,819**

Types of dialysis	Dialysis machine and disposable	Nursing	ICT	Reimbursemen t	Direct Costs
MPD with nursing support (simulated scenario)	€ 16,919	€ 9,100		€ 620	**€ 26,639**
APD with nursing support (simulated scenario)	€ 28,199	€ 9,100		€ 620	**€ 37,919**
SDHHD with CG + Video-assistance (New introduction in TD)	€ 26,260		€ 10,672	€ 930	€ 37,861
SDHHD with nursing + Video-assistance (simulated scenario)	€ 26,260	€ 19,500	€ 10,672	€ 930	€ 57,361
SDHHD with CG support (standard of care)	€ 26,260			€ 930	€ 27,190
SDHHD (self/CG and nursing support) (simulated scenario)	€ 26,260	€ 19,500		€ 930	€ 46,690
CHHD (self/CG and nursing support) (simulated scenario)	€ 15,756	€ 19,500		€ 930	€ 36,186

This initial exclusion of the costs deriving from the Control Room and its management allow to better highlight the proportional diversity among different cost items for each TD setting through the graphic representation in Figure 6.

Figure 6 –Proportion of different direct costs per type of dialysis



CONTROL ROOM COSTS ASSESSMENT

In order to determine the total annual patient expenditure for each setting, the overall costs of the Control Room (including technology and personnel involved) needed to be considered. Personnel had a high impact on budget.

The Control Room costs are reported in Table 13 as declared by PB's clinicians, assuming the maximum management capacity of 150 patients a day (50 patients per nurse work-shift). The Control Room staff was supposed to involve 5 health professionals, 3 nurses (on 3 daily shifts) and 2 Nephrologists (on 2 daily shifts).

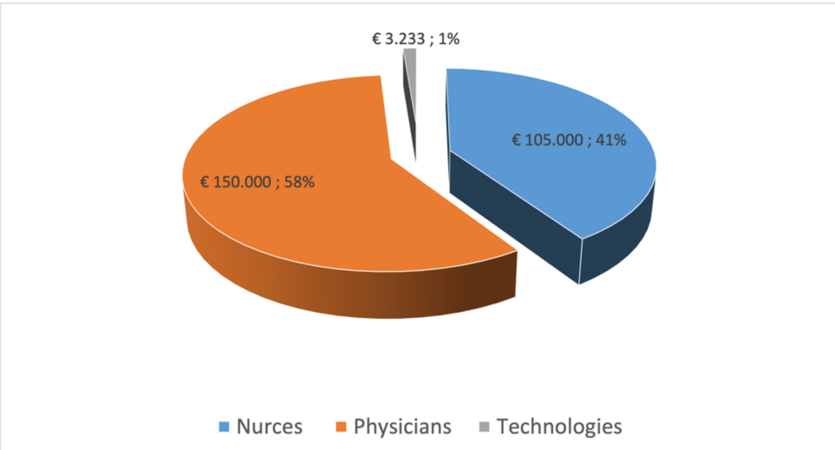
Differently from the method used to calculate the nursing costs, the 5 health professionals in the Control Room (both physicians and nurses) have been considered as PB employees, or at least full-time engaged staff- hired by Public Administration – with annual salary mention (the economic impact of occasional personnel replacement by means of other employees were not considered).
The annual overall cost for the control room was estimated to be €258,233 (indirect cost).

Table 13 – Control room costs

CONTROL ROOM N° nurses /day	Annual average salary for Nurse as internal employee (a)	CONTROL ROOM N° Health Practitioners /day	Annual average salary for H.P. (Nephrologist) as internal employee (a)	Annual cost of monitoring technology in Control Room (b)	Annual overall charge for CONTROL ROOM
3	€ 35,000	2	€ 75,000	3,233	**€ 258,233**

The pie chart (Figure 7), concerning the Control Room annual operating costs, highlights very well how relevant is the Control Room Staff cost (99 % overall considering both Physicians and Nurses) versus the proportionally small cost of the monitoring technology (1%).

Figure 7 - – Operating costs of Control Room (€ per year)



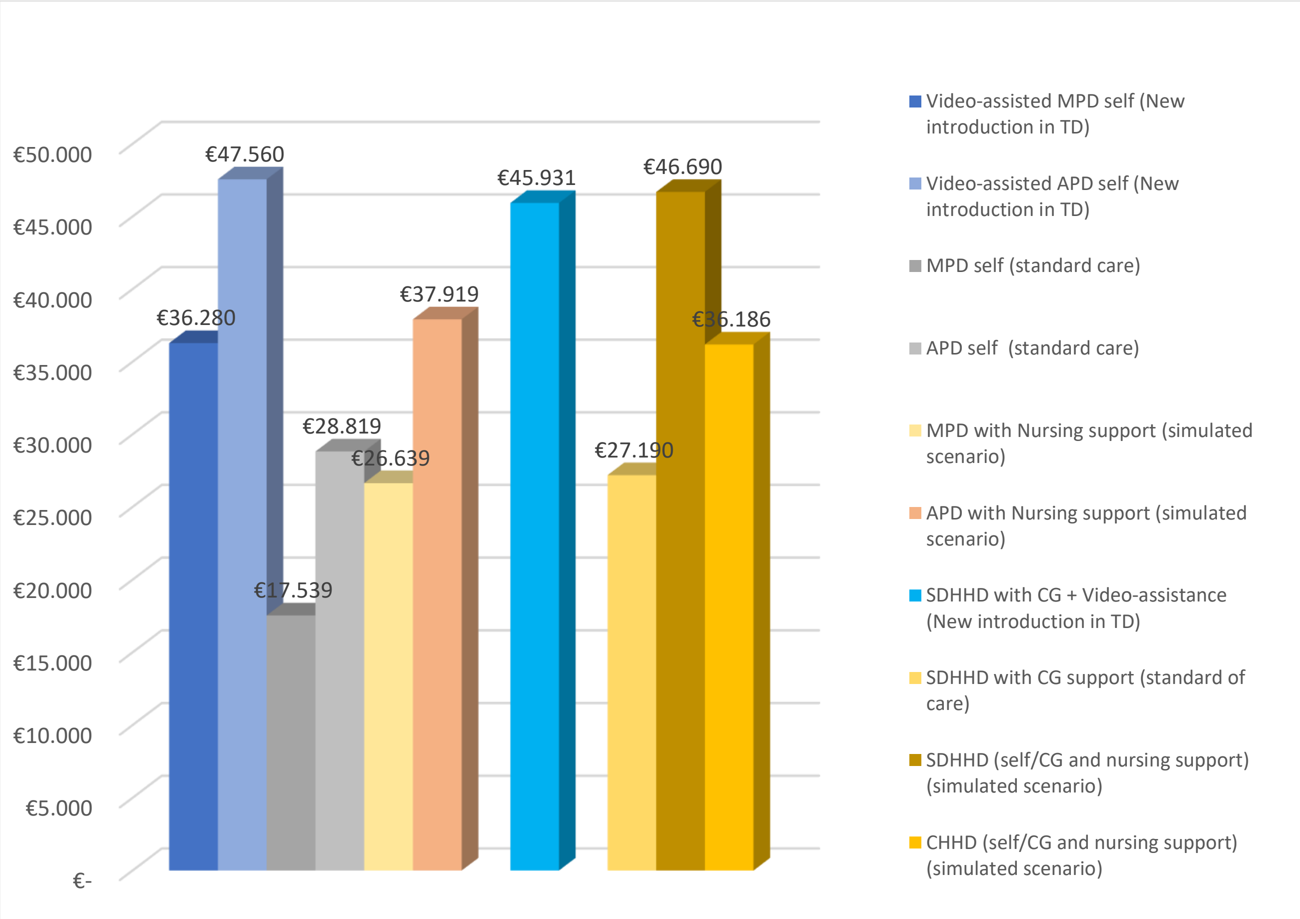
At this point we can calculate how the fixed cost of the control room might be optimized depending on the number of patients enrolled.

