XXXI Corso Nazionale ANTE - Dialisi e Tecnologia
"Evoluzione tecnologica nei trattamenti dialitici cronici e acuti: dalla teoria alla pratica"

15-16-17 Aprile 2024 Sala Congressi Hotel CORALLO
Viale Antonio Gramsci, 113, 47838 Riccione RN

Telemedicina e gestione dei dati informatici in emodialisi

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World Health Organization

Telemedicina

L'effettuazione di servizi di assistenza sanitaria, dove la **distanza** *è un fattore critico, da parte di tutti gli operatori sanitari che utilizzano le informazioni e tecnologie di comunicazione per lo scambio di informazioni valide per diagnosi, trattamento e prevenzione di malattie e ferite, ricerca e valutazione, e per la formazione continua degli operatori sani-tari, tutti nell'interesse di promuovere la salute delle persone e le loro comunità* (WHO, 2011).

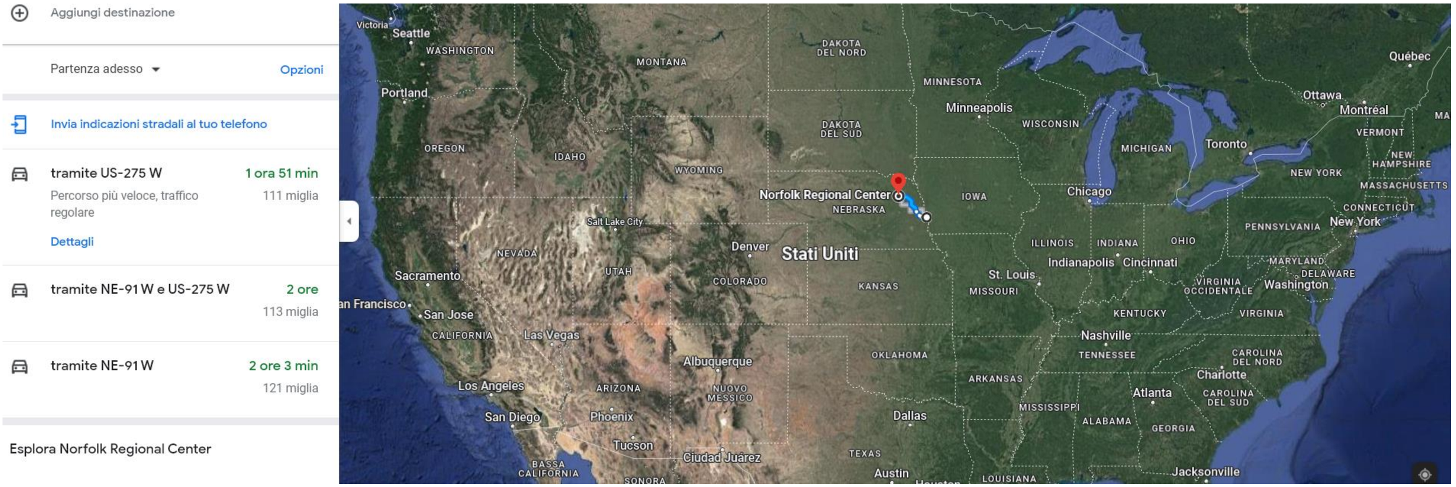
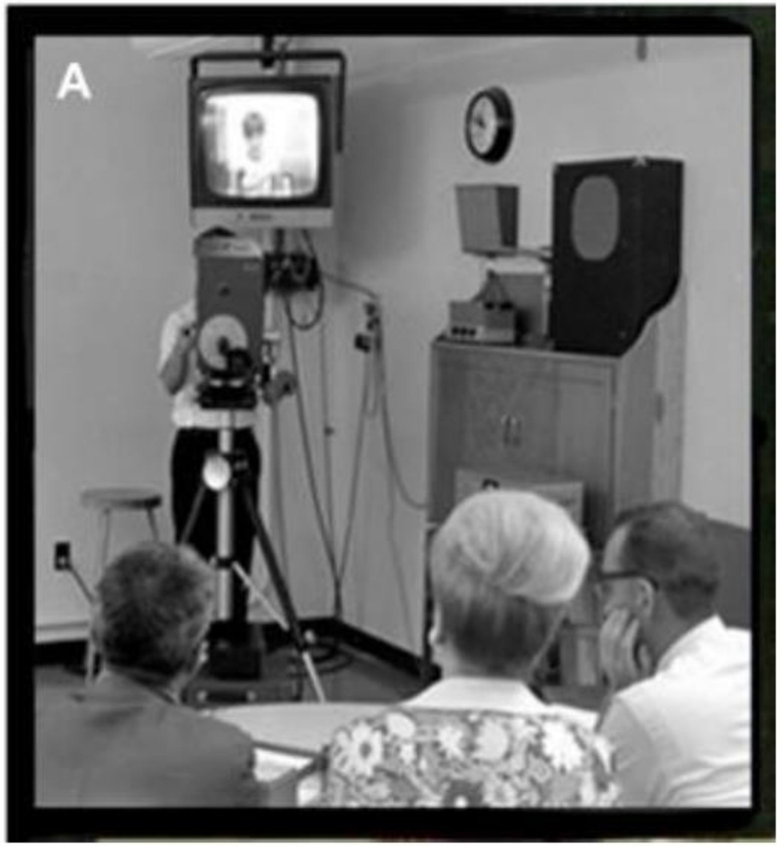


Fig. 1 – Sistema di telemedicina tra il Nortfolk State Hospital e il Nebraska Psychiatric Insititute



Il primo pionieristico sistema risale al ***1959****, anno in cui il Dott. Wittson metteva in comunicazione attraverso un monitor il Nortfolk State Hospital con il Nebraska Psychiatric Institute a 112 miglia di di-stanza*

Telediagnosis

Telemedicine (initially called "Telediagnosis" at the MGH) was featured in the January 11, 1969, issue of the popular magazine "TV Guide," nine months after the Logan International Airport-MGH Medical Station telediagnosis program became operational, on April 8, 1968

A dermatology patient at the walk-in Logan International Airport MGH Medical Station "Telediagnosis clinic" is being examined remotely by television. (Lower photo) Kenneth T. Bird, MD, at the MGH, is examining the dark irregular purple skin lesion on the patient's left foot, using the robotically controlled-TV camera out at the Logan Airport

PNRR e Telemedicina

55 ANNI…

Missione 6
Componente 1

L'investimento 1.2.3 "Telemedicina per un migliore supporto ai pazienti cronici" con il DM del 1° aprile 2022 è stato articolato in due sub-interventi:

- 1.2.3.1 – Piattaforma di Telemedicina;
- 1.2.3.2 – Servizi di Telemedicina.

2. ELEMENTI GENERALI DELL'INIZIATIVA

2.1. Contesto di riferimento

La presente iniziativa si colloca nel contesto delle misure di attuazione della Missione 6 "Salute", Componente 1 del Piano Nazionale di Ripresa e Resilienza (di seguito, per brevità, anche "**PNRR**") e si pone, inoltre, in continuità con alcune linee di investimento rientranti nella Componente 2 della Missione 6 del PNRR.

Nell'ambito della Missione 6 "Salute", il PNRR prevede i due seguenti obiettivi primari:

- la **Missione 6, Componente 1 (M6C1)** – "Reti di prossimità, strutture e Telemedicina per l'assistenza territoriale": gli interventi di questa componente intendono rafforzare le prestazioni erogate sul territorio grazie al potenziamento e alla creazione di strutture e presidi territoriali (come le Case della Comunità e gli Ospedali di Comunità) nonché al rafforzamento dell'assistenza domiciliare, allo sviluppo della Telemedicina e a una più efficace integrazione con tutti i servizi sociosanitari.

Nell'ambito di tale Componente, si inserisce l'investimento 1.2 ("*Casa come primo luogo di cura e telemedicina*") e, in particolare, il sub-investimento 1.2.3 ("*Telemedicina per un migliore supporto ai pazienti cronici*"), sub-codifica 1.2.3.2 ("*Servizi di Telemedicina*"), cui afferisce l'iniziativa oggetto del presente capitolato tecnico;

- la **Missione 6, Componente 2 (M6C2)** – "*Innovazione, ricerca, digitalizzazione del Servizio Sanitario Nazionale*": le misure incluse in questa componente hanno l'obiettivo di garantire il rinnovamento e l'ammodernamento delle strutture tecnologiche e digitali esistenti (con particolare attenzione alla digitalizzazione delle strutture sanitarie sede di Dipartimenti di emergenza e accettazione (DEA) di I e II livello), il completamento e la diffusione del Fascicolo Sanitario Elettronico (FSE), una migliore capacità di erogazione e monitoraggio dei Livelli Essenziali di Assistenza (LEA) attraverso più efficaci Sistemi Informativi. Rilevanti risorse sono destinate anche alla ricerca scientifica e a favorire il trasferimento tecnologico, oltre che a rafforzare le competenze e il capitale umano del Sistema Sanitario Nazionale (di seguito anche "**SSN**") anche mediante il potenziamento della formazione del personale.

PNRR e Telemedicina

Missione 6
Componente 1

L'investimento 1.2.3 "Telemedicina per un migliore supporto ai pazienti cronici" con il DM del 1° aprile 2022 è stato articolato in due sub-interventi:

- 1.2.3.1 – Piattaforma di Telemedicina;
- 1.2.3.2 – Servizi di Telemedicina.

Il Decreto interministeriale del 30.09.2022 riguarda le procedure di selezione delle soluzioni di telemedicina e diffusione sul territorio nazionale, nonché i meccanismi di valutazione delle proposte di fabbisogno regionale per i servizi minimi di telemedicina e l'adozione delle linee di indirizzo per i Servizi di Telemedicina.
Il decreto prevede che ogni Regione e Provincia autonoma compili un Piano Operativo (all. A del Decreto) contenente il fabbisogno per i servizi di telemedicina

TELEMEDICINA Linee di indirizzo nazionali

Tabella 2.1 Classificazione dei servizi di Telemedicina

TELEMEDICINA					
CLASSIFICAZIONE		**AMBITO**	**PAZIENTI**		**RELAZIONE**
TELEMEDICINA SPECIALISTICA	TELE VISITA	sanitario	Può essere rivolta a patologie acute, croniche, a situazioni di post-acuzie	Presenza attiva del Paziente	B2C B2B2C
	TELE CONSULTO			Assenza del Paziente	B2B
	TELE COOPERAZIONE SANITARIA			Presenza del Paziente, *in tempo reale*	B2B2C
TELE SALUTE		sanitario	E' prevalentemente rivolta a patologie croniche	Presenza attiva del Paziente	B2C B2B2C
TELE ASSISTENZA		socio-assistenziale	Può essere rivolta ad anziani e fragili e diversamente abili		

* B2B: individua la relazione tra medici

B2B2C: individua la relazione tra un medico e un paziente mediata attraverso un operatore sanitario

B2C: individua la relazione tra medico e paziente

Tabella 2.2 Telemedicina specialistica

TELEMEDICINA SPECIALISTICA					FINALITA'				RELAZIONE*		
									B2C B2B2C	B2B2C	B2B
	PAZIENTI	AMBITO		Monitoraggio	Prevenzione	Diagnosi	Cura	Riabilitazione	Televisita	Telecooperazione sanitaria	Teleconsulto
TELEMEDICINA DEI MEDICI SPECIALISTI	tutti	sanitario	TelePatologia (Laboratorio Biomedico e Anatomia Patologica)								
			TeleRadiologia								
			TeleCardiologia								
			TelePneumologia								
			TeleDermatologia								
			TeleOftalmologia								
			TelePsichiatria/TelePsicologia								
			TeleNeurologia								
			TeleChirurgia								
			TeleEmergenza								
			TeleRiabilitazione								
			TelePediatria								
			**........								
TELEMEDICINA del TERRITORIO			TeleMMG								
			TelePLS								

* B2B: individua la relazione tra medici

B2B2C: individua la relazione tra un medico e un paziente mediata attraverso un operatore sanitario

B2C: individua la relazione tra medico e paziente

** tutte le specialità mediche e chirurgiche

Finanziato dall'Unione europea NextGenerationEU

Italiadomani PIANO NAZIONALE DI RIPRESA E RESILIENZA

PIÙ Salute PROSSIMITÀ INNOVAZIONE UGUAGLIANZA

agenas. AGENZIA NAZIONALE PER I SERVIZI SANITARI REGIONALI

Le Regioni

Infrastrutture regionali dovranno Garantire:

1.Supporto funzionale alla fruizione dei servizi minimi alla Televisita, Teleassistenza…

2. i dispositivi per la rilevazione dei parametri di salute direttamente al domicilio del paziente

Tabella fabbisogni

Diabete, Resp, Cardio, Oncologici,Neuro

	Servizio da acquistare						Pazienti in Telemonitoraggio						Utenti Televisita/Teleconsulto						Utenti Teleassistenza				Utenti IRT
	Tvisita	Tassistenza	Tconsulto	Tmon. 1	Tmon. 2	Infrastruttura	Diabete	Resp	Cardio	Onco	Neuro	Tot	MMG	PLS	Specialisti	Altro	Tecnico-amm	Tot	Infermieri	Altro	Tecnico-amm	Tot	
Abruzzo	si	si	si	si	si	si	4.800	3.200	3.150	393	3.100	14.643	954	133	2.915	357	99	4.359	1.186	432	99	1.618	5.620
Calabria	si	si	si	si	si	si	5.583	1.016	236	nd	nd	6.835	1.353	224	3.090	1.301	49	5.968	1.142	772	60	1.914	7.110
Campania	no	si	no	si	si	si	34.002	27.030	15.495	nd	370	76.897	3.554	705	10.123	5.886	12.655	20.268	22.088	5.886	12.655	27.974	42.356
Emilia Romagna	si	si	si	si	si	si	4.000	3.000	5.000	nd	nd	12.000	2.713	568	11.432	1.780	111	16.493	4.523	1.780	111	6.303	21.016
Friuli Venezia Giulia	no	no	no	si	si	si	1.318	1.199	590	1.609	114	4.830	751	117	2.994	9.904	2.985	13.766	7.634	9.904	2.985	17.538	21.400
Lazio	si	si	si	si	si	si	6.200	2.600	6.000	1.200	1.050	17.050	4.346	764	9.990	11.988	499	27.088	7.498	3.000	499	10.498	34.586
Liguria	no	si	si	si	si	si	1.974	868	8.440	3.420	301	15.003	995	155	2.957	700	168	4.807	1.300	694	150	1.994	6.107
Lombardia	si	si	si	si	si	si	38.367	25.190	69.335	42.440	24.668	200.000	5.623	1.088	16.907	0	0	23.618	9.027	1.127	0	10.154	33.772
Marche	si	si	si	si	si	si	19.450	8.330	5.100	4.200	1.450	38.530	1.043	168	2.900	2.520	192	6.631	1.013	1.006	112	2.019	7.644
Molise	si	si	si	si	si	si	1.608	0	4.470	904	306	7.288	236	31	437	100	200	804	750	100	200	850	1.554
PA Trento	no	no	no	no	si	si	2.423	492	1.665	37	206	4.823	330	68	1.319	5.266	195	6.983	3.547	1.719	195	5.266	10.530

- L'Infrastruttura Regionale di Telemedicina dovrà garantire il supporto funzionale alla fruizione dei servizi minimi di Televisita, Teleassistenza, Teleconsulto e Telemonitoraggio, come indicato dalle Linee Guida a livello nazionale.