The allocation of Control Room fixed costs will range through the behaviour of hyperbolic equation ($= \frac{C}{x}$, where C= cost of Control Room, "x" – variable- is the number of patients enrolled between [min 1- max 150]): costs are minimized only with the maximum amount of patients that a single Control Room allows to handle, that is 150 patients.

Once the number of 150 patients is reached, the yearly cost per patient would reduce to the minimum value possible, approximately € 1,722 per patient. The mean yearly cost per patient of the control room as it stands (32 patients) is in the amount of €8,070

A comprehensive simulation of **annual unit costs per each setting**, considering the Control Room costs included in the active TD settings, with the **32 patients so far enrolled**, is available in Figure 8 below.

Figure 8 – Total costs per type of dialysis and per patient



As a consequence, the more the saturation level of the control room remains low, the more the fixed cost of control room overwhelmingly affects the sustainability of the overall TD treatments. Conversely, the costs of devices and consumables remain relevant and strictly related to medical prescription about the weekly frequency use of device.

We also analyzed the cost of a single treatment for both the three active tele-monitoring settings and standard home-care settings (HPD and HHD) reported in Fig. 9 and 10. In the **TD/video-assisted settings** costs were estimated from €100 (Video -assisted MPD self) to €177 (Video-Assistance SDHHD with CG), €131 (Video-assisted APD self) depending on the type of dialytic approach. APD and MPD are always cost saving compared to SDHHD.

As regards total cost assumption per single treatment of "**standard of care**" and "**simulated settings**" (**without Telemedicine**) the costs range is large, from €48 (MPD self - standard care) to €232 (Conventional Home HD– CHHD with/without Caregiver but with additional nursing). Costs for an additional Nurses assistance has been here taken into consideration.

Figure 9 - TD Settings' cost assumption per single treatment

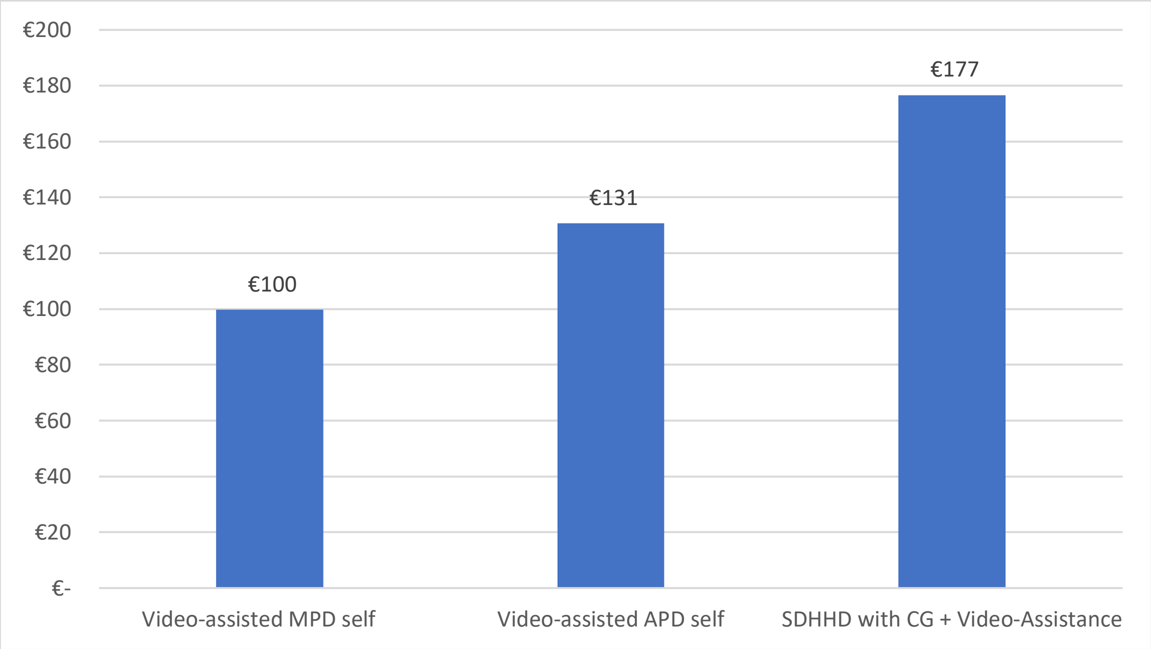
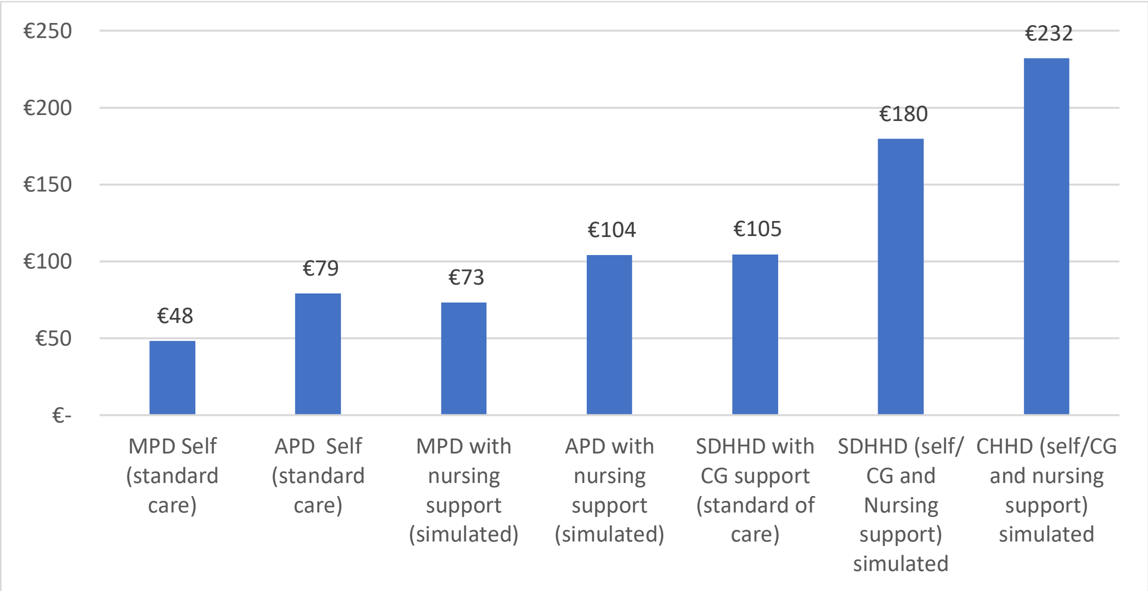


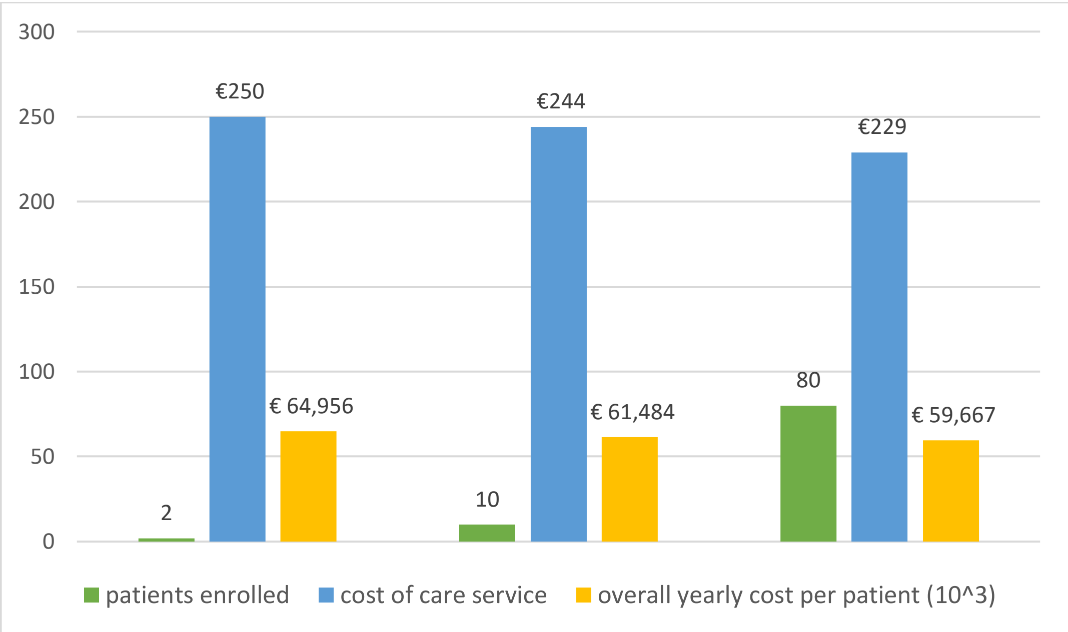
Figure 10 - cost assumption per treatment for standard of care & **simulated settings** (without *Telemedicine)*



SDHHD setting with Nursing & Video-Assistance simulated setting

A separate analysis was carried out on the most complex simulated TD scenario of “SDHHD setting with Nursing & Video-Assistance”.
The variation of the single treatment costs for the simulated scenario of “SDH dialysis video-assisted with home nursing support” according to the increasing of the number of patients enrolled (from 2 to 10 and then to 80), and the breakdown of the indirect costs, is displayed in Figure 11.
The amount of €250/treatment with only 2 patients enrolled, may become of €229 increasing the number of treated patients to 80 (blue column).
The yellow column in Fig.11 represents the overall yearly cost per patients, the indicated value must be multiplied by a factor of 10^3.

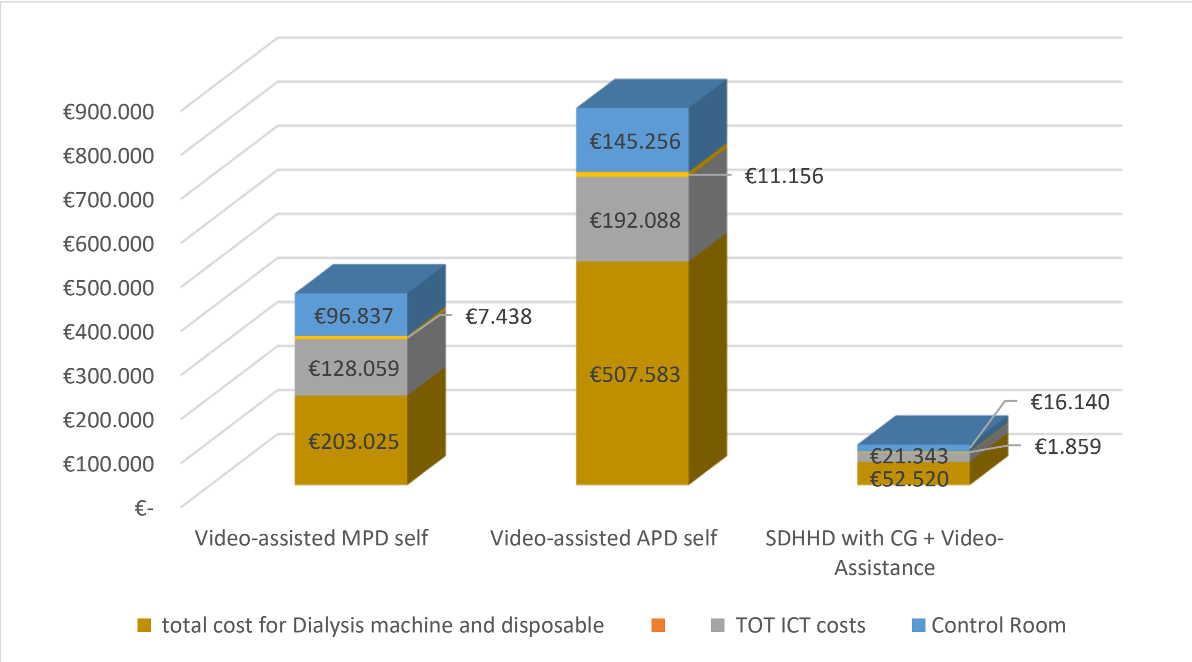
Figure 11 - cost assumption per treatment for SDH dialysis video-assisted with home nursing support (3 scenario approaches)



Finally, we calculated (Figure 12) the total incurred costs for the whole PB Project about the active Telemedicine settings considering the population so far enrolled (n° 32 pts).
It leads around 1.4 M€ /year.
We could also identify, within the limitation of the assumptions and boundary conditions above, every single cost item that determined the overall cost. The greatest weight of costs is represented by investments for the control room and those of personnel.

Therefore, the cost component concerning device, consumables, and the ICT supply costs, can be considered relevant as well.