- A supporto di operatori sociosanitari e utenti si prevede che, per assicurare l'efficace funzionamento del servizio minimo di Telemonitoraggio nell'ambito dell'Infrastruttura Regionale di Telemedicina, vengano resi disponibili dalle Regioni e dagli Enti Sanitari i dispositivi per la rilevazione dei parametri di salute

Infrastruttura Regionale di Telemedicina

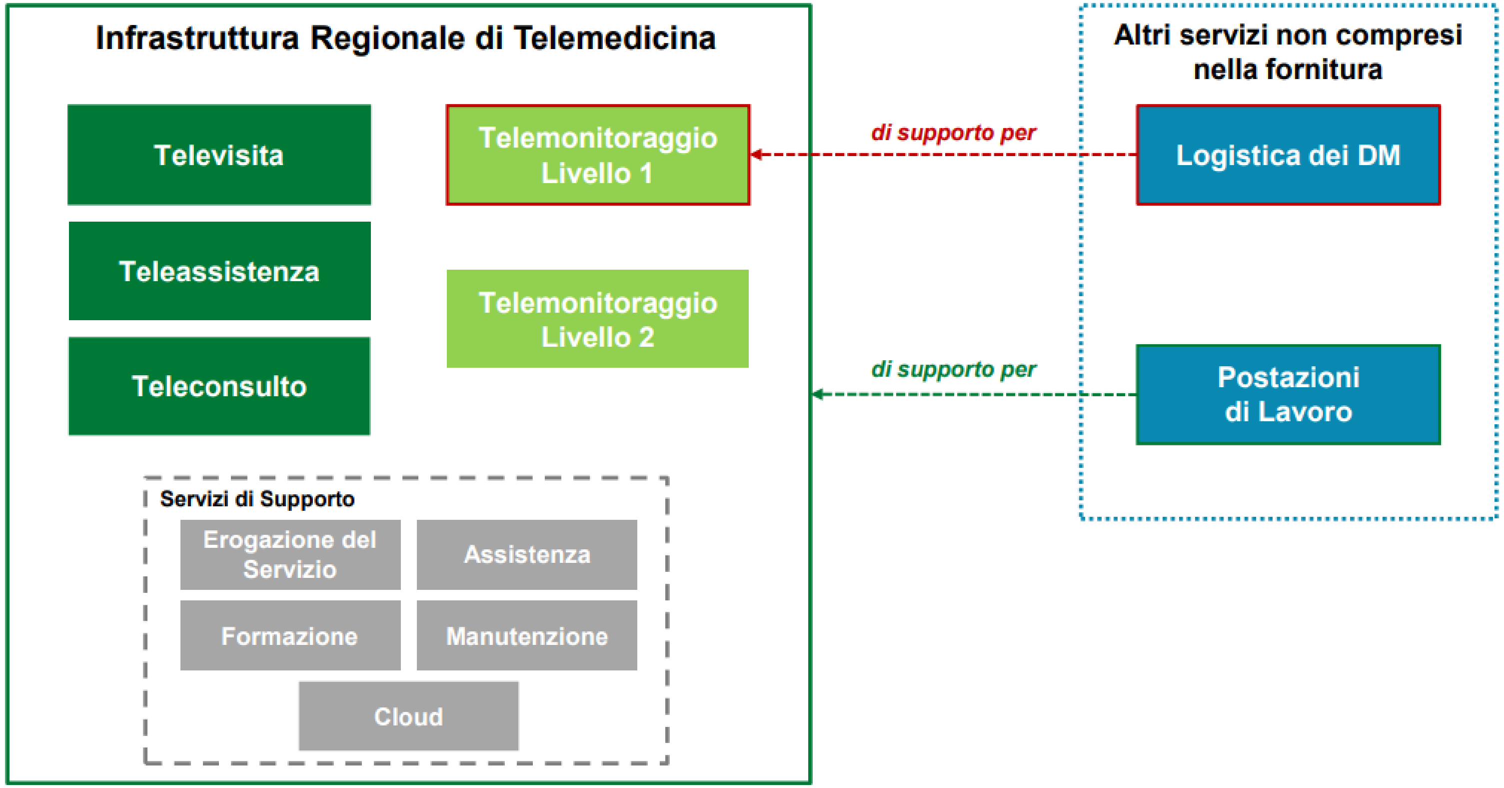


Figura 1 - Schema della IRT e altri servizi non compresi

…disponibilità di postazioni di Lavoro di Telemedicina dedicate da collocare presso le Strutture del SSR e presso gli studi dei MMG

A supporto di operatori sociosanitari e utenti si prevede che, per assicurare l'efficace funzionamento del servizio minimo di Telemonitoraggio nell'ambito dell'Infrastruttura Regionale di Telemedicina, vengano resi disponibili dalle Regioni e dagli Enti Sanitari i dispositivi per la rilevazione dei parametri di salute direttamente al domicilio del paziente

Livelli di telemonitoraggio

- **telemonitoraggio "base" (livello 1)** Afferente a uno scenario di "closed loop" dove i dati provengono da **dispositivi "generalisti"** (saturimetri, elettrocardiografi, bilance, termometri, spirometri, glucometri, altri), tipicamente assegnati a un determinato paziente in base al suo quadro patologico complessivo, senza alcuna intermediazione o operazione manuale da parte del paziente o del suo caregiver

- **telemonitoraggio "avanzato" (livello 2)** si applica nei casi di pazienti sottoposti a monitoraggio attraverso **piattaforme software specialistiche prodotte da società terze** che comunicano direttamente con dispositivi assegnati o impiantati sul paziente.

NB inserimento nel **catalogo nazionale delle soluzioni di Telemedicina**

L'attuazione della Missione M6C1 intende perseguire una nuova strategia sanitaria, sostenuta dalla definizione di un adeguato assetto istituzionale e organizzativo, che consenta allo Stato italiano di conseguire *standard* qualitativi di cura adeguati, in linea con i migliori standard degli Stati membri, e che consideri, sempre più, il SSN come parte di un più ampio sistema di *welfare* europeo. Essa prevede due attività principali:

- la definizione di **standard strutturali, organizzativi e tecnologici** omogenei per l'assistenza territoriale e l'identificazione delle strutture a essa deputate;
- la **definizione di un nuovo assetto istituzionale** per la prevenzione in ambito sanitario, ambientale e climatico, in linea con l'approccio "One-Health".

In questo senso, costituiscono elementi chiave:

- la creazione delle **Case di Comunità** e degli **Ospedali di Comunità**;
- la diffusione della **Telemedicina**;
- il **potenziamento dei servizi domiciliari**.

Sostenibilità

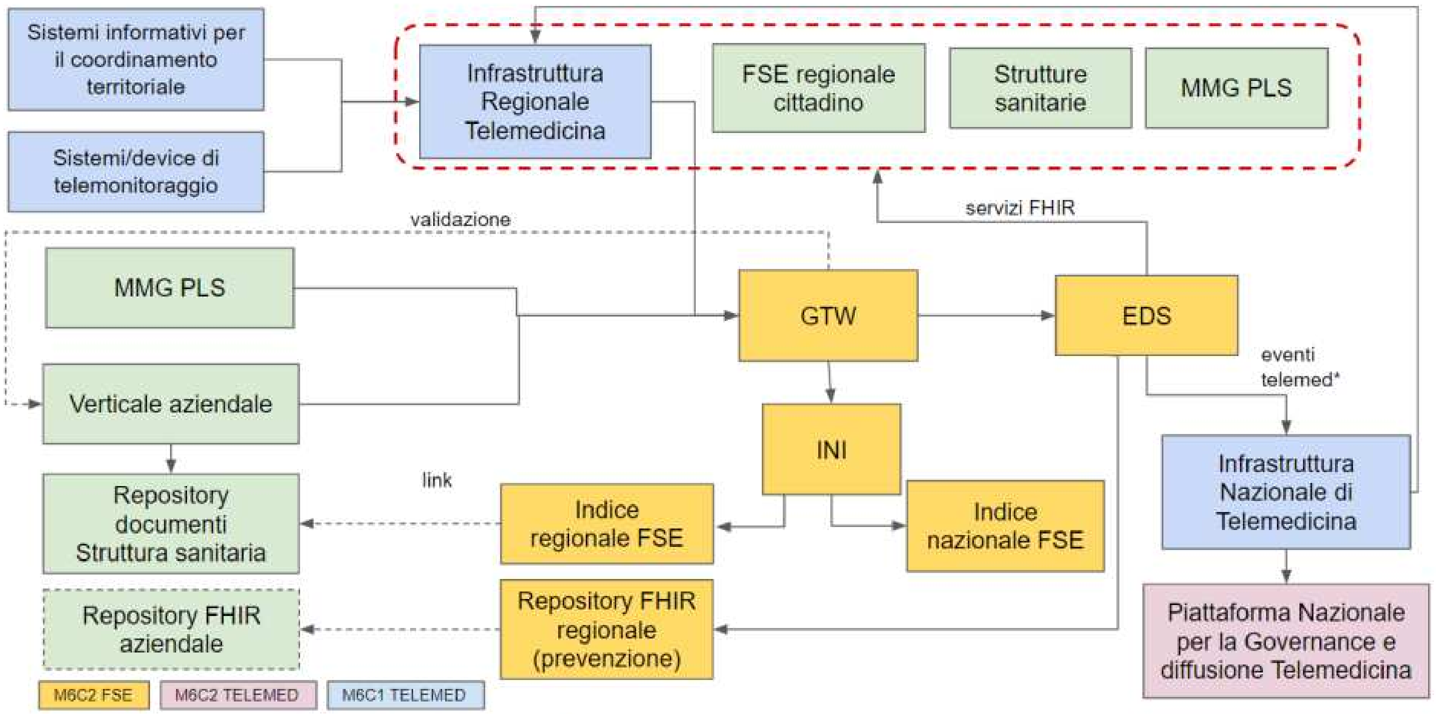
La Digitalizzazione dei servizi sociosanitari

Infine, l'iniziativa si inserisce in un percorso più ampio, tracciato dal Ministero della Salute e da Agenas nel tempo, che sta portando ad una progressiva **digitalizzazione dei servizi sociosanitari territoriali** tramite la pubblicazione di specifica documentazione di riferimento:

- Linee di indirizzo nazionali di Telemedicina – Ministero della Salute (2014);
- Indicazioni nazionali per l'erogazione di prestazioni di telemedicina (27 ottobre 2020) – Conferenza Stato-Regioni;
- Linee guida per i servizi di telemedicina, Investimento 1.2.3, Requisiti funzionali e tecnologici.

In tale prospettiva si rende quindi necessario progettare e realizzare una nuova **soluzione applicativa e tecnologica per l'introduzione di una Infrastruttura Regionale di Telemedicina**.

Piattaforma di Telemedicina ed Ecosistema FSE
Punti di contatto e raccordo tra i due progetti



Modello logico di interazione a regime

L'infrastruttura **nazionale di telemedicina** è uno strumento di programmazione e

OUR PRIORITIES

Digital Health

EXPLORE

Medical technologies generate information and data that are critical for the prevention, diagnosis, treatment, monitoring and management of health and lifestyle. More and more of this data is now digitised; it can be stored and accessed on electronic health records and personal devices, Digital Health

MedTech Europe from diagnosis to cure

: Homepage » What we work on » Digital Health

Innovazione tecnologica e la digitalizzazione

Medical technologies **generate information and data** that are critical for the **prevention, diagnosis, treatment, monitoring and management of health and lifestyle**. More and more of this data is now digitised; it can be stored and accessed on electronic health records and personal devices, shared among patients and healthcare professionals, and aggregated and processed with data advanced analytics

MedTech Europe works with policymakers and relevant stakeholders to realise the potential of data-driven healthcare. Together we focus on legal and regulatory issues (privacy, safety), technology (cybersecurity, interoperability), the business case (incentives, reimbursement), and emerging technologies (precision medicine, artificial intelligence).

La digitalizzazione - CKD

U.S. Department of Health & Human Services

NIH National Institutes of Health
Turning Discovery Into Health

- **Health Information Technology Working Group**

The Health Information Technology Working Group (HITWG) works to enable and support the widespread interoperability of data related to kidney health among healthcare software applications to optimize CKD detection and management. The group aims to provide easy and uniform access to kidney health information that will enable researchers to better understand the national burden of CKD, health care professionals to better care for CKD patients, and people living with kidney disease to better manage their health. The working group is focused on incorporating CKD data into electronic health records in a consistent and searchable manner, and improving management of CKD populations using HIT.

Table 1 | **Health categories and applications in kidney care**

Category	Description	Applications in kidney disease
Electronic health records	Digital versions of patient medical records that may contain demographic information, diagnoses, biometric and vital sign measurements, treatment notes, medication information, laboratory and radiology results, and billing information Electronic health records can be accessed by patients or providers through portals with functions to support care-related activities (for example, place orders, make appointments)	Provider alerts and decision aids for management of AKI and CKD Screening for CKD Identification of potential candidates for research and clinical trials Engagement of patients in self-management by tracking and presenting data and providing individualized recommendations
Telehealth	The use of digital devices and applications such as video conferencing and digital stethoscopes to allow interactions between providers and patients and bridge geographical barriers	Virtual visits for patients with CKD in rural areas Multidisciplinary care visits for patients with multiple providers from different disciplines Video consultations with nephrologists for primary care providers Discharge follow-up after procedures such as PD catheter placement Replacement of in-person visits in prospective studies and clinical trials to minimize participant burden Urgent visits with providers for patients on dialysis in outpatient facilities with acute issues (for example, cloudy PD fluid)
Mobile health	The use of mobile devices such as personal digital assistants, mobile phones, tablets, smartphones, and wearables (for example, watches, skin patches) to provide medical care Methods of care provision include text messaging and mobile apps	Mobile app to check medication safety for patients with CKD Educational app for care after transplantation Smartphone camera read of urine test strips for urinary tract infection or proteinuria detection Blood pressure monitoring and transmission of data to health-care providers Mobile app for dietary monitoring (for example, salt and potassium intake) Electronic pillboxes for medication adherence monitoring and reminders Fluid overload monitoring via bioimpedance sensors
Web app	A programme delivered through a web browser to internet-connected devices such as computers and smartphones	Educational modules for patients with CKD Online cognitive behavioural therapy for patients on dialysis who have depression
Social media	Web and mobile applications that serve as platforms for social networking	Discussion forums for patients on dialysis Promotion of donor registration and finding living kidney donors

The listing of categories and applications is not comprehensive; many eHealth interventions are multimodal and definitions may overlap. AKI, acute kidney injury; app, application; CKD, chronic kidney disease; PD, peritoneal dialysis.

Monitoring

National Institute of Diabetes and Digestive and Kidney Diseases

eHealth in kidney care

Chia-shi Wang[1,2] *and Elaine Ku*[3]

eHealth is gaining momentum in nephrology, although evidence for its efficacy remains unclear and challenges to its widespread adoption persist. Successful integration of eHealth into kidney care will require patient engagement to develop effective interventions and issues such as data validity, regulation, oversight and adequate infrastructure to be addressed.