Figure 12 - Overall actual cost assumption for the project (32 patients)



11.Domain: Socio-cultural, ethical and legal aspects

11.1. Ethical issues

Legal and ethical concerns are very common in telemedicine. The review by Nittary et al. [Nittari 2020] evaluates different critical concerns regarding personal data privacy. Moreover, the ethical aspects of telemedicine are sufficiently analyzed in many studies. All authors agree on importance of patient information protection, informed consent, as well as human approach focusing on patient. Of paramount importance is also the period of training addressed to patients and to their caregiver, in order to acquire sufficient autonomy in the use of medical devices. The training aims to ensure sufficient autonomy and to use the devices safely. Furthermore, the training should be customized to overcome any cultural/personal limitation in the use of technologies.

Overall questions:

- Some religions may refuse treatment.
- cultural limitations and poor aptitude in the use of medical devices and information and communication technologies

According to information provided by clinicians during interviews, in the context of the Pivotal PB Project, ethical issues have been taken into the right consideration, first of all paying attention in the very first selection of the patients to involve, more suitable patients with an adequate cultural and technical background have been asked to participate and informed in a congruous way. A great importance has been attributed the training period for the use of home TM service as described in the ORG Domain.

11.2. Legal issues

In European Countries the GDPR helps to develop telemedicine establishing tasks and responsibilities for assuring privacy and data protection. However, several concerns should be addressed, including the maintenance, use, and replacement of devices [Nittari 2020] as well as a cybersecurity system. Other important issues are the staff training and behaviour, the review by Nittari highlights that many studies show that the legislation on telemedicine activity is lacking or completely absent in many cases.

Currently, no clinical accreditation is envisaged for the telemedicine service.

Tele-dialysis implies the storage, archiving and transmission of health data concerning the health of patients, as well as the remote collaboration of professionals who provide their competencies and time, therefore there might be problems related to privacy protection.

In compliance with the new EU regulation n.679/2016 known as GDPR - General Data Protection Regulation, the following security measures and subsequent amendments are adopted in the pivotal PB Project.

The provider of tele-dialysis technology, as data processor, has adopted the Privacy Protection principles in the design of the system, i.e. it has arranged for the implementation of functions equipped with adequate security features to keep personal data protected, including any encryption of personal data, where necessary, and the encryption of the data (Please refer to Par. 4.2 “Technical safety and privacy assurance mechanism” and Par. 4.3 “ICT safety and cyber security”).

The technology provider has also adopted the following:

- Choice of its own DPO
- Adoption of the treatment register
- Data Breach Management Manual
- Choice of data processors
- Continuous training for its employees

Regulatory aspects and the main reference Italian guidelines are reported in Appendix 5.

12.Conclusions

Remote patient management can help clinicians to follow up patient in Home Dialysis more frequently, preventing complications and avoiding the worsening of the patient's condition. For patient in dialysis potential benefits might be the reduction of visits to the dialysis centre (that in most case is represented by nephrology outpatient clinic), and preventing acute and side effects of the treatment potentially followed by hospitalizations. Moreover, Home Dialysis could be more advantageous for the healthcare system, in terms of costs, patient's well-being and quality of life.

The TD project by PB is an innovative prototype of PD and HD tele-dialysis. Currently, 30 patients are enrolled in Video assisted PD and only 2 in SDHHD with the support of a Caregiver and Video-assistance. Unfortunately, no data are yet available in terms of outcomes and cost-effectiveness. Especially for video assisted SDHHD dialysis in which more patients should be recruited to gather reliable data.

In the literature, data on telemedicine seems to be encouraging. Unfortunately, they came from a single systematic review by Ramar et al. [Ramar 2017] in which the authors reported that home haemodialysis patients with telemedicine visits had a hospitalization rate that was half that of home haemodialysis patients without telemedicine visits. They also described the additional benefit of added surveillance as error avoidance, and an increase in focused attention from nurses with teleconsultation difficult to achieve in a busy multiple-bed hospital setting. In our literature search was included a retrospective cohort study by Weinhandl and Collins [Weinhandl 2017] also. In the study, enrolling 286 patients, authors declared a conflict of interest and found that use of Nx2me was associated with lower risk of technique failure, but not with risk of dialysis cessation. Nevertheless, the pooled rate of death and technique failure due to vascular access or health issues was modestly lower in Nx2me users vs. matched controls.

For the future implementation of the tele-dialysis project, a systematic collection of outcomes and costs is recommended before implementing teledialysis at a larger scale. Subsequently, a modular implementation of the tele-dialysis service within the regional nephrology network across local health authorities would be appropriate.

The low number of patients' enrolled, the lack of results in terms of outcomes, and the not well-defined settings, do not allow to bring conclusion on sustainability or cost-effectiveness.
The organizational model of the new Tele-dialysis home service consists of an accurate patient monitoring. PB has a pivotal role in the organization model for TD. The control room is located at PB and the staff is composed by 2 medical doctors and 3 nurses. Before their admission to the TD Protocol, patients receive a training. Some barriers to the introduction of tele-dialysis can be patients themselves, their families, or Institutions.
Our economic analysis included different dialysis approaches (Peritoneal Dialysis and Haemodialysis) synthesized in 3 treatment scenarios: 1. Standard Care (non-video-assisted), 2. new introduction (TD/Video Assisted) and 3. simulated scenarios (both non-video-assisted and TD/video assisted).
Standard Care scenarios are always cheaper than the “New Introduction” ones.

The potential advantage of TD is the ability to follow a large number of patients at a distance and simultaneously, reducing costs.
But comparing the costs of PD as standard care with those of PD with the TD approach, they seem roughly to double. Specifically, from **€17,539** of MPD self, it turns to **€36,280** adding the video-assistance; and the standard APD self-treatment cost/pt/year goes from **€28,819** to **€47,560**.
Data suggest some optimizations as: better use of human resources (nurses), ancillary technological equipment (eg. POCT) and a better identification of usage time (eg. Training period, patient condition).

Conversely, in relation to the Conventional Home HD (CHHD), it can be considered an innovative approach.
The most expensive setting was the simulated scenario **SDHHD with Nursing & Video-Assistance**. The co-existence of both video assistance and supplementary home Nursing appear to be the less convenient.