NIH definisce le categorie tecnologiche e le rispettive applicazioni in campo nefrologico

TELEMEDICINA IN DP
LA VIDEODIALISI - ASL VCO

COMPONENTI TECNICI:

- STAZIONE PERIFERICA A DOMICILIO / RSA
- STAZIONE DI CONTROLLO IN SEDE OSPEDALIERA
- CENTRO DI CONTROLLO INFORMATICO CON SERVER CLOUD

eVisus
Electronic Video Supporting System

ASL del Verbano Cusio Ossola (VCO)

Dal QR Code alla Videodialisi lo sviluppo di un programma di telemedicina in ambito nefrologico in un territorio montano.... *primi 6 mesi di esperienza*

Obiettivo

Svolgimento della terapia dialitica presso il domicilio, date le caratteristiche orografiche del territorio (al 99% montuoso) e l'elevata età anagrafica della popolazione residente e conseguentemente dei pazienti con patologie renali, aumentando l'empowerment del paziente e dandogli un supporto in tempo reale

Funzionalità

- **Sistema di videodialisi** che permette di acquisire video/fotografie indicative della condizione di salute del paziente (es. presenza di edemi, aspetto del liquido peritoneale, ecc.) e che consentono al medico di fornire **in tempo reale indicazioni personalizzate**
- **Archiviazione di dati clinici** (es. pressione arteriosa, volume di scarico, glicemia)

Risultati ottenuti

- La nuova modalità di gestione dei pazienti rende necessario un **numero minore di visite** domiciliari e di visite del paziente in struttura, snellisce la procedura di addestramento
- Si riduce il **rischio infettivo**
- Con riferimento alla pandemia Covid, il sistema ha permesso di gestire quadri clinici particolarmente fragili e **nessun paziente in dialisi peritoneale** nel periodo febbraio-aprile **è risultato positivo** al Covid (che invece ha interessato il 5% dei pazienti in terapia emodialitica)

Sviluppi futuri

- Migliorare le modalità operative con cui le diverse figure professionali seguono l'attività
- Migliorare la qualità del percorso di cura dei pazienti, **rendendolo più sicuro e più facilmente fruibile al domicilio**

Videodialisi

Journal of Nephrology
https://doi.org/10.1007/s40620-019-00647-6

TECHNICAL NOTE

Videodialysis: a pilot experience of telecare for assisted peritoneal dialysis

Giusto Viglino[1] · Loris Neri[1] · Sara Barbieri[1] · Catia Tortone[1]

	2009 - 2014	2015 – 2018
MODEL	VIDEODIALYSIS MODEL-1	VIDEODIALYSIS MODEL-2 (eViSuS)
LINE	HDSL	3G - 4G / ADSL
CONNECTIVITY	POINT-TO-POINT	INTERNET

Journal of Nephrology
https://doi.org/10.1007/s40620-020-00822-0

EDITORIAL

Remote patient monitoring in peritoneal dialysis helps reduce risk of hospitalization during Covid-19 pandemic

Roberto Scarpioni[1] · Alessandra Manini[1] · Paola Chiappini[1]

L’esperienza in Italia e l’evoluzione dal 2001

Videodialisi peritoneale: primo audit italiano

Articoli originali

Loris Neri[1], Simonetta Caria[2], Katia Cannas[2], Roberto Scarpioni[3], Alessandra Manini[3], Chiara Cadoni[4], Rosella Malandra[5], Ines Ullo[6], Giuseppe Rombolà[6], Maurizio Borzumati[7], Francesca Bonvegna[7], Giusto Viglino[1]

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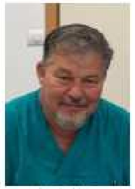
2 Nephrology and Dialysis, Cagliari Local Health Authority, Quartu Sant’Elena
3 Nephrology and Dialysis, Piacenza Local Health Authority
4 Nephrology and Dialysis, Nostra Signora di Bonaria Hospital, San Gavino Monreale
5 Nephrology and Dialysis, Teramo Hospital
6 Nephrology and Dialysis, Sette Laghi Local Health Authority, Varese
7 Nephrology and Dialysis, Verbano Cusio Ossola Local Health Authority, Verbania


Loris Neri

Corrispondenza a:
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ABSTRACT
La Videodialisi (VD) è stata ideata e sviluppata dal 2001 presso il Centro di Alba.
Inizialmente impiegata per prevenire il drop-out nei pazienti prevalenti in DP guidandoli dal Centro nell’esecuzione della dialisi (VD-Caregiver), successivamente il suo utilizzo è stato esteso al follow-up clinico di pazienti critici (VD-Clinica), per problemi di trasporto in Centro (VD-Trasporto) ed infine, dal 2016, per il training/retraining di tutti i pazienti (VD-Training).
Dal 2017 altri Centri hanno utilizzato la VD con modalità di impiego analizzate nel presente lavoro.
Metodologia: il lavoro riporta l’Audit (febbraio 2021) dei Centri che utilizzavano la VD al 31-12-2020.
I Centri hanno fornito le seguenti informazioni :

- caratteristiche dei pazienti in VD;
- motivazione principale e secondarie alla VD considerando i pazienti in Residenze Sanitarie Assistite (VD-RSA) a parte;
- outcome della VD: durata, drop-out, peritoniti, gradimento del paziente/caregiver (1: minimo – 10 massimo).

Risultati: la VD, avviata tra Settembre 2017 e Dicembre 2019, è stata utilizzata in 6 Centri per 54 pazienti (età: 71,8±12,6 anni – M:53,7% – CAPD:61,1% – DP-Assisita:70,3%).
Le motivazioni sono state: VD-Training (70,4%), VD-Caregiver (16,7%), VD-RSA (7,4%), VD-Clinica (3,7%) e VD-Trasporto (1,9%) con differenze tra i Centri.
Il VD-Training è maggiormente utilizzato nei pazienti Autonomi (93,8% – p<0,05) mentre nei pazienti in DP-Assistita è associato a motivazioni secondarie (95,7% – p<0,02). Il VD-Training (durata 1-4 settimane) si è sempre concluso con successo.

1 Impiegata per prevenire il drop-out nei pazienti prevalenti in DP

2 utilizzo esteso al follow-up clinico di pazienti critici (VD-Clinica)

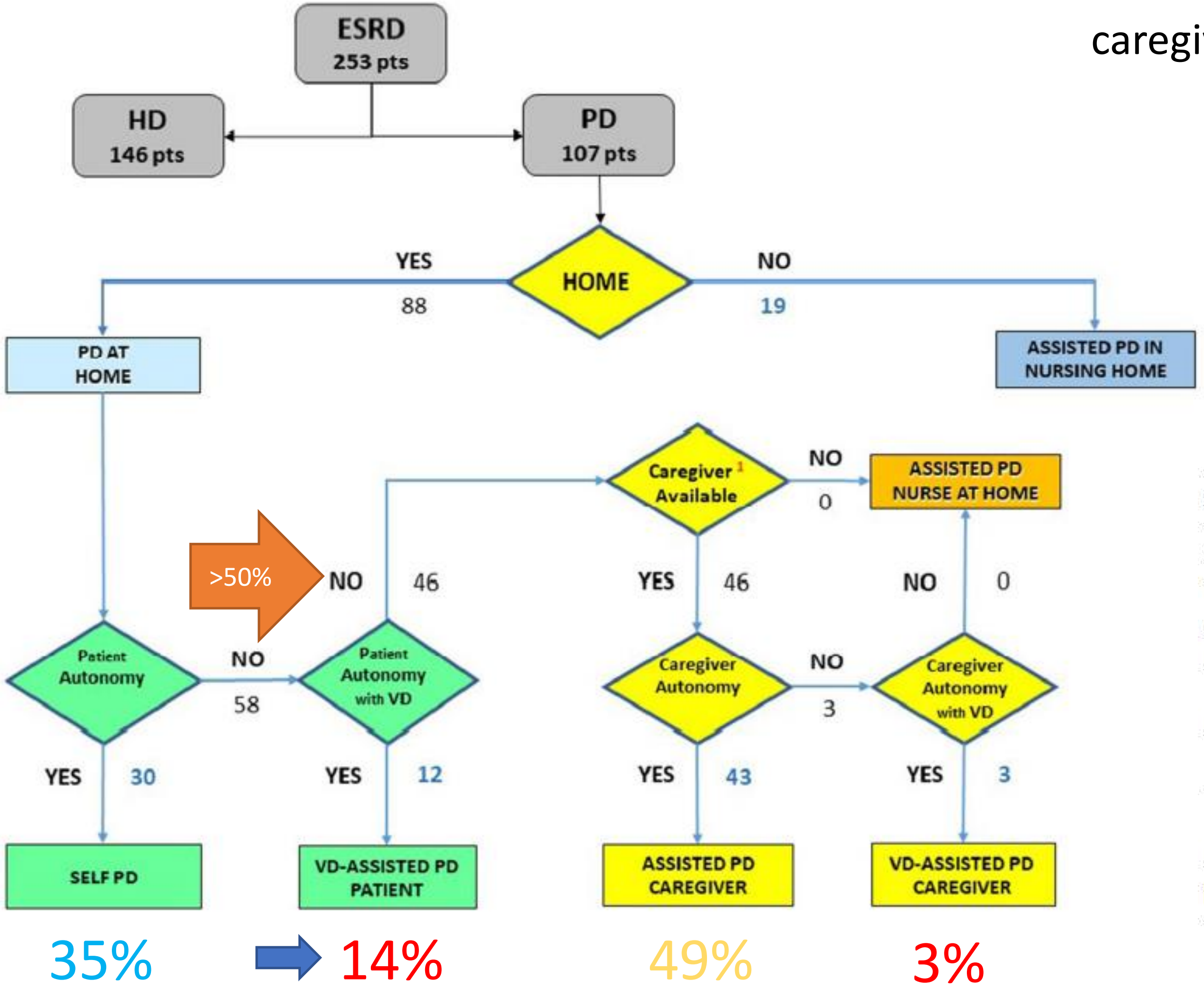
3 lontananza e problemi di trasporto

4 training/retraining

Videodialisi - Self PD vs Assisted PD + Cargiver

A seconda dell'Autonomia del paziente e del caregiver viene deciso il servizio idoneo.

Fig. 3 Flow chart and results of the choice between self PD and the various methods of Assisted PD (Assisted PD VD Patient, Assisted PD Caregiver, Assisted PD VD Caregiver, Assisted PD Nurse at Home, Assisted PD in Nursing Home). [1]The choice of family caregiver must prioritize the lowest possible financial and quality-of-life impact on the household



PD modality	Number	Age	Male	DM
Self PD	30	60.5 ± 14.0	23	8
VD-assisted PD (patient)	12	73.7 ± 9.3	6	7
Assisted PD caregiver (spouse)	13	66.4 ± 9.7	9	8
Assisted PD caregiver (son/daughter)	19	80.4 ± 7.0	7	5
Assisted PD caregiver (live-in carer)	11	80.1 ± 7.2	6	7
VD-assisted PD caregiver (spouse)	3	77.1 ± 2.5	3	2
Assisted PD in nursing home	19	80.0 ± 8.4	9	8
Total	107	72.2 ± 13.1	63	45

Fattore distanza

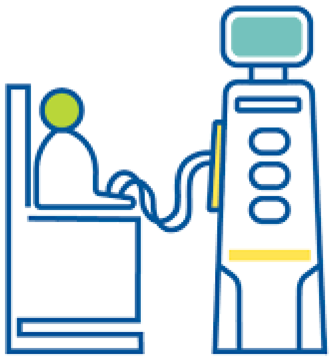
Tonelli et al. described increased complications with PD if patients lived >50km away from the renal centre

Tonelli M, Hemmelgarn B, Culleton B et al. Mortality of Canadians treated by peritoneal dialysis in remote locations. Kidney Int 2007; 72: 1023–1028

Distance to healthcare as a risk factor in patients with renal failure

Kosnik MB, Reif DM, Lobdell DT et al. Associations between access to healthcare, environmental quality, and end-stage renal disease survival time: Proportional-hazards models of over 1,000,000 people over 14 years. PLoS One 2019; 14: e0214094

Barriere e soluzioni alla dialisi domiciliare



Mancanza confidenza e percezione di isolamento

AJKD AMERICAN JOURNAL OF KIDNEY DISEASES

NATIONAL KIDNEY FOUNDATION®

SPECIAL REPORT | VOLUME 73, ISSUE 3, P363-371, MARCH 01, 2019

Exploring Barriers and Potential Solutions in Home Dialysis: An NKF-KDOQI Conference Outcomes Report

Christopher T. Chan • Eric Wallace • Thomas A. Golper • ... Martin Schreiber • Patrick Gee • Michael V. Rocco • Show all authors

Published: December 10, 2018 • DOI: https://doi.org/10.1053/j.ajkd.2018.09.015 • Check for updates

Barriers that may prevent a more widespread uptake of home therapy include patient-related factors such as lack of confidence and the **perception of isolation**, as well as socio-economic factors

Contents lists available at ScienceDirect

International Journal of Medical Informatics

journal homepage: www.elsevier.com/locate/ijmedinf

Patient expectations and experiences of remote monitoring for chronic diseases: Systematic review and thematic synthesis of qualitative studies

Rachael C. Walker[a,*], Allison Tong[b,c], Kirsten Howard[c], Suetonia C. Palmer[d,e]

A **systematic review** and thematic synthesis of patient expectations and experiences of remote monitoring (RM) in chronic diseases reported benefits

•including increasing disease-specific knowledge, (conoscenza della malattia)

•triggering of earlier clinical assessment and treatment, (valutazione clinica e trattamento più precoci)

•improved self-management and shared decision making. (autogestione e condivisione delle decisioni)

However, there were concerns including **losing interpersonal contact and increased personal responsibility**.

Isolation is common and requires to be actively considered with management plans developed to counter it.

Walker RC, Tong A, Howard K, et al. Patient expectations and experiences of remote monitoring for chronic diseases: systematic review and thematic synthesis of qualitative studies. Int J Med Inform 2019; 124: 78–85.

Impact of contraindications, barriers to self-care and support on incident peritoneal dialysis utilization

Matthew J. Oliver et Al

Nephrol Dial Transplant (2010) 25: 2737–2744

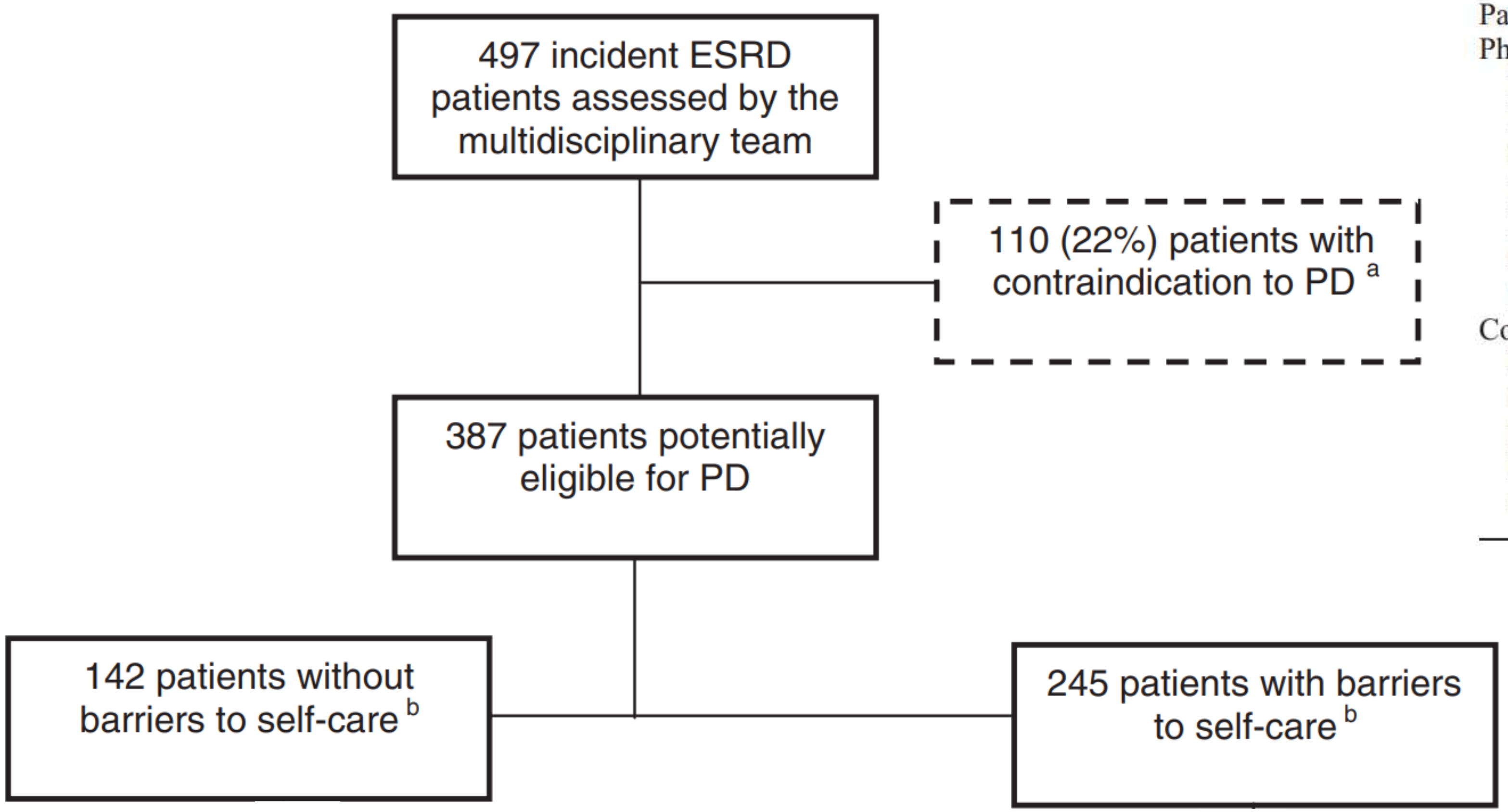


Table 2. Barriers to self-care PD among incident ESRD patients without contraindications to PD

		Count (%)
Patients assessed for barriers		245
Physical barriers to self-care		
Decreased strength	Forza	131 (53)
Decreased manual dexterity	Manualità	105 (43)
Decreased vision		80 (33)
Decreased hearing		38 (16)
Immobility		62 (25)
Poor health/frailty		35 (14)
Poor hygiene		8 (3)
Cognitive barriers to self-care		
Language barrier		38 (15)
History of non-compliance		33 (13)
Psychiatric condition		19 (8)
Dementia/poor memory		19 (8)
Other[a]		20 (8)

HHD-APD vs CAPD

Un gruppo norvegese ha valutato il potenziale percepito del supporto della telemedicina per un piccolo numero di pazienti in PD e in emodialisi domiciliare (HHD) e ha scoperto che i

pazienti che utilizzavano macchinari per la dialisi, cioè HHD e APD, erano ricettivi all'idea di utilizzare la telemedicina,

mentre i pazienti che eseguivano la continua ambulatoriale (CAPD) non lo erano.