To save the high costs of new types of TDs we suggest the following consideration:

Factors affecting the treatment cost	Considerations
Type of Dialytic Approach	Assess the best cost-effectiveness strategy to prescribe TD, defining time and way of use (eg. For Training period) according to the patient condition.
Home Nursing Staff	Assuming that there is a certain difference of clinical risk for each organizational home setting, we suggest a deep focus to this point to measure the risk in the development of dialysis for each setting and comparisons between them (HHD vs PD, self vs caregiver, nurse or not) also in order to analyze improvements in terms of effectiveness of a single tele-home dialysis assisted approach, compared to traditional home dialysis settings. Such a revaluation could be developed considering further national experiences of PD where the support of the tele-assistance shall be limited to the training period of the patient.
Control Room Medical Equipe	Evaluate strategies to optimize the staff resources dedicated to the control room
Medical Devices	Evaluate new procurement strategies
DEVICE PACK and ICT	Properly distribute the kits according to actual patient needs
Electricity Refund	Electricity refund should take into consideration both the frequency of use and the type of TD, and should be updated with the current cost of Energy and consumption of the modern devices used

13.Future prospect and suggestions

The next essential steps we would encourage to pursue are:

- Enrol more patients and simultaneously build an economic model for the recording of costs.
- Assess the best cost-effectiveness strategy to prescribe TD defining the time of use (eg. Training period) or according to the patient condition.
- Clinical Risk analysis of organizational settings in telemedicine. Assuming that there is a certain difference of clinical risk for each organizational home setting, a study will be essential if related to the clinical risk in the development of dialysis for each setting, separate for type (HHD vs PD, self vs caregiver, nurse or not) and study that should be able to analyze improvements in terms of effectiveness of a single tele-home dialysis assisted compared to traditional home dialysis settings. Such a revaluation could be developed considering further national experiences of PD where the support of the tele-assistance shall be limited to the training period of the patient.
- Evaluate strategies to optimize the staff resources dedicated to the control room
- Evaluate new procurement strategies for buying medical devices.
- Once the context has been made clear in all its complexity, a randomized clinical trial including a wide number of patients enrolled (so that the currently available control room system could be entirely exploited), comparing Home TD approaches Vs Home Standard Care should be drawn and run out, with the collection of the related clinical efficacy and safety high quality data.

Annex 1 – Technical Standards and Best Practices for TM

The home and / or hospital Tele-dialysis platform is compliant with the main standards:

- health informatics: HL7, IHE, DICOM, CDA;
- ISO / IEC 15445: 2000 (E) (HTML);
- the ISO / IEC 16262: 2002 standard (ecma-script);
- the W3C Recommendations relating to HTML in version 4.01 and later and XHTML in version 1.0 and later;
- the W3C Recommendations relating to the CSS language in version 1.0 and later;
- the W3C Recommendations relating to languages and technical specifications relating to the creation of web pages, objects and applications, such as, for example, HTTP, URI, URL, HTML, XHTML, XML, SVG, SMIL, SOAP;
- compatibility, depending on the operating system, with the following browsers: Mozilla Firefox (version 15 and above) and Chrome (version 15 and above);
- standards for secure access to web pages: SSL 2.0 and SSL 3.0 as a text-based browser;
- compatibility with the XML standard (Extensible Markup Language) for the description of the contents;
- the clinical data collected, together with the patient's identification, travel on the network in encrypted and secure mode with TLS (Transport Layer Security) protocol;
- the connection with the home dialysis equipment takes place in a secure way by establishing an encrypted tunnel-VPN connection;
- MQTT messaging protocol (MQ Telemetry Transport or Message Queue Telemetry Transport);

Annex 2 – Search strategy

Technology				
("Kidney Failure, Chronic"[Mesh] OR ("kidney failure, chronic"[MeSH Terms] OR ("kidney"[All Fields] AND "failure"[All Fields] AND "chronic"[All Fields]) OR "chronic kidney failure"[All Fields] OR ("chronic"[All Fields] AND "kidney"[All Fields] AND "failure"[All Fields]	AND	home[All Fields] AND ("telemedicine"[MeSH Terms]	AND	"telemedicine"[All Fields]) AND ("2015/03/22"[PDat] : "2020/03/19"[PDat] AND English[lang])

Searched on 19 Mar 2020. 15 item

Annex 3 – List of studies matching inclusion criteria

1. Chan CT, Collins K, Ditschman EP et al. Overcoming Barriers for Uptake and Continued Use of Home Dialysis: An NKF-KDOQI Conference Report. 20202 Article in press
2. Susie Q. Lew and Neal Sikka. Operationalizing Telehealth for Home Dialysis Patients in the United States. 2019 AJKD Policy Forum Perspective
3. Susie Q. Lew. Telehealth in Peritoneal Dialysis: Review of Patient Management. Advances in Peritoneal Dialysis, Vol. 34, 2018
4. Scott D. Bieber and Daniel E. Weine. Telehealth and Home DialysisA New Option for Patients in the United States. Clin J Am Soc Nephrol13: 1288–1290, 201
5. Lew SQ, Sikka N, Thompson C et al. Impact of remote biometric monitoringon cost and hospitalization outcomesin peritoneal dialysis. Journal of Telemedicine and Telecare2019, Vol. 25(10) 581–586
6. Malkina A, Tuot DS. Role of telehealth in renal replacement therapy education. Semin Dial. 2018 Mar;31(2):129-134. Epub 2018 Jan 3. Review.
7. Drepper VJ, Martin PY, Chopard CS et al. remote patient Management in Automated peritoneal Dialysis: A promising New tool. Peritoneal Dialysis International. jAnuAry2018 – Vol. 38, no. 1
8. Eric D. WEINHANDL ED, COLLINS AJ. Relative risk of home haemodialysis attrition in patients using a telehealth platform. Hemodialysis International 2018;22:318–327
9. Makhija D, Alscher MD, Becker S et al. Remote Monitoring of Automated Peritoneal Dialysis Patients: Assessing Clinical and Economic Value. VOL. 24 NO. 4. APRIL 2018 TELEMEDICINE and e-HEALTH
10. Osner MH, Lew SQ, Conway P et al. Perspectives from the Kidney Health Initiative onAdvancing Technologies to Facilitate RemoteMonitoring of Patient Self-Care in RRT. Clin J Am Soc Nephrol12: 1900–1909, 201
11. Thilly N, Chanliau J, Frimat L et. al. Cost-effectiveness of home telemonitoringin chronic kidney disease patients at different stages by a pragmatic randomized controlled trial (eNephro): rationale and study design. BMC Nephrology (2017) 18:126
12. Ramar P, Ahmed T, Wang Z et al. Effects of Different Models of Dialysis Care on Patient-Important Outcomes: A Systematic Review and Meta-Analysis. POPULATION HEALTH MANAGEMENT Volume 20, Number 6, 2017
13. Krishna VN, Managadi K, Smith M, Wallace E. Telehealth in the Delivery of Home Dialysis Care: Catching up With Technology. Adv Chronic Kidney Dis. 2017 Jan;24(1):12-16. Review.
14. Ong SW, Jassal SV, Miller JA, Porter EC, Cafazzo JA, Seto E, Thorpe KE, Logan AG. Integrating a Smartphone-Based Self-Management System into Usual Care of Advanced CKD. Clin J Am Soc Nephrol. 2016 Jun 6;11(6):1054-62. Epub 2016 May 12.
15. Ferguson TW, Zacharias J, Walker SR, Collister D, Rigatto C, Tangri N, Komenda P. An Economic Assessment Model of Rural and Remote Satellite Hemodialysis Units. PLoS One. 2015 Aug 18;10(8):e0135587. eCollection 2015.

Annex 4 – AMSTAR

Reference	Objective	Searches	Included studies	AMSTAR
Ramar P, Ahmed T, Wang Z et al. Effects of Different Models of Dialysis Care on Patient-Important Outcomes: A Systematic Review and Meta-Analysis. POPULATION HEALTH MANAGEMENT Volume 20, Number 6, 2017	This systematic review underscores the importance of multidisciplinary care, and also the value of telemedicine as a means to increase access to providers and enhance outcomes for those dialyzing at home or in alternate settings, including those with limited access to nephrology expertise because of travel distance.	Searchers were performed on search MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and Scopus databases.	21 comparative studies.	9/11

Annex 5 – Regulatory aspects and the main reference guidelines

- D. Lgs. 7 marzo 2005, n. 82 e s.m.i. modificato dal D. Lgs. 13 dicembre 2017, n. 217 (CAD - Codice Amministrazione Digitale)
- D. Lgs. 30 giugno 2003, n. 196 modificato dal D. Lgs. 10 agosto 2018, n. 101 per l'adeguamento al Regolamento (UE) 2016/679 del Parlamento Europeo e del Consiglio del 27 aprile 2016
- Misure minime per la sicurezza ICT delle Pubbliche amministrazioni;
- Conservazione a norma (Disciplinata dal CAD e dal DCPM 3-12-2013);
- Piano Triennale per l'informatica nella Pubblica Amministrazione;
- SPC (Sistema Pubblico di connettività);
- D. Lgs. 23 gennaio 2002, n. 10 (Firme elettroniche);
- Programma nazionale di abilitazione al Cloud della PA (Cloud Enablement Program);
- DPCM 13 novembre 2014 - Regole tecniche in materia di formazione, trasmissione, copia, duplicazione, riproduzione e validazione temporale dei documenti informatici;
- Circolare n. 60 del 23 gennaio 2013 - Formato e definizioni dei tipi di informazioni minime ed accessorie associate ai messaggi scambiati tra le pubbliche amministrazioni;
- Circolare n. 62 del 30 aprile 2013 - Linee guida per il contrassegno generato elettronicamente ai sensi dell'articolo 23-ter, comma 5 del CAD; Schemi XML del contrassegno generato elettronicamente
- D.Lgs 21/09/2019 n 150 (disposizioni urgenti in materia di perimetro di sicurezza nazionale cibernetica)
- D.Lgs 18/05/2018, 65 (Decreto attuativo della direttiva UE 2016/1148 recante misure per un livello comune elevato di sicurezza delle reti e dei sistemi informativi nell'Unione);
- AGiD - Linee guida di design per i servizi digitali della PA;
- AGiD - Linee guida per l'adozione di un ciclo di sviluppo di software sicuro;
- AGiD - Linee Guida per la configurazione per adeguare la sicurezza del software di base;
- AGiD - Linee guida per la modellazione delle minacce ed individuazione delle azioni di mitigazione conformi ai principi del secure/privacy by design;
- AGiD - Linee guida sull'accessibilità degli strumenti informatici;
- AGiD - Linee Guida sulla formazione, gestione e conservazione dei documenti informatici;
- AGiD - Linee guida per il disaster recovery delle pubbliche amministrazioni;

Annex 6 – SUTAQ_ITA v1.0_CReHTA

SUTAQ *(Service User Technology Acceptability Questionnaire)*
Versione Adattata dal CReHTA

Gentile Signore/Signora M / F

La ringraziamo per aver accettato di partecipare a questa intervista telefonica condotta da AReSS Puglia per indagare il grado di accettazione del Servizio di Telemedicina che ha ricevuto per supportare le sue cure.
Come riportato nell'informativa che le è stata fornita, tutte le informazioni che lei darà verranno anonimizzate appena dopo la nostra intervista e le sue risposte non saranno riconducibili alla Sua persona.

L'intervista consta di due parti:
La prima parte è costituita da 5 domande per la rilevazione di alcuni dati anagrafici utili per l'analisi dei dati

I Parte – Raccolta dati anagrafici

1. Data di Nascita ___/____/_____
2. Stato di Nascita _______________
3. Numero di Patologie di cui è affetto 0__, 1__, 2__, 3__, 4__, 5__ o più
4. GRADO DI ISTRUZIONE

Scuola Elementare__
Scuola Media__
Istituto Superiore___
Laurea___
Specializzazione post Laurea___

5. Cap della sua attuale abitazione___

La prima parte di rilevazione anagrafica è terminata.
Adesso iniziamo la seconda parte che riguarda l'indagine vera e propria che dura al massimo 15 minuti.
Le leggerò 22 asserzioni che si riferiscono specificamente al Servizio di Telemedicina di cui sta fruendo/ha fruito.
Per ciascuna affermazione che le riporterò dovrà cortesemente indicarmi la risposta corrispondente al suo grado di accordo o disaccordo con ciascuna delle affermazioni.

II Parte - SUTAQ

1. Il Servizio di Telemedicina mi ha fatto risparmiare tempo in quanto non ho dovuto recarmi dal mio medico o in ospedale con la stessa frequenza con cui lo facevo in precedenza.

- Totalmente d’accordo
- Moderatamente d’accordo
- Parzialmente in accordo
- Parzialmente in disaccordo
- Moderatamente in disaccordo
- Totalmente in disaccordo

2. Il Servizio di Telemedicina ha interferito con la mia vita quotidiana modificando le mie abitudini.
   - Totalmente d’accordo
   - Moderatamente d’accordo
   - Parzialmente in accordo
   - Parzialmente in disaccordo
   - Moderatamente in disaccordo
   - Totalmente in disaccordo

3. Il Servizio di Telemedicina ha aumentato la mia possibilità di accesso alle cure (contatto con gli operatori sanitari e / o sociali).
   - Totalmente d’accordo
   - Moderatamente d’accordo
   - Parzialmente in accordo
   - Parzialmente in disaccordo
   - Moderatamente in disaccordo
   - Totalmente in disaccordo

4. Il Servizio di Telemedicina mi ha aiutato a migliorare lo stato di salute.
   - Totalmente d’accordo
   - Moderatamente d’accordo
   - Parzialmente in accordo
   - Parzialmente in disaccordo
   - Moderatamente in disaccordo
   - Totalmente in disaccordo

5. Il Servizio di Telemedicina ha invaso la mia privacy.
   - Totalmente d’accordo
   - Moderatamente d’accordo
   - Parzialmente in accordo
   - Parzialmente in disaccordo
   - Moderatamente in disaccordo
   - Totalmente in disaccordo

6. Il Servizio di Telemedicina mi è stato sufficientemente spiegato.
   - Totalmente d’accordo
   - Moderatamente d’accordo
   - Parzialmente in accordo
   - Parzialmente in disaccordo
   - Moderatamente in disaccordo
   - Totalmente in disaccordo

7. Il Servizio di Telemedicina merita di essere considerato un mezzo di cura affidabile.
   - Totalmente d’accordo
   - Moderatamente d’accordo
   - Parzialmente in accordo
   - Parzialmente in disaccordo
   - Moderatamente in disaccordo
   - Totalmente in disaccordo