Rygh E, Arild E, Johnsen E et al. Choosing to live with home dialysis-patients' experiences and potential for telemedicine support: a qualitative study. BMC Nephrol 2012; 13: 13

A primary care study reported that both telephone and video consultations appeared less ‘information rich’ than face-to-face consultations

Hammersley V, Donaghy E, Parker R, et al. Comparing the content and quality of video, telephone, and face-to-face consultations: a non-randomised, quasi-experimental, exploratory study in UK primary care. Br J Gen Pract 2019; 69(686): e595–e604.

Telenephrology has particular advantages for those living in remote communities and is potentially more cost-effective with a reduced carbon footprint

Koraishy FM and Rohatgi R. Telenephrology: an emerging platform for delivering renal health care. Am J Kidney Dis2020; 76(3): 417–426.

However, there is a clear need for robust, high-quality research that reports a core data set to enable meaningful evaluation of the literature.

Telemedicine in the Satellite Dialysis Unit: Is It Feasible and Safe?

Sabrina Haroon [1], Titus Lau [1], Gan Liang Tan [2] and Andrew Davenport [3]*

[1] National University Hospital, Singapore, Singapore, [2] Department of General Medicine, Sengkang General Hospital, Singapore, Singapore, [3] University College London (UCL) Centre for Nephrology, Royal Free Hospital, University College London, London, United Kingdom

We feel that telemedicine is complementary and can reduce the frequency of physical rounds. The use of technology in any healthcare setting should always align with existing clinical workflow and protocols…

•safe, accurate, and reliable in some clinical settings

•short term and long-term outcome validations for in-center dialysis patients are necessary

Information technology will shape and continue to evolve many aspects of medical practice.

Vantaggi della telemedicina in dialisi

CKJ REVIEW

Opportunities in the cloud or pie in the sky? Current status and future perspectives of telemedicine in nephrology

Madelena Stauss[1], Lauren Floyd[1], Stefan Becker[2,3], Arvind Ponnusamy[1] and Alexander Woywodt[1]

Table 1. Advantages of telemedicine use in dialysis [10–17]

Patient-related

- Technology may facilitate home therapy and/or shorten duration of home training. La tecnologia facilita la terapia domiciliare e una durata inferiore del training
- Reduction in patient travel time and costs. Riduzione di tempo di viaggio e costi (one health)
- Patient empowerment and engagement in self-care. Responsabilizzazione e coinvolgimento nel self-care
- Less impact on work and employment. Minor impatto nel lavoro
- Increased patient confidence. Cresce la fiduca

For the health economy

- Reduction in staff travel time and costs for satellite clinics.
- Reduction in costs for outpatient clinics, clinic room usage, nursing support, parking.
- Improved access to healthcare for remote areas.
- Scarce resources such as outpatient clinics focus on those most in need.
- Less ambulance costs for transport and unscheduled visits.

Riduzione viaggi dello staff
Riduzione uso spazi, ambienti, parcheggio e personale di supporto
Accesso alle cure per aree remote
....

For climate/environment

- Considerably reduced fossil fuels used for commute to routine low-impact outpatient appointments.
- Less parking in hospital.

Telemedicina nella guida alla scelta del trattamento dialitico

Studio osservazionale prospettico multicentrico (…VCO + Altri) Dr. Borzumati

Verificare se l'utilizzo della Telemedicina nella scelta del trattamento dialitico consente di:

- ridurre la necessità di **spostamenti** verso l'ospedale dei pazienti caregivers e degli infermieri a domicilio;
- garantire maggiore **flessibilità** degli incontri,
- agevolare la **partecipazione** dei pazienti, famigliari e/o caregiver al percorso di scelta, favorendo la possibilità di individuare le risorse che potrebbero orientare alla scelta di un trattamento domiciliare
- garantire al malato e alla sua famiglia un **programma educazionale** efficace e adattato al paziente/caregiver.

Trend attuale: early stage – pre-dialysis

L'applicazione raccoglie dati su:

- Testing equipment and sensor
- Faciliate communication between patients and Hospital staff
- Manage equipment orders for treatments

1 Identificare pz idonei a dialisi domiciliare in una fase precoce

2 Creare una applicazione intelligente che agevoli pz e professionisti

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RESEARCH GROUP

BEHAVIOUR CHANGE AND WELLBEING

< Home

Projects

Behaviour Change Science & Policy (BeSP)

Citizen Shield – technological, be-havioural and societal solutions for protective actions to tackle pandemics

Evaluating intervention reception and the path toward successful lifestyle change

Improving motivating styles: Toward a complex dynamical systems approach (MotiStyleSport) >

Home > Behaviour Change and Wellbeing > Projects > eHealth in Home Dialysis

EHEALTH IN HOME DIALYSIS

The eHealth in Home Dialysis project is a Business Finland-funded collaboration with HUS, Aalto University and King's College London which seeks to understand and improve the treatment pathways experienced by people with chronic kidney disease.

The project aims to identify patients suitable for home dialysis at an early stage, and to create an application that patients can use already at the pre-dialysis stage and continue to use throughout their dialysis therapy. The application will gather monitoring data via testing equipment and sensors, facilitate communication between patients and hospital staff, and manage equipment orders for home dialysis treatment. The goal is to create an intelligent application to make home dialysis easy and problem-free for both the patient and professionals. The project includes efforts to systematically review the literature on patient experiences with home dialysis treatments, longitudinal studies to understand the impact of peoples' illness perceptions on their satisfaction with care and treatment-related decision making, as well as user experience and design work to create these digital self-management tools.

Digital Patient Engagement Platform

Developing eHealth for Home Dialysis: Clinicians' Needs for a Digital Patient Engagement Platform

Sini HÖLSÄ[a], Johanna VIITANEN[a,1], Paula VALKONEN[a], Tinja LÄÄVERI[a,b] and Virpi RAUTA[c]

Obiettivo di DPEP è di migliorare la comunicazione e la collaborazione tra pazienti e medici

Pazienti:
predialysis, home peritoneal dialysis, and home hemodialysis

•enable individualized care
•improve patient safety
•increase patients' comprehension and responsibility for their care
•enhance motivation

In addition to being a digital platform where patients can document information from each dialysis treatment, order dialysis supplies, and respond to symptom questionnaires, the solution includes a smart scale, blood pressure monitor, wristband actigraphy, and sleep tracking device, all of which provide data to the DPEP solution. In addition, artificial intelligence-based decision support notifications are being designed to alert the patient of risk for adverse outcomes.

Alcuni considerazioni in merito allo sviluppo

Developing eHealth for Home Dialysis: Clinicians' Needs for a Digital Patient Engagement Platform

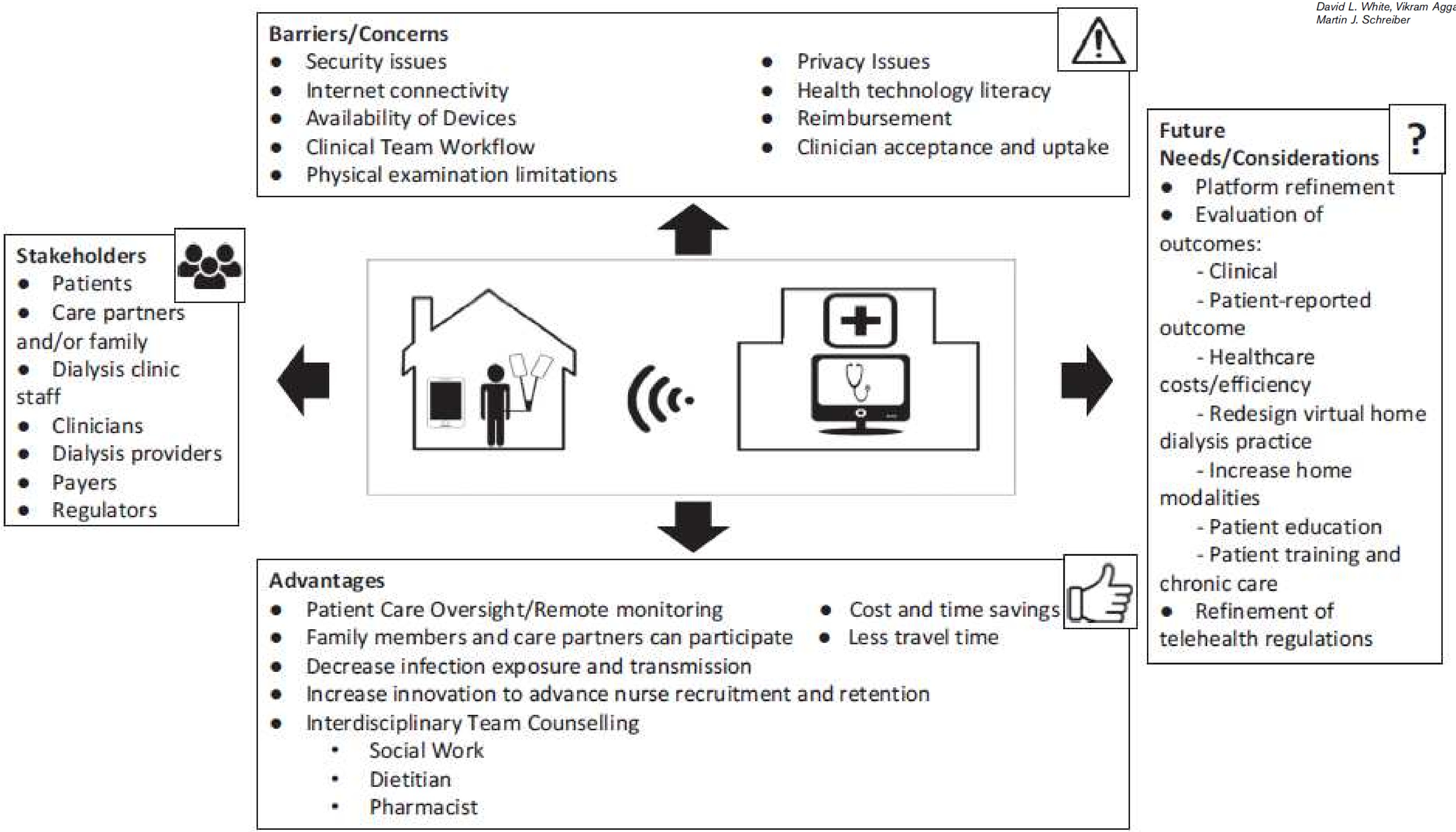
Sini HÖLSÄ[a], Johanna VIITANEN[a,1], Paula VALKONEN[a], Tinja LÄÄVERI[a,b] and Virpi RAUTA[c]

- The clinicians raised concerns about adding one more solution to the already complex body of ISs in clinics need for a common
- understanding of how the new solution is used: How often and by whom should data from the solution be reviewed?
- What can patients expect, and what is the organization's future vision for the numerous ISs?
- the solution should support the needs of different patient groups
- some patients will not want to use the system
- possible changes in clinical workflows

Telemedicina per dialisi domiciliare – COVID-19

Telehealth for Home Dialysis in COVID-19 and Beyond: A Perspective From the American Society of Nephrology COVID-19 Home Dialysis Subcommittee

Susie Q. Lew, Eric L. Wallace, Vesh Srivatana, Bradley A. Warady, Suzanne Watnick, Jayson Hood, David L. White, Vikram Aggarwal, Caroline Wilkie, Mihran V. Naljayan, Mary Gellens, Jeffrey Perl, and Martin J. Schreiber



ure 1. The current and future landscape of home dialysis telehealth, showing the stakeholders, advantages, barriers/concerns, d future needs/considerations of telehealth.

FUTURO:

- Sviluppo piattaforma
- Valutazioni outcomes
- Costo/efficacia
- Patient education
- Patient training
- Regulation

Formazione di persone con competenze tecnologiche

There are also implications for education in that we need to train up a workforce that has more advanced information technology skills than ever before

Telemedicine Training in Undergraduate Medical Education: Mixed-Methods Review

Shayan Waseh, MPH and Adam P Dicker, MD, PhD, FASTRO

JMIR Medical Education
Technology, Innovation and Openness In Medical Education
mededu.jmir.org

Safety concerns – failure – invalid data

First, although eHealth can enhance disease detection and monitoring, it can **introduce new safety concerns** owing to:

- suboptimal design
- technological failures or
- invalid data.

For example, the study of mobile apps discussed above found that only two of seven health tracking apps generated alerts for abnormal values such as extremely high blood pressure

Foster, B. J. et al. A randomized trial of a multicomponent intervention to promote medication adherence: the Teen Adherence in Kidney Transplant Effectiveness of Intervention Trial (TAKE- IT). Am. J. Kidney Dis. ***72****, 30–41 (2018).*

Device failures in clinical trials have resulted in reduced participant satisfaction, engagement and retention with eHealth monitoring

Stevenson, J. K. et al. eHealth interventions for people with chronic kidney disease. Cochrane Database Syst. Rev. ***8****, CD012379 (2019).*

Review Article

PERITONEAL DIALYSIS INTERNATIONAL

Peritoneal Dialysis International
2021, Vol. 41(1) 32–41

DOI: 10.1177/0896860820918135
journals.sagepub.com/home/ptd
SAGE

eHealth interventions to support patients in delivering and managing peritoneal dialysis at home: A systematic review

Emma J Cartwright[1], Zack ZS Goh[1], Marjorie Foo[2], Choong M Chan[2], Htay Htay[2] and Konstadina Griva[1]

Peritonitis rates
Exit-site infection
Hospitalisation
Mortality

Secondary outcomes
Biochemical parameters
Quality of life KDQOL-36 *and* EQ-5D
Patient knowledge
Patient skills
Patient satisfaction

Despite the enthusiasm for eHealth interventions to support PD patients deliver and manage their PD at home, **the evidence of effectiveness is limited.** Both primary and secondary outcomes reported mixed evidence on the impact of eHealth interventions, however no adverse were reported

More high-quality research exploring the feasibility, acceptability and effectiveness of these interventions is needed before any firm conclusions can be drawn.

To do this, we urgently need better evidence of its effectiveness.

Modello di valutazione dei sistemi di telemedicina

International Journal of Technology Assessment in Health Care, 28:1 (2012), 44–51.

doi:10.1017/S0266462311000638

A MODEL FOR ASSESSMENT OF TELEMEDICINE APPLICATIONS: MAST

Kristian Kidholm
Odense University Hospital
kristian.kidholm@ouh.regionsyddanmark.dk
Anne Granstrøm Ekeland
Norwegian Center for Intergrated Care and Telemedicine
Lise Kvistgaard Jensen, Janne Rasmussen, Claus Duedal Pedersen
Alison Bowes
University of Stirling
Signe Agnes Flottorp
Norwegian Knowledge Centre for the Health Services
Mickael Bech
University of Southern Denmark

Il *Model for Assess-ment of Telemedicine* (MAST) è un modello di valutazione con un focus sulle misure di efficienza e qualità delle cure (Kidholm et al., 2017). Rappresenta un importante processo multidisciplinare, valutando gli aspetti medici, sociali, economici e etici della telemedicina con una metodologia sistematica, forte e senza fattori di confondimento (Kidholm et al., 2017), principi questi su cui si basa HTA nell'EUnetHTA.

Kidholm K., Clemensen J., Caffery L.J., Smith A.C. (2017): The Model for Assessment of Telemedi-cine (MAST): A scoping review of empirical studies, *Journal of Telemedicine and Telecare*, 23; 7: 803-813.
Kidholm K. et al. (2012): A model for assessment of telemedicine applications: MAST, Interna-tional *Journal of Technology Assessment in Health Care*, 28; 1: 44-51.
Krampe J. et al. (2016): Building Evidence. CIN: Computers, Informatics, *Nursing*, 34; 6: 241-244.
Kruse C.S. et al. (2016): Evaluating barriers to adopting telemedicine worldwide: A system-atic review, *Journal of Telemedicine and Telecare*, 24; 10: 4-12.
Lampe K. et al. (2009): The HTA

The Model for Assessment of Telemedicine (MAST): A scoping review of empirical studies

Journal of Telemedicine and Telecare
2017, Vol. 23(9) 803–813

DOI: 10.1177/1357633X17721815
journals.sagepub.com/home/jtt
SAGE

Kristian Kidholm[1], Jane Clemensen[1], Liam J Caffery[2] and Anthony C Smith[2]

MAST includes pre-implementation assessment (e.g. by use of participatory design), followed by:
multidisciplinary assessment, including
description of the patients
Description of the application and

- valutazione della sicurezza,
- valutazione dell'efficacia clinica,
- prospettiva del paziente,
- aspetti economici,
- Aspetti organizzativi
- aspetti socio-culturali
- aspetti legali ed etici

Conclusions

…most of the included articles describe results within a single MAST domain.

…clinical, economic or organisational aspects are not fully included.

Criteri di valutazione

STEP 1 - Valutazione procedurale:

•- qual è l'obiettivo dell'applicazione?

•- tecnologia e organizzazione sono mature?

STEP 2 - Valutazione multidisciplinare:

•- problemi di salute e caratteristiche dell'applicazione

•- sicurezza

•- efficacia clinica

•- prospettive del paziente

•- aspetti economici

•- aspetti organizzativi

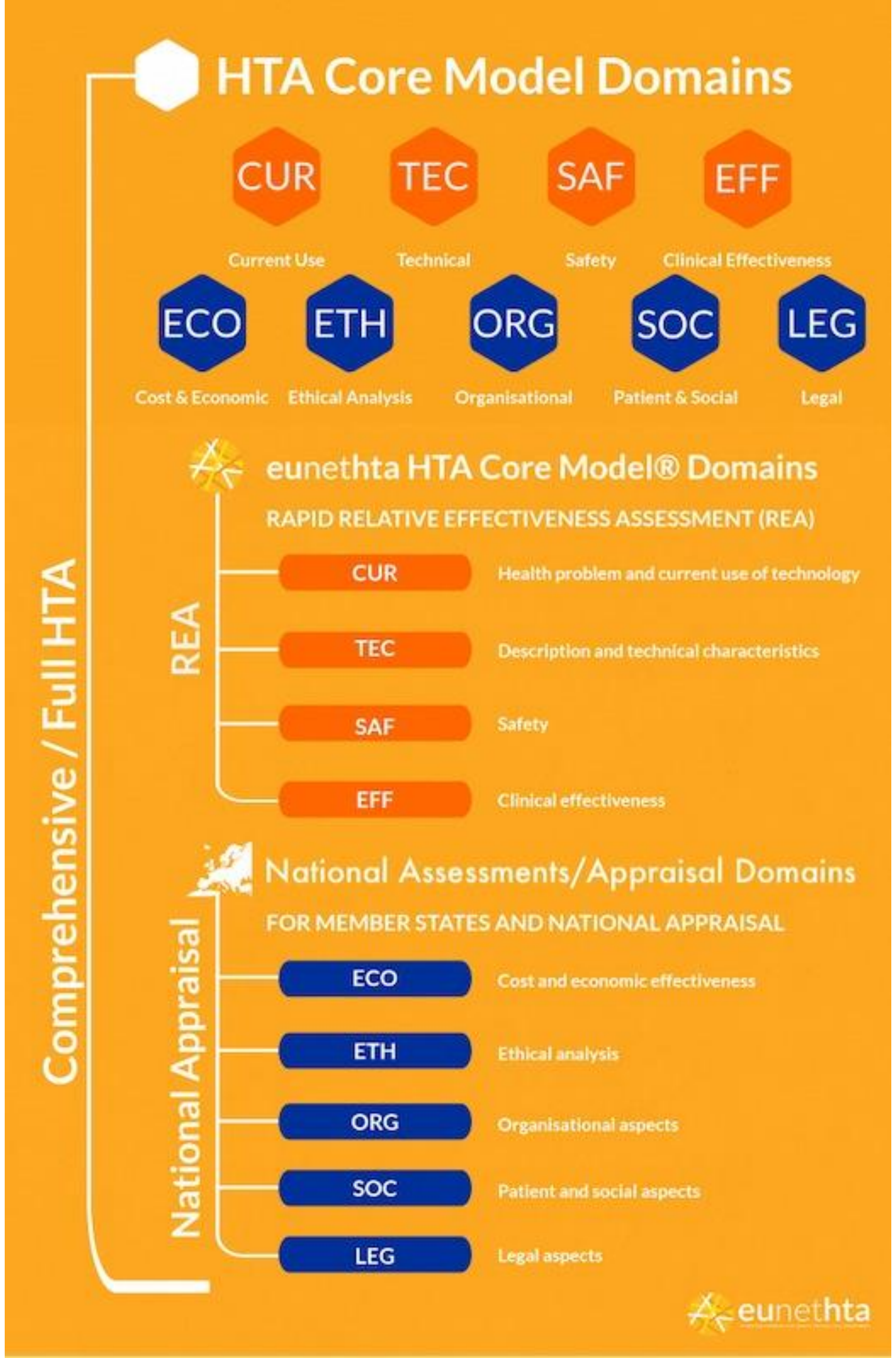
•- aspetti socioculturali, etici e legali.

STEP 3 - Trasferibilità della valutazione:

•- esportazione del modello

•- standardizzazione

•- scalabilità.



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EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

I

(Atti legislativi)

REGOLAMENTI

REGOLAMENTO (UE) 2021/2282 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO

del 15 dicembre 2021

relativo alla valutazione delle tecnologie sanitarie e che modifica la direttiva 2011/24/UE

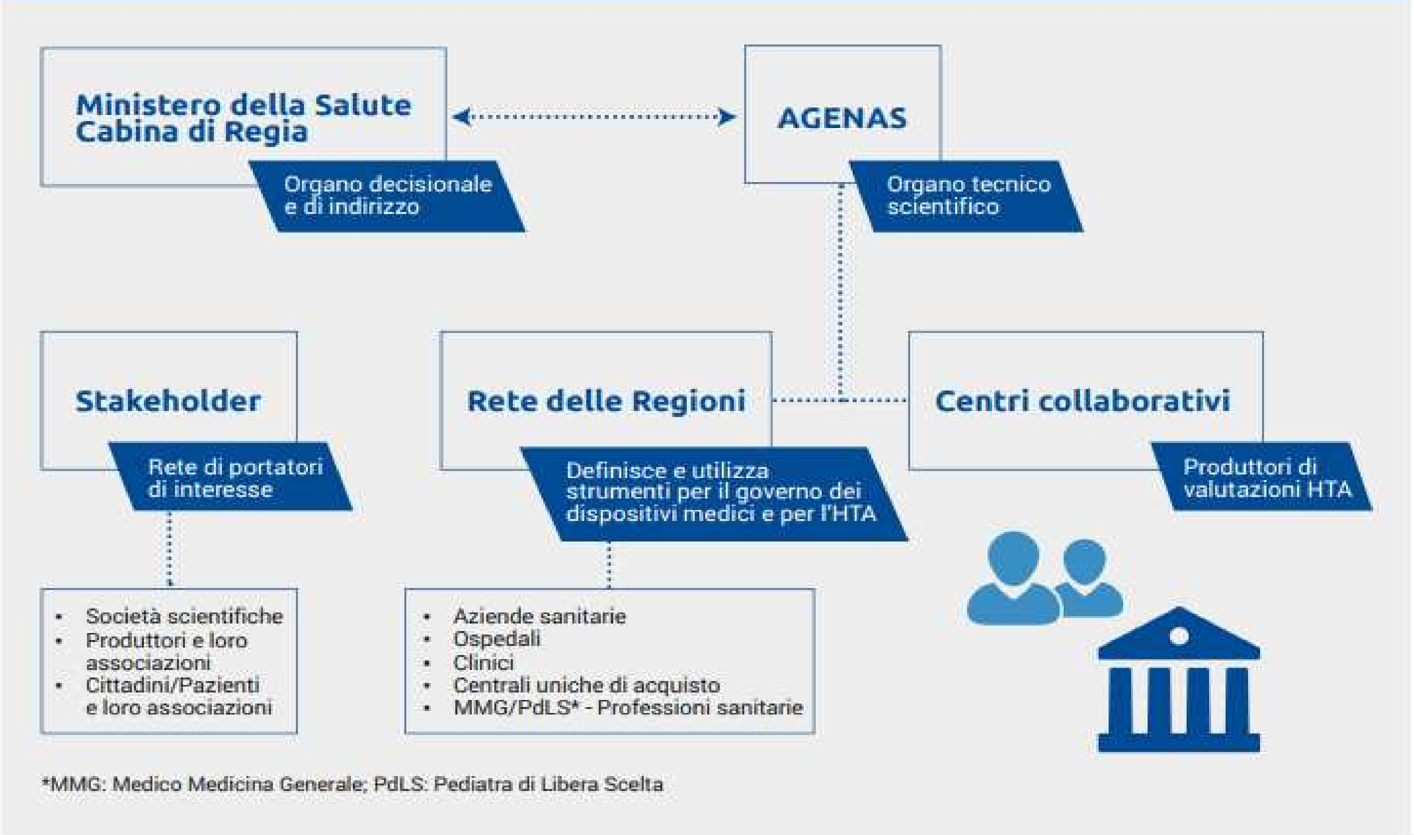
(Testo rilevante ai fini del SEE)

AGENAS

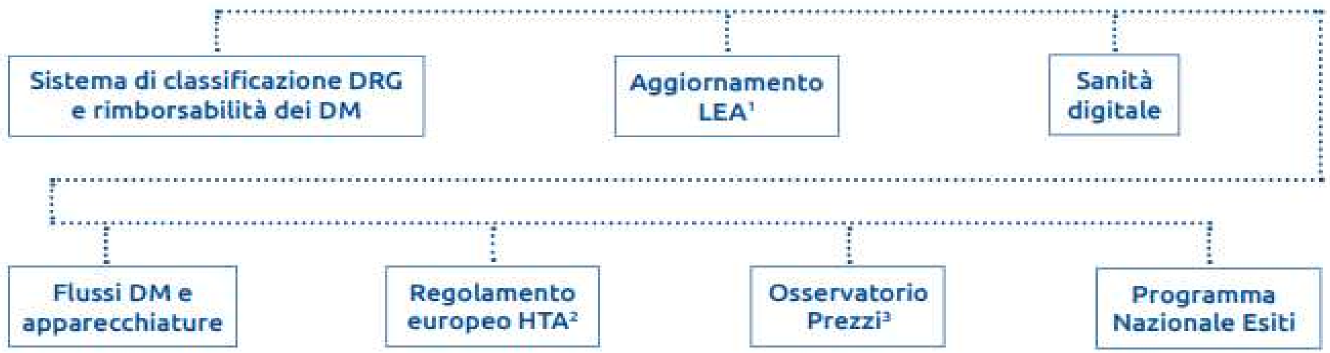
AGENAS | AREE TEMATICHE | PROGETTI DI RICERCA | COMUNICAZIONE | PNRR | PORTALE STATISTICO

AGENAS presenta il Programma Nazionale HTA - Dispositivi Medici (PNHTA 2023-2025)

Attori coinvolti e ruolo: Organigramma PNHTA 2023-2025

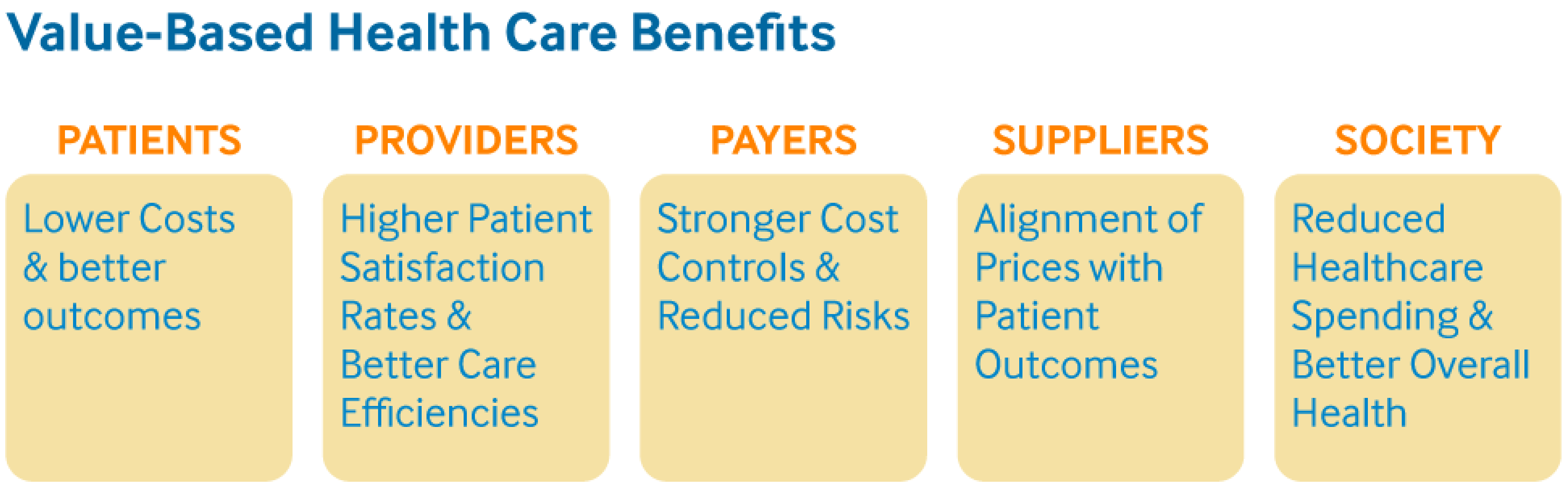


Aree di integrazione con il PNHTA 2023-2025



Value Based Healthcare

1. misurazione e valutazione degli esiti e dei costi per ciascun paziente;
2. organizzazione delle unità di assistenza integrate (Integrated Practice Units – IPUs);
3. integrazione dell'assistenza anche in caso di strutture separate;
4. superamento del limite geografico;
5. riorganizzazione delle modalità di finanziamento, con l'implementazione dei rimborsi per processi assistenziali (bundled payments);
6. costruzione di una piattaforma informatica efficace



NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society

Monitoraggio remoto (+ Bidirezionale)

PD

Information Communication Technology and Remote Monitoring

Ronco C, Crepaldi C, Rosner MH (eds): Remote Patient Management in Peritoneal Dialysis.
Contrib Nephrol. Basel, Karger, 2019, vol 197, pp 17–27 (DOI: 10.1159/000496314)