8. Il Servizio di Telemedicina mi ha fatto sentire a disagio, ad esempio fisicamente o emotivamente.
   - Totalmente d’accordo
   - Moderatamente d’accordo
   - Parzialmente in accordo
   - Parzialmente in disaccordo
   - Moderatamente in disaccordo
   - Totalmente in disaccordo

9. Sono preoccupato per il livello di competenza delle persone che monitorano il mio stato di salute tramite il servizio di Telemedicina.
   - Totalmente d’accordo
   - Moderatamente d’accordo
   - Parzialmente in accordo
   - Parzialmente in disaccordo
   - Moderatamente in disaccordo
   - Totalmente in disaccordo

10. Il Servizio di Telemedicina mi ha permesso di essere meno preoccupato riguardo alla mia assistenza sanitaria o sociosanitaria.
   - Totalmente d’accordo
   - Moderatamente d’accordo
   - Parzialmente in accordo
   - Parzialmente in disaccordo
   - Moderatamente in disaccordo
   - Totalmente in disaccordo

11. Il Servizio di Telemedicina mi ha reso più attivamente coinvolto nel monitorare il mio stato di salute.
    - Totalmente d'accordo
    - Moderatamente d'accordo
    - Parzialmente in accordo
    - Parzialmente in disaccordo
    - Moderatamente in disaccordo
    - Totalmente in disaccordo

12. Il Servizio di Telemedicina determina in me uno stato di preoccupazione a riguardo del grado di riservatezza con cui viaggiano le informazioni personali.
    - Totalmente d'accordo
    - Moderatamente d'accordo
    - Solo in parte d'accordo
    - Solo in parte in disaccordo
    - Moderatamente in disaccordo
    - Totalmente in disaccordo

13. Il Servizio di Telemedicina consente alle persone che mi stanno curando di monitorare meglio il mio stato di salute.
    - Totalmente d'accordo
    - Moderatamente d'accordo
    - Parzialmente in accordo
    - Parzialmente in disaccordo
    - Moderatamente in disaccordo
    - Totalmente in disaccordo

14. Sono soddisfatto del servizio di Telemedicina.
    - Totalmente d'accordo
    - Moderatamente d'accordo
    - Parzialmente in accordo
    - Parzialmente in disaccordo
    - Moderatamente in disaccordo
    - Totalmente in disaccordo

15. Il Servizio di Telemedicina può essere/dovrebbe essere raccomandato a persone in condizioni di salute simili alle mie.
    - Totalmente d'accordo
    - Moderatamente d'accordo
    - Parzialmente in accordo
    - Parzialmente in disaccordo

- Moderatamente in disaccordo
- Totalmente in disaccordo

16. Il Servizio di Telemedicina può sostituire la mia tradizionale assistenza sanitaria o socio-sanitaria
    - Totalmente d'accordo
    - Moderatamente d'accordo
    - Parzialmente in accordo
    - Parzialmente in disaccordo
    - Moderatamente in disaccordo
    - Totalmente in disaccordo

17. Il Servizio di Telemedicina può sicuramente essere un buon supplemento alla mia tradizionale assistenza sanitaria o sociosanitaria.
    - Totalmente d'accordo
    - Moderatamente d'accordo
    - Parzialmente in accordo
    - Parzialmente in disaccordo
    - Moderatamente in disaccordo
    - Totalmente in disaccordo

18. Il Servizio di Telemedicina non è adeguato rispetto alle visite faccia a faccia da parte del personale sanitario che mi cura.
    - Totalmente d'accordo
    - Moderatamente d'accordo
    - Parzialmente in accordo
    - Parzialmente in disaccordo
    - Moderatamente in disaccordo
    - Totalmente in disaccordo

19. Il Servizio di Telemedicina ha reso più facile il mettersi in contatto con medici, infermieri, operatori socio-sanitari.
    - Totalmente d'accordo
    - Moderatamente d'accordo
    - Parzialmente in accordo
    - Parzialmente in disaccordo
    - Moderatamente in disaccordo
    - Totalmente in disaccordo

20. Il Servizio di Telemedicina interferisce con la continuità dell'assistenza che ricevo (ad esempio non vedo sempre lo stesso professionista ogni volta).
    - Totalmente d'accordo

- Moderatamente d’accordo
- Parzialmente in accordo
- Parzialmente in disaccordo
- Moderatamente in disaccordo
- Totalmente in disaccordo

21. Sono preoccupato che chi monitora il mio stato di salute attraverso il Servizio di Telemedicina non conosca la mia storia personale di assistenza sanitaria o sociosanitaria.
    - Totalmente d’accordo
    - Moderatamente d’accordo
    - Parzialmente in accordo
    - Parzialmente in disaccordo
    - Moderatamente in disaccordo
    - Totalmente in disaccordo

22. Il Sistema di Telemedicina mi ha reso meno preoccupato per il mio stato di salute.
    - Totalmente d’accordo
    - Moderatamente d’accordo
    - Parzialmente in accordo
    - Parzialmente in disaccordo
    - Moderatamente in disaccordo
    - Totalmente in disaccordo

Annex 7 – Data collection questionnaire 1

Aspetti generali

- La disponibilità della tecnologia modifica il numero di pazienti assistibili a domicilio? Se si, in che percentuale?
- Questo approccio richiede un impegno maggiore o minore di risorse umane? Se si, in che misura?

Aspetti organizzativi:

- Descrizione del processo:
    - modalità di selezione dei pazienti
    - criteri di inclusione
    - modalità e durata della formazione
    - impegno orario giornaliero per profilo professionale
    - criteri per valutare l'autonomia del paziente e del caregiver (check list, …) nella gestione della procedura
- Descrizione delle attività della control room:
    - disponibilità oraria del servizio
    - numero dipendenti e qualifica
    - numero di turni
- A seguito del programma di formazione quali sono gli elementi che scoraggiano l'uso telemedicina

Aspetti economici:

- Stima dei costi in relazione a (specificare le eventuali voci raggruppate in voci di costo più ampie omnicomprensive):

Ambito/livello	**Architettura e/o componenti del sistema**	**Costo (es. importo canone annuale, prezzo di acquisto, ecc.)**
Home	Sistema per dialisi HD	
	Costo trattamento (HD) x numero trattamenti/anno	
	Sistema per dialisi PD	
	Costo trattamento (PD) x numero trattamenti/anno	
	Telecamera robotizzata	
	POCT	
	Bilancia	
	Misuratore di pressione	
	Glucometro	
	ECG	
	Termometro	
	Modem/router	
	Tablet	
	SW – SMARTDIAL 2.0(*)	
	SW - NEPHROCAD(*)	
	Piattaforma, gestione, social networking… (*)	
	Poltrona	
	ICT – Dialnet E10, server, ecc	
Cloud	Canone annuo	
Hospital	HW incluso wall monitor	
	SW	
Servizi di manutenzione	Canone manutenzione apparecchiature biomediche	
	Canone manutenzione software (eventualmente suddivisa tra manutenzione evolutiva e preventiva)	

(*) Nel caso dei software specificare se il pagamento avviene una tantum oppure vi un canone. Eventualmente specificare se canone è unico per tutti i software.