Two-Way Patient Monitoring in PD: Technical Description of Sharesource

Andrew T. Gebhardt • Arvind Mishra

Baxter Healthcare Corporation, Deerfield, IL, USA

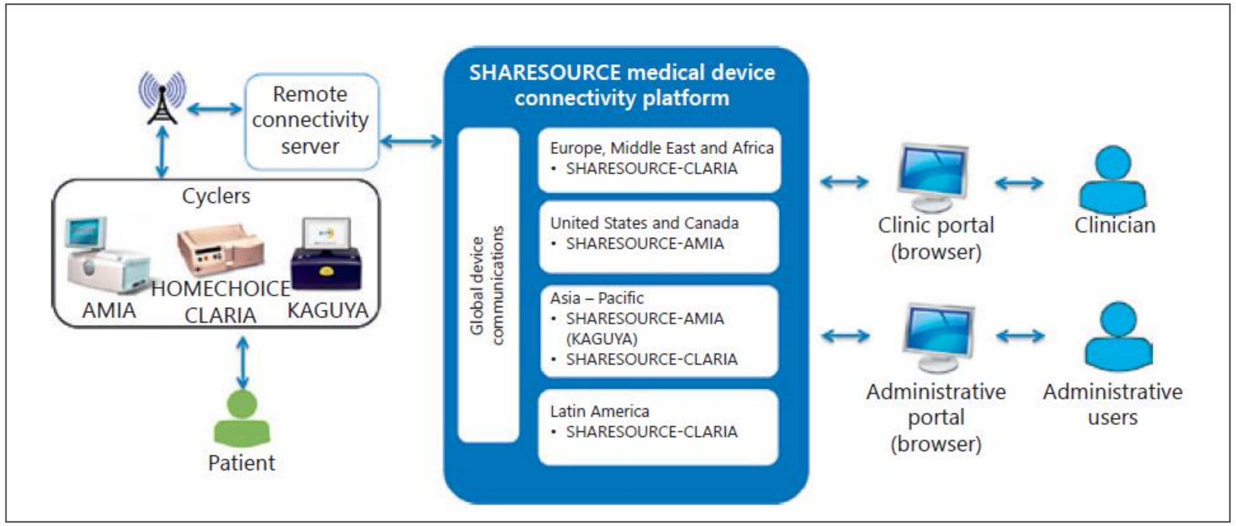
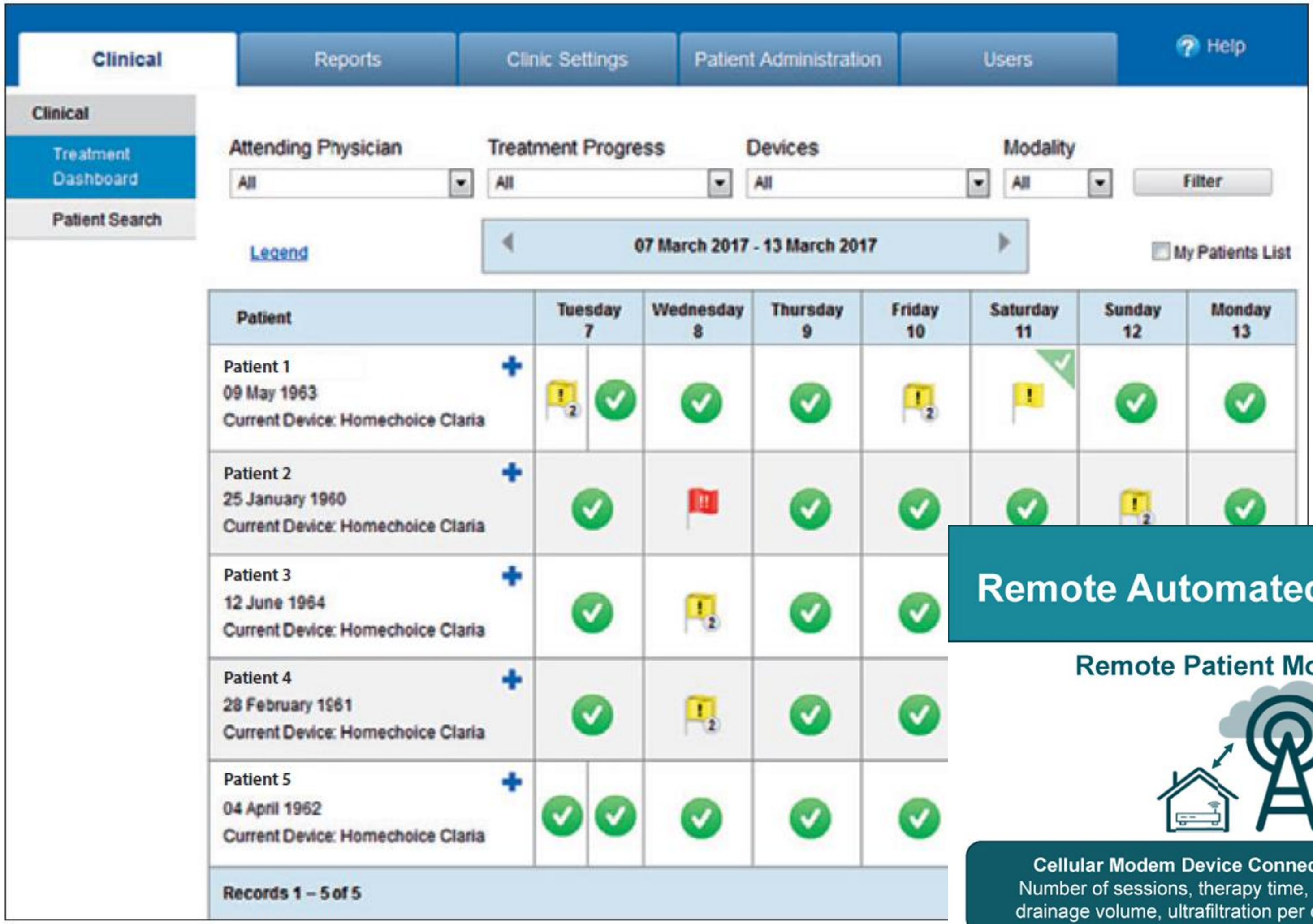


Fig. 1. SHARESOURCE medical device connectivity platform.

Two-Way Patient Monitoring in PD: Technical Description of Sharesource
Andrew T. Gebhardt, Arvind Mishra



<u>Incentivare l'aggiustamento della terapia</u>
-> obiettivo migliorare la cura del paziente e gli esiti clinici

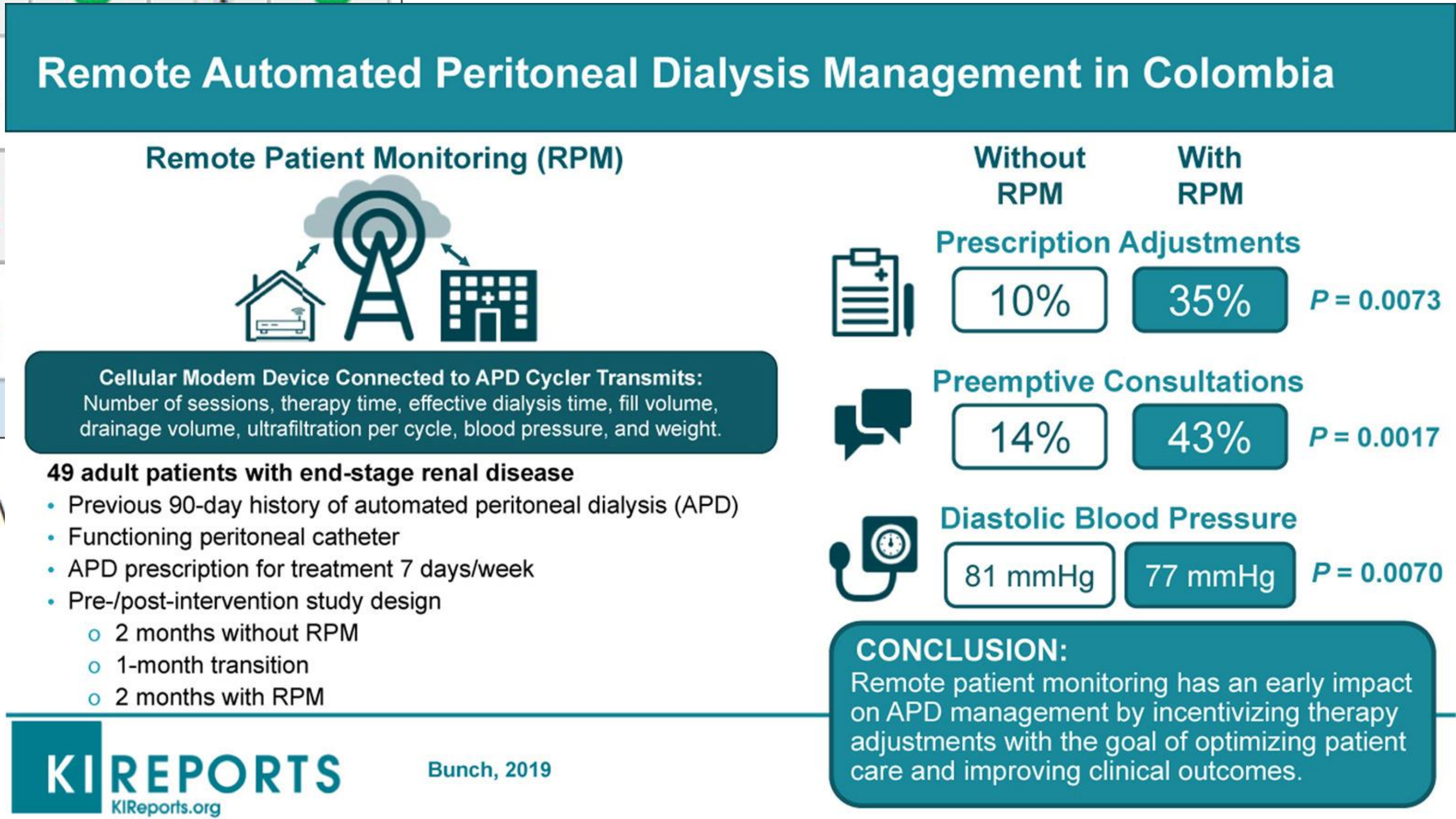


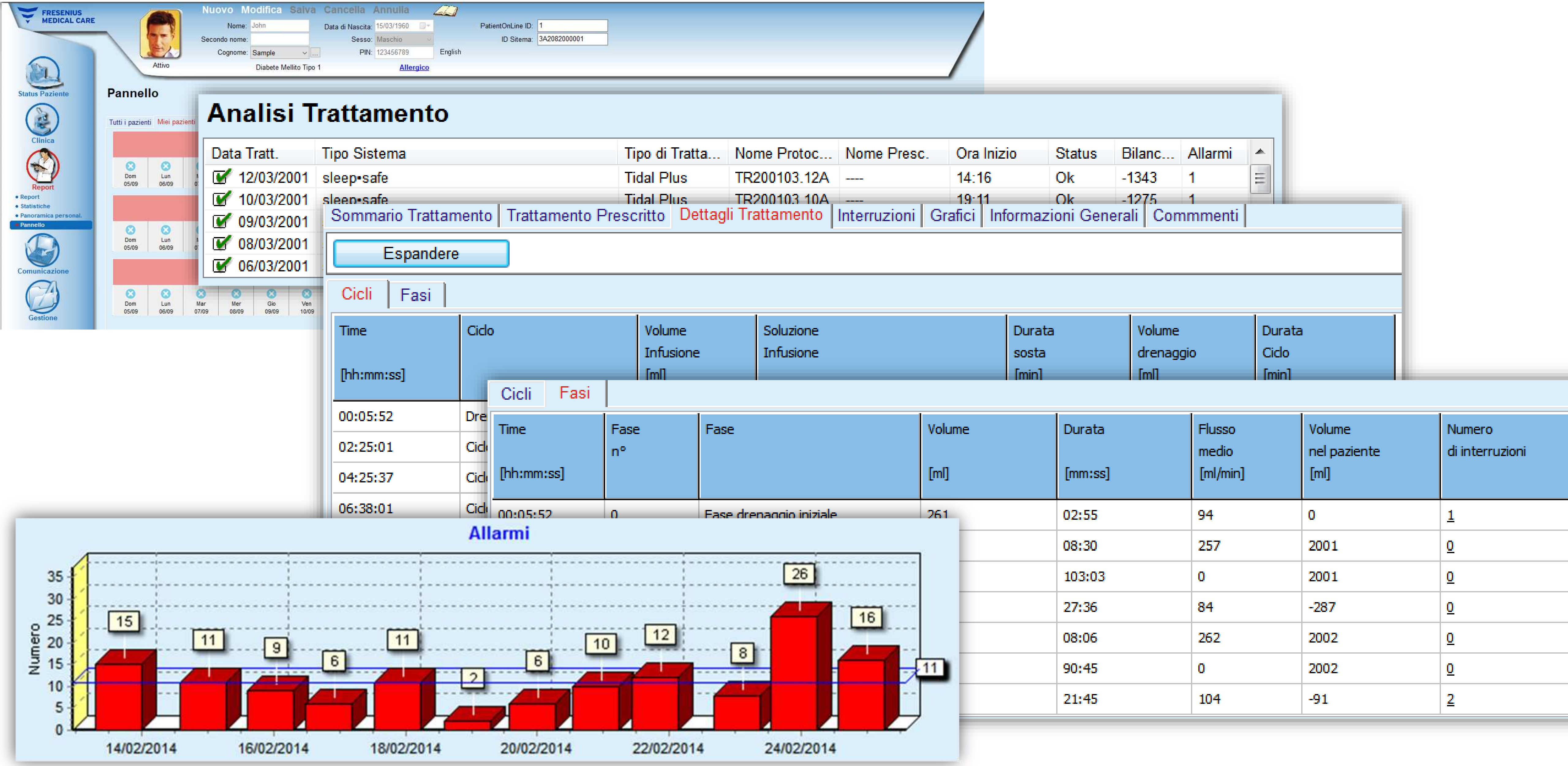
Fig. 2. Clinical treatment dashboard example for patients with HOM
[2].

Homebridge patient kit

DOTAZIONE OSPEDALE

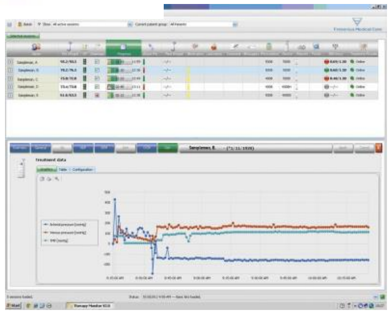
DOTAZIONE DOMICILIO PAZIENTE

Visualizzazione dati, parametri statistiche

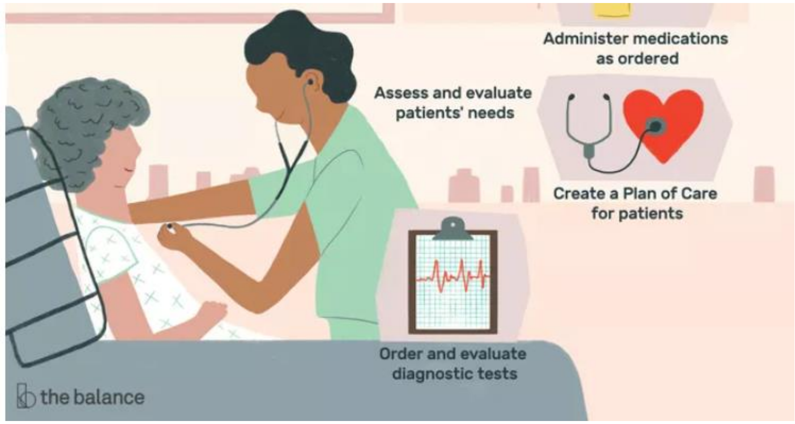


HHD + Monitoraggio Remoto Bi-direzionale

USA



HHD + assistenza domiciliare



Software dedicato

HHD + assistenza domiciliare

Dialisi domiciliare assistita

HHD + assistenza domiciliare

Software dedicato

AJKD Core Curriculum in Nephrology

Home Hemodialysis: Core Curriculum 2021

Scott D. Bieber, DO and Bessie A. Young, MD, MPH

HHD ostacoli e soluzioni

Training inadeguato

Miti ed incomprensioni/malintesi con informazioni da altri pazienti o centri
Centro dialisi non disponibile
Disincentivi economici

Ansietà del paziente/paura di essere da solo/mancanza di confidenza

Table 1. Common HHD Obstacles and Solutions

Obstacle	Solution
Inadequate training/education about modality options	Early education about kidney replacement therapies, especially HHD
Myths and misconceptions propagated by other patients, health care providers	Additional classes on the benefits of HHD therapy and patient testimonials
Lack of nursing or physician expertise	Physician champion and dedicated HHD nursing staff
Patient ability to self-cannulate	In-center training while receiving in-center hemodialysis
Unavailable dialysis center infrastructure	Dedicated HHD team
Economic disincentives	Dedicated home dialysis program that integrates PD and HHD; payment for HHD helpers
Patient anxiety/fear of being home alone/lack of confidence	Increased education, "buddy system," telemedicine home monitoring
Patient or caregiver burnout	Regular dedicated in-center respite care
Concern over "medicalization" of the home	Home visit and efforts to incorporate patient-centered approach to HHD
Lack of adequate space, stable housing	Social services may help establish better HHD access; in-house self-care programs may allow patients to initiate their own dialysis with patient-friendly machines

Abbreviations: HHD, home hemodialysis; PD, peritoneal dialysis.

Nephrol Dial Transplant (2020) 1–4
doi: 10.1093/ndt/gfaa009

ndt digest

ndt
Nephrology Dialysis Transplantation

Nomenclature for renal replacement therapies in chronic patients

Federico Nalesso[1] and Francesco Garzotto[2]

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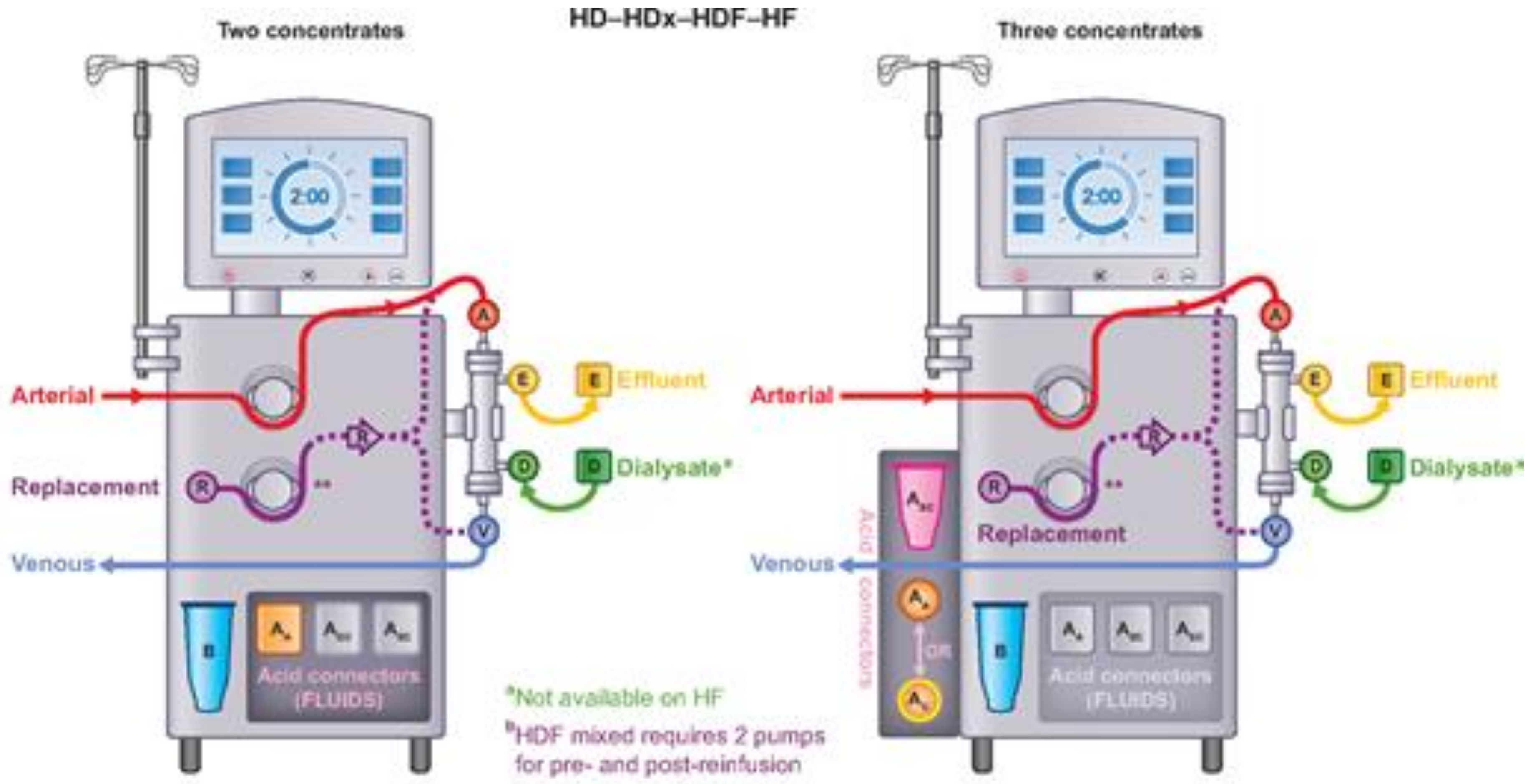
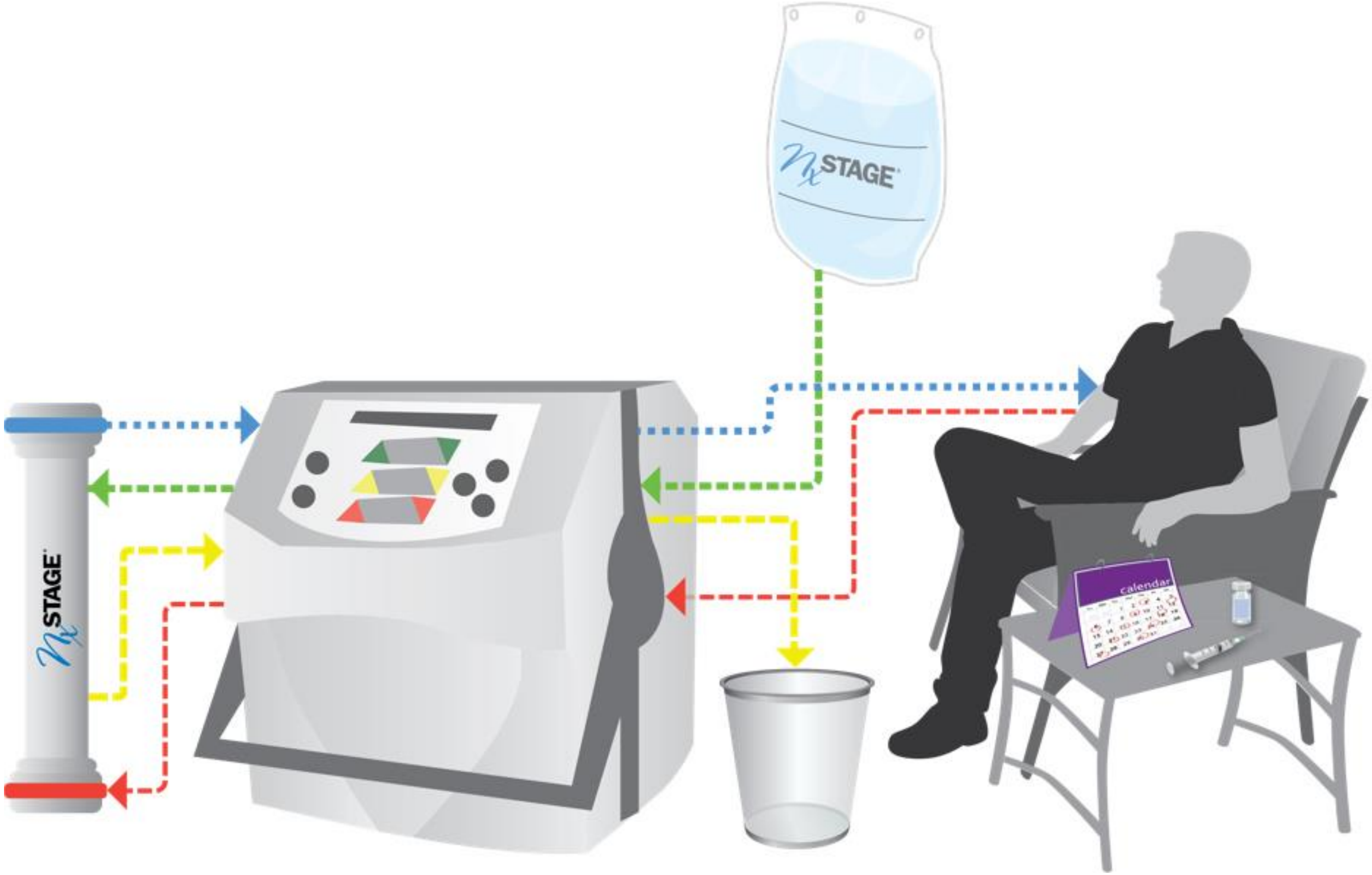
Correspondence and offprint requests to: Francesco Garzotto; E-mail: f.garzotto@gmail.com

Società Europea di Nefrologia



HHD dedicata



Hemodialysis International 2018; 22:318–327

Original Article

Home Hemodialysis

Relative risk of home hemodialysis attrition in patients using a telehealth platform

Eric D. WEINHANDL,[1,2] Allan J. COLLINS[1,3]
[1]NxStage Medical, Inc., Lawrence, Massachusetts, USA; [2]Department of Pharmaceutical Care and Health Systems; [3]Department of Medicine, University of Minnesota, Minneapolis, Minnesota, USA

L'utilizzo di un sistema di telemedicina:

- 29% in meno di fallimenti terapeutici
- Chi inizia HHD con telemedicina tende a terminare il training ed iniziare i trattamenti domiciliari-> migliora trattenimento pazienti

We 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.

Journal of
Clinical Medicine

MDPI

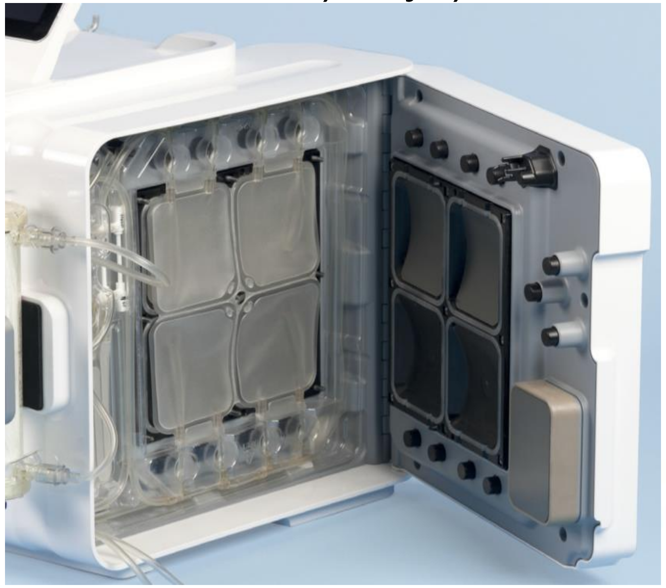
Article

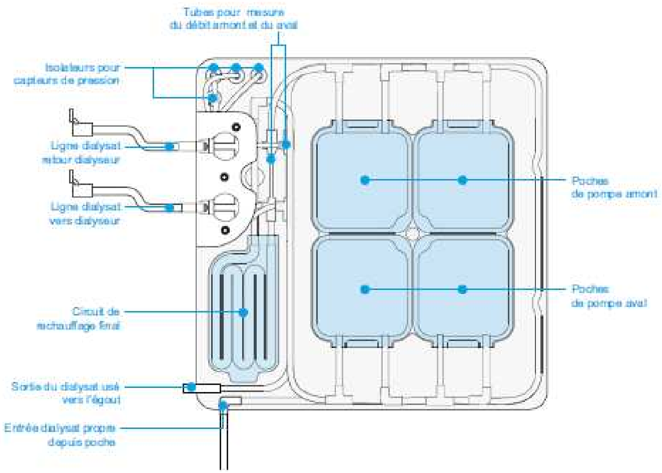
Safety and Efficacy of Short Daily Hemodialysis with Physidia S^3 System: Clinical Performance Assessment during the Training Period

Hafedh Fessi [1], Jean-Christophe Szelag [2], Cécile Courivaud [3], Philippe Nicoud [2,4], Didier Aguilera [5], Olivia Gilbert [6], Marion Morena [7], Michel Thomas [8], Bernard Canaud [6,9] and Jean-Paul Cristol [6,7,*]

After the training period, 78 patients (97.5%) were successfully installed at home and used the device for an average duration of 3.4 years (1255 (1561–3005) days).

Figure 1. A Physidia S^3 hemodialysis device.

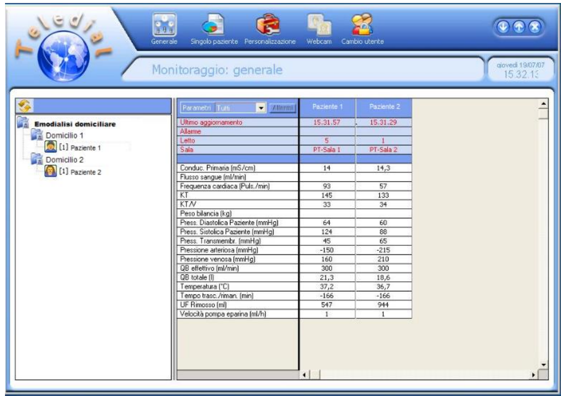




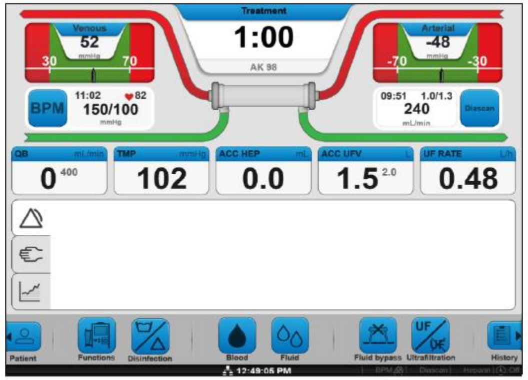
This device has a compact and portable cubic design (dimension 40 40 40 cm) weighing less than 25 kilograms (Figure 1) and specifically designed for short daily lowdialysate-flow HHD

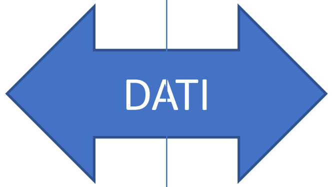
HHD + Monitoraggio Remoto

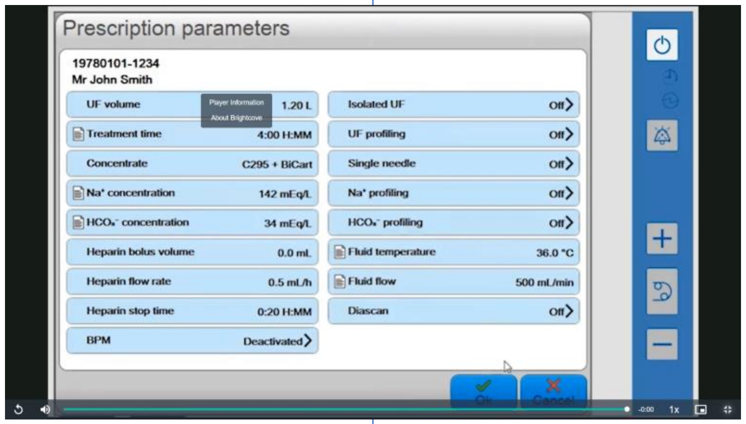
Figure 1. A Physidia S^3 hemodialysis device.



HHD (dedicata) + Monitoraggio Remoto Bi-direzionale







Baxter Announces U.S. FDA 510(k) Clearance of AK 98 Hemodialysis Machine

- Latest technology offers a compact, portable and easy-to-use system for dialysis providers
- Includes two-way connectivity to securely transfer prescription and treatment data
- Can be used alongside **Theranova**, Baxter's novel dialysis membrane

THE WHITE HOUSE
WASHINGTON

EXECUTIVE ORDERS

Executive Order on Advancing American Kidney Health

HEALTHCARE | Issued on: July 10, 2019

- Reducing the number of Americans developing kidney failure by 25% by 2030.
- Ensuring 80% of new kidney failure patients in 2025 either are receiving dialysis at home or are receiving a transplant.
- Doubling the number of kidneys available for transplant by 2030.

Sec. 6. Encouraging the Development of an Artificial Kidney. Within 120 days of the date of this order, in order to increase breakthrough technologies to provide patients suffering from kidney disease with better options for care than those that are currently available, the Secretary shall:

HHD Devices

Cost-Effectiveness of Home Hemodialysis With Bedside Portable Dialysis Machine "DIMI" in the United Arab Emirates

Chandra Mauli Jha [1, 2]

DIMI

Specifications and Features

SPECIFICATIONS

PHYSICAL DIMENSIONS

Height: 128cm, (58cm in box) (50.39", 22.93" in box)
Width: 60cm (23.62")
Depth: 63cm (24.8")
Floor space: 58cm x 58cm (23" x 23")
Weight: 47kg

	Flow rate range	Increment
Blood	0-350 mL/min	1 mL/min
Blood flow rate accuracy	± 20 mL/min or ± 10%, greater value to consider at all pressures	
Filtrate/Replacement	0-11000 mL/h	1 mL/h
Accuracy	± 50 mL/h or ± 10%, greater value to consider at all pressures	
Dialysate	0-11000 mL/h	1 mL/h
Accuracy	± 50 mL/h or ± 10%, greater value to consider at all pressures	

Original Article

Home Hemodialysis

Human factors testing of the Quanta SC+ hemodialysis system: An innovative system for home and clinic use

Oksana HARASEMIW,[1,2] Clara DAY,[3] John E. MILAD,[4] James GRAINGER,[4] Thomas FERGUSON,[1,2] Paul KOMENDA[1,2,4]

Figure 1 Quanta SC+ system, original design. [Color figure can be viewed at wileyonlinelibrary.com]

Quanta wins FDA clearance for portable dialysis system

By Liz Hollis Jan. 22, 2021

- Virtually unlimited online dialysate generation, unrestricted by bags or batching
- Connectivity through bank-level data encryption using the latest technology ensuring the highest level HIPAA compliance.
- Quanta's Service Portal enables remote monitoring of treatment parameters, technical support and troubleshooting.