Annex 8 – Data collection questionnaire 2

QUESITI RESIDUI INERENTI AI COSTI E ALL'ORGANIZZAZIONE HS TELEDIALISI

LE INFORMAZIONI DEVONO ESSERE RIFERITE AL DICEMBRE 2020, PRIMA DELL'APPLICAZIONE DELLA DGR 1961/2020

SETTING ORGANIZZATIVI

1. In riferimento alla sperimentazione del modello organizzativo di teledialisi (PD e HD) domiciliare, (dialisi domiciliare con monitoraggio da remoto = dialisi domiciliare con telemonitoraggio), sulla base dei setting organizzativi sotto riportati, desidereremmo conoscere il numero di pazienti in carico nel vostro centro dialisi al dicembre 2020 (prima dell'applicazione della DGR 1961 del 7/12/2020) ripartiti per dialisi domiciliare tradizionale e teledialisi domiciliare.
2. Dei pazienti trattati in modalità domiciliare in TELEDIALISI PERITONEALE, indicare la proporzione (%) tra utilizzo di dispositivo di PD AUTOMATICA vs PD MANUALE

FREQUENZA SETTIMANALE DI TRATTAMENTO E MISURAZIONE PARAMETRI

3. frequenza settimanale dialisi e tele dialisi domiciliare HD/PD e misurazione parametri (POCT): si desidera sapere quanti trattamenti dialitici esegue il singolo paziente per settimana (o una loro media se il n. è variabile); (es.: N° 3 dialisi/week); inoltre si desidera conoscere l'intensità di utilizzo del POC

INFERMIERE DOMICILIARE

4. (Se applicabile) In caso di presenza di assistenza infermieristica <u>domiciliare</u> indicare il rapporto numerico tra infermiere e paziente (es. 1 INF. ogni 4 pz.) e la frequenza di visite paziente (esempi: 4 visite / mese, 1 visita/settimana, 1 visita ogni 10 dialisi domiciliari ...) sia in trattamento domiciliare tradizionale, sia in teledialisi.

DISPOSITIVI A CORREDO

5. Assodata la dotazione al paziente di un set di devices specifici per la misurazione dello status clinico composto dal set tecnologico * **,** si vorrebbe conoscere se lo stesso "set" tecnologico è detenuto dai pazienti nei differenti setting assistenziali a prescindere dalla eventuale visita a domicilio di personale sanitario. La domanda vuole conoscere se ad es. un paziente in HD domiciliare con assistenza infermieristica ha in dotazione gli stessi devices sia che effettui la dialisi in maniera tradizionale, sia in teledialisi (ad esclusione della telecamera)
6. Specificare se, oltre alla dotazione riportata, è necessario dotare del set sopra indicato anche l'"*operatore che si reca domicilio*" (oltre al paziente).
7. L'infermiere che eventualmente si rechi a domicilio del paziente è dotato delle stesse tecnologie sia che si rechi da paziente in dialisi domiciliare, sia che si rechi da paziente in teledialisi domiciliare? Se no, specificare.

SMALTIMENTO RIFIUTI

8. Se informazione conosciuta, confermare che gli oneri (le attività/ i costi) di smaltimento dei rifiuti post trattamento sono inclusi nei costi degli stessi kit di materiale di consumo acquisiti e utilizzati per dialisi domiciliare.

ORGANIZZAZIONE ATTUALE DEL SERVIZIO (per attuale si intende fino al dicembre 2020)

9. Su quanti turni attualmente è distribuito il servizio? Per quanti giorni/settimana è attiva la control room? Per quante ore?

COMPOSIZIONE ATTUALE DEL PERSONALE (per attuale si intende fino al dicembre 2020)

10.
    - Quanti medici sono attualmente in servizio nella control room?
    - Quanti infermieri sono attualmente in servizio nella control room?
    - Quanti infermieri operano al di fuori della control room con specifica attività a domicilio del paziente in teledialisi?
    - E' presente turnazione degli stessi infermieri per attività in control room e quella a domicilio del paziente in teledialisi?

PRESA IN CARICO DEL PAZIENTE:

11. Qual è il modello di presa in carico del paziente, ovvero da chi viene inviato il paziente al centro? (MMG, specialista ambulatoriale del Distretto sociosanitario, specialista ambulatoriale ospedaliero, etc.)? In quale proporzione? (tutti i soggetti)

Esiste un livello di raccordo con i medici di medicina generale?

Annex 9 – List of direct cost for platform and devices involved in TD experience by PB

Ambito/livello	**Architettura e/o componenti del sistema**	**Costo (es. importo canone annuale, prezzo di acquisto, ecc.)**
Home	Sistema per dialisi HD	Comodato d'uso gratuito
	Tariffa per trattamento HD domiciliare	€ 103,29
	Materiale di consumo per trattamento (HD)	€ 101,00 (comprende l'apparecchiatura per la dialisi)
	Sistema per dialisi PD	Comodato d'uso gratuito per OCPD e CAPD
	Tariffa per trattamento PD domiciliare	€ 77,47 Dialisi peritoneale automatizzata (OCPD) € 46,48 Dialisi peritoneale manuale (CAPD)
	Materiale di consumo per trattamento (PD)	OCPD € 48,00 (ca) CAPD € 33,00 (ca)
	Telecamera robotizzata	TelCare: € 3.079,00 Costo annuo (su contratto triennale)
	POCT	No (ancora da quotare)
	Bilancia	Si
	Misuratore di pressione	Si
	Pulsossimetro	SI
	Glucometro	SI
	ECG	SI
	Termometro	SI
	Modem/router	Si
	Tablet	Si
	-Dotazione paziente con tutti i device sopra elencati, escluso il POCT (manutenzione e assistenza); -Sw Control Room ospedaliera (Fornitura e assistenza) -Dotazione stessi device del pz ad operatore a domicilio (1 ogni 4 pz)	Canone 2.691,67 – costo annuo per paziente, con un minimo di 20 pz (su contratto triennale)
	SW – SMARTDIAL 2.0(*)	no
	SW - NEPHROCAD(*)	no
	Piattaforma, gestione, social networking… (*)	no
	Poltrona	900,90/annuo per paziente (su contratto triennale)
	ICT – Dialnet E10, server, ecc	no
Cloud	Canone annuo	
Hospital	HW incluso wall monitor (con 3 postazioni di monitoraggio)	3.233,33 – costo annuo (su contratto triennale)
	SW	no
Servizi di manutenzione	Canone annuo manutenzione sistema per HD	No (comodato d'uso gratuito)
	Canone annuo manutenzione sistema per PD	No (comodato d'uso gratuito)
	Canone manutenzione software (eventualmente suddivisa tra manutenzione preventiva e correttiva)	No (comodato d'uso gratuito)

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