DIALYSIS CARE, ALMOST ANYWHERE

Choose more. The dialysis industry is antiquated and inconvenient—filled with little change over the last 30 years. We designed the Quanta Dialysis System to provide quality care while giving patients and caregivers the clinical performance, choice, and access to treatment they deserve. It's our vision to deliver innovative dialysis care to every patient in every setting.

OUR COMPANY

< Back

Quanta Announces FDA 510(k) Submission for Home Use of Quanta Dialysis System

Articles

09/19/2023

New expanded indication will increase home hemodialysis device options available to patients with end-stage kidney disease

BEVERLY, Massachusetts – September 19, 2023 – Quanta Dialysis Technologies®, a medical technology company committed to making kidney care more accessible, today announced that it has submitted a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) for indication expansion of the Quanta™ Dialysis System, a compact and easy-to-use hemodialysis device. The Quanta Dialysis System is currently indicated for use in chronic and acute care settings. The new submission seeks to expand use to include self-care, in-home hemodialysis.

Hemodialysis International 2020; **24**:22–28

ORIGINAL ARTICLE

Home Hemodialysis

Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis

Troy J. PLUMB,[1] Luis ALVAREZ,[2] Dennis L. ROSS,[3] Joseph J. LEE,[4] Jeffrey G. MULHERN,[5] Jeffrey L. BELL,[6] Graham ABRA,[7] Sarah S. PRICHARD,[8] Glenn M. CHERTOW[9], Michael A. ARAGON[10,11]

Tablo® Hemodialysis System Cartridge Receives FDA 510(k) Clearance Enabling Production in North America

November 29,

PDF \

Tablo quickly purifies water and produces dialysis on demand, removing the need for premixed batches of dialysate or bags to run treatments

Automated, Secure Data Transfer: Tablo keeps track of your treatment data for you and wirelessly transfers your treatment records to your health care provider

Nephrol Dial Transplant (2017) 32: 685–692
doi: 10.1093/ndt/gfw044
Advance Access publication 7 April 2016

ndt
Nephrology Dialysis Transplantation

Original Articles

Clinical safety and performance of VIVIA: a novel home hemodialysis system

Angelito A. Bernardo[1]*, Thomas C. Marbury[2], Phil A. McFarlane[3], Robert P. Pauly[4], Michael Amdahl[1],

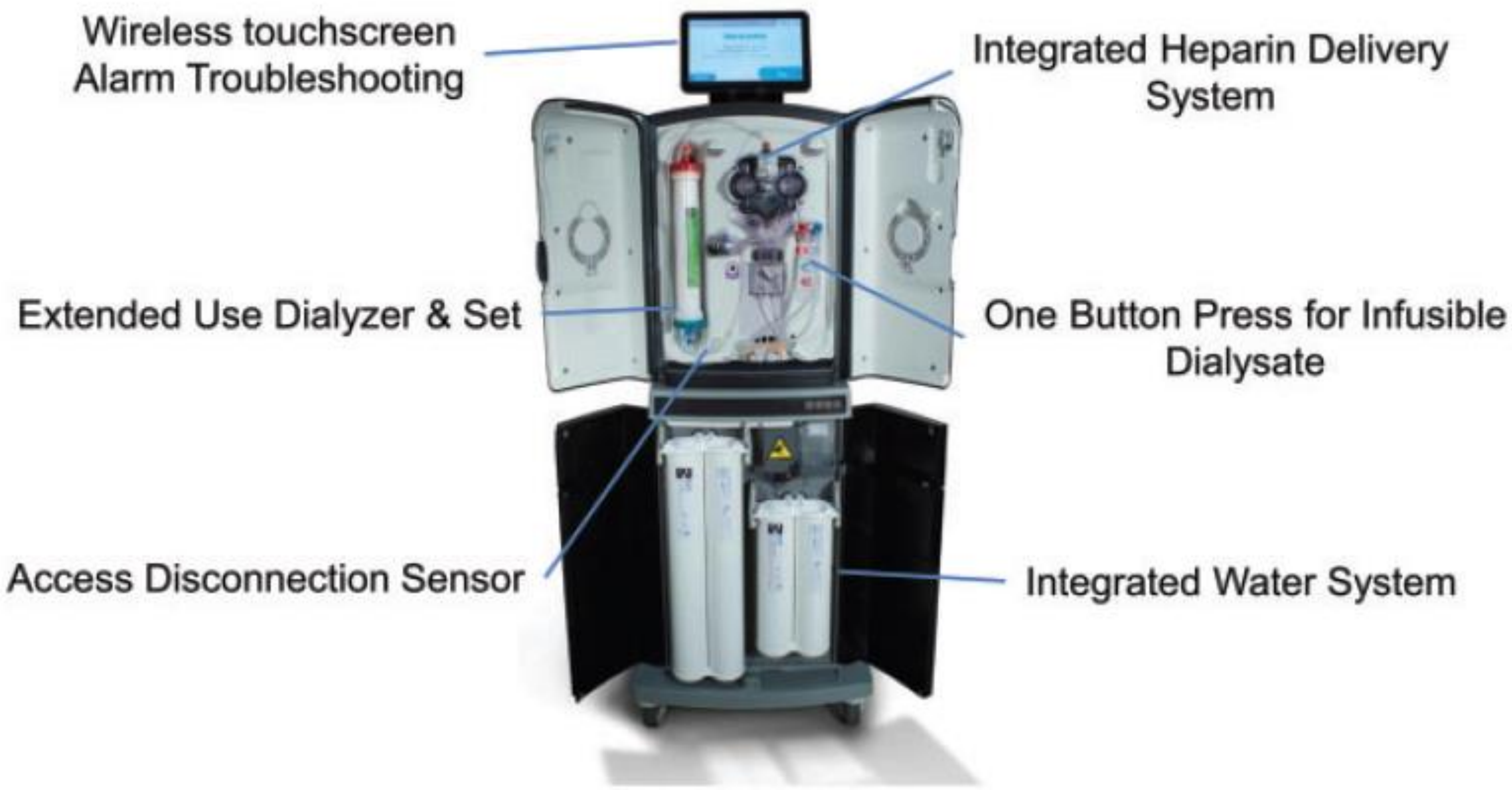


FIGURE 1: Features of the VIVIA Hemodialysis System treatment device.

VIVIA has been validated to generate in situ dialysate for infusion (for priming, bolus administration and rinseback), avoiding the extra steps needed to set up.

The VIVIA Water Device is designed to supply ultrapure water (via reverse osmosis and electronic deionization)

Solution

kablooē design
A FORWARD INDUSTRIES COMPANY

Kablooe helped Medtronic design and prototype a device that weighs about 50 pounds and is the size of a large suitcase, making it roughly 10 times smaller and lighter than conventional dialysis machines. It is designed to only use approximately 20 liters of potable water per treatment, which is 75 percent less than current systems. The machine is designed to be affordable and expand patient access in more parts of the world.

Outcomes

In China, this device was granted priority status in 2017 under the innovative device pathway, also known as the Green Channel. Medtronic also intends to seek

NEXT-GEN HEMODIALYSIS

RCS is developing a next generation chronic hemodialysis machine technology that is intended to help make dialysis more accessible, while lowering the cost of care by being more efficient and using less water.

http://medtronicsolutions.medtronic.ca/Renal-Care-Solutions

ELSEVIER

Journal of Cleaner Production
Volume 280, Part 1, 20 January 2021, 124354

Review

Forward osmosis technology for water treatment: Recent advances and future perspectives

Jianlong Wang [a, b], Xiaojing Liu [a]

Artificial Organs

Forward Osmosis Process for Dialysis Fluid Regeneration

Khaled Mohamed Talaat

First published: 15 December 2009 | https://doi.org/10.1111/j.1525-1594.2009.00816.x |

In a preliminary experiment, 38% of the spent dialysis fluid water was reclaimed by a forward osmosis process through a cellulose triacetate membrane.

One Health
Green

Ridurre i consumi elettrici e di acqua

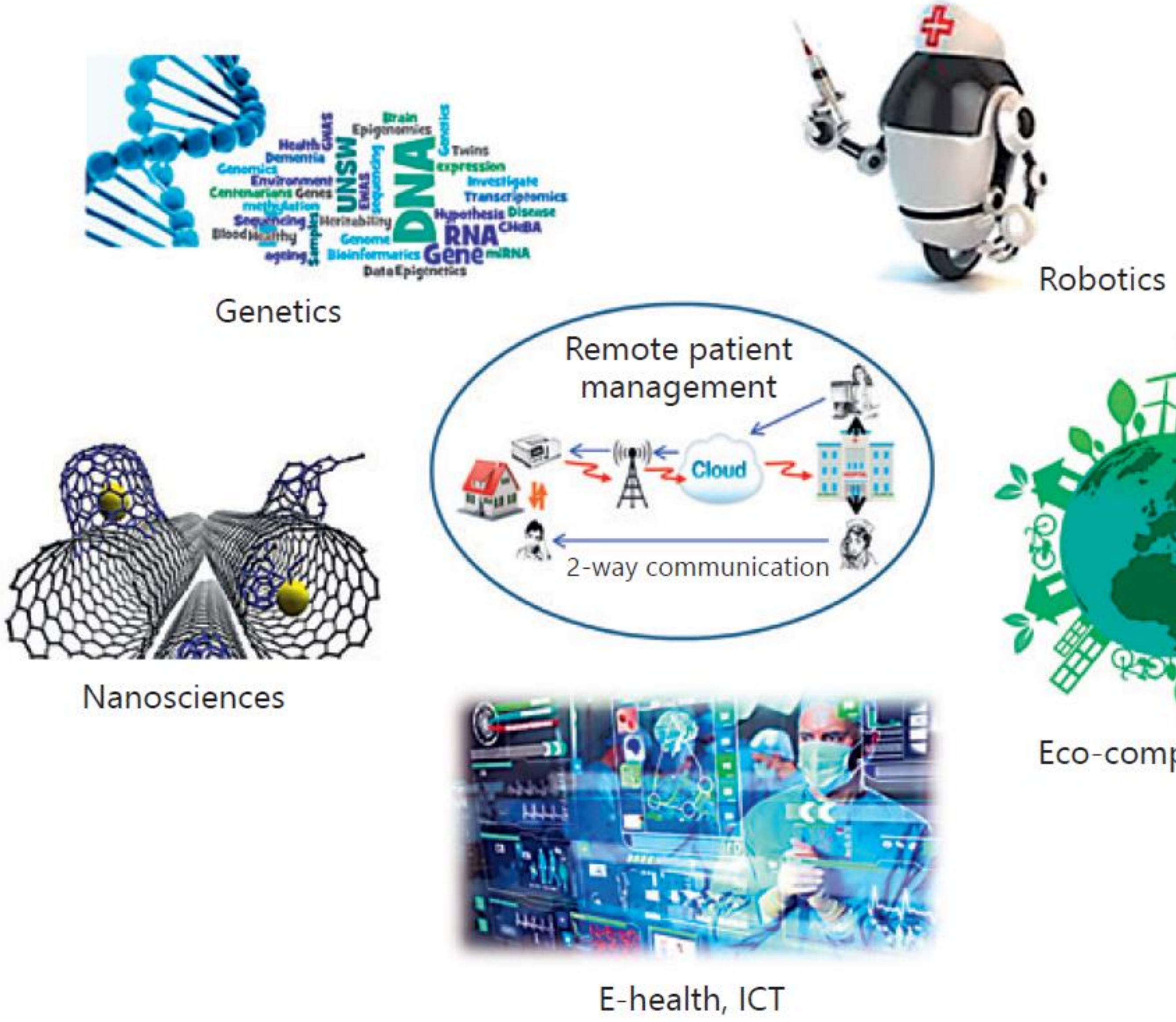
Recupero del calore

Sfruttamento metodiche (back-filtration)

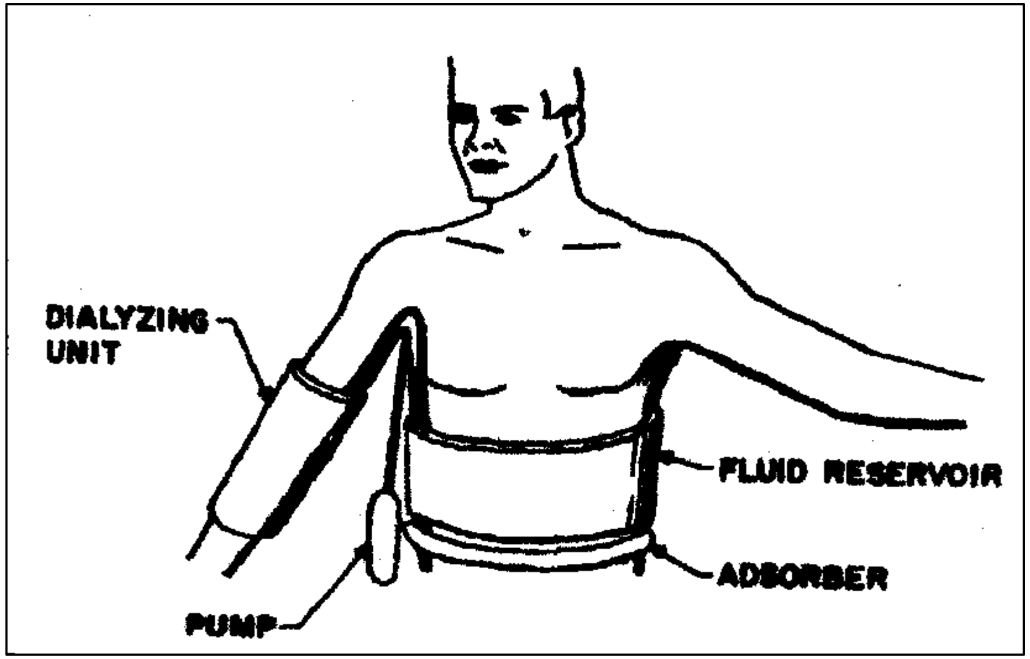
Remote Patient Management: The Future Is G.R.E.E.N.

Claudio Ronco[a–c] • Carlo Crepaldi[b] • Sabrina Milan Manani[b] • Anna Giuliani[b] • Mitchell H. Rosner[d]

[a]University of Padova, Padova, Italy; [b]Department of Nephrology, Dialysis and Transplant, San Bortolo Hospital, Vicenza, Italy; [c]International Renal Research Institute Vicenza (IRRIV), Vicenza, Italy; [d]Division of Nephrology, University of Virginia Health System, Charlottesville, VA, USA



Hemodialysis with sorbent regeneration of dialysate



ADSORPTION: A STEP TOWARD A WEARABLE ARTIFICIAL KIDNEY

Ted L. Blaney*, Olgierd Lindan+ and Robert E. Sparks*

There are many possible conceptions of the ideal artificial kidney, each approaching closely some of the ultimate goals of a chronic dialysis program. This paper will examine one of the critical problems arising upon consideration of one possible conception: the wearable artificial kidney. Such a device would permit nearly normal mobility of the patient and make possible continuous, or daily, dialysis. From a pragmatic point of view, it remains an open question, of course, whether it is better for the patient to be constantly encumbered with a small amount of apparatus or to be dialyzed at intervals at home. However, since any gain in the direction of a wearable artificial kidney will require a drastic decrease in the weight of the apparatus and an increase in the efficiency of its operation, it would appear to be a worthwhile long-range goal.

Achieving such a goal would require the solution of many complex medical and engineering problems, but the entire concept is ludicrous unless a technique can be found for drastically reducing the required volume of dialyzing fluid. The remaining discussion will focus on this problem.

DECREASING DIALYZING FLUID VOLUME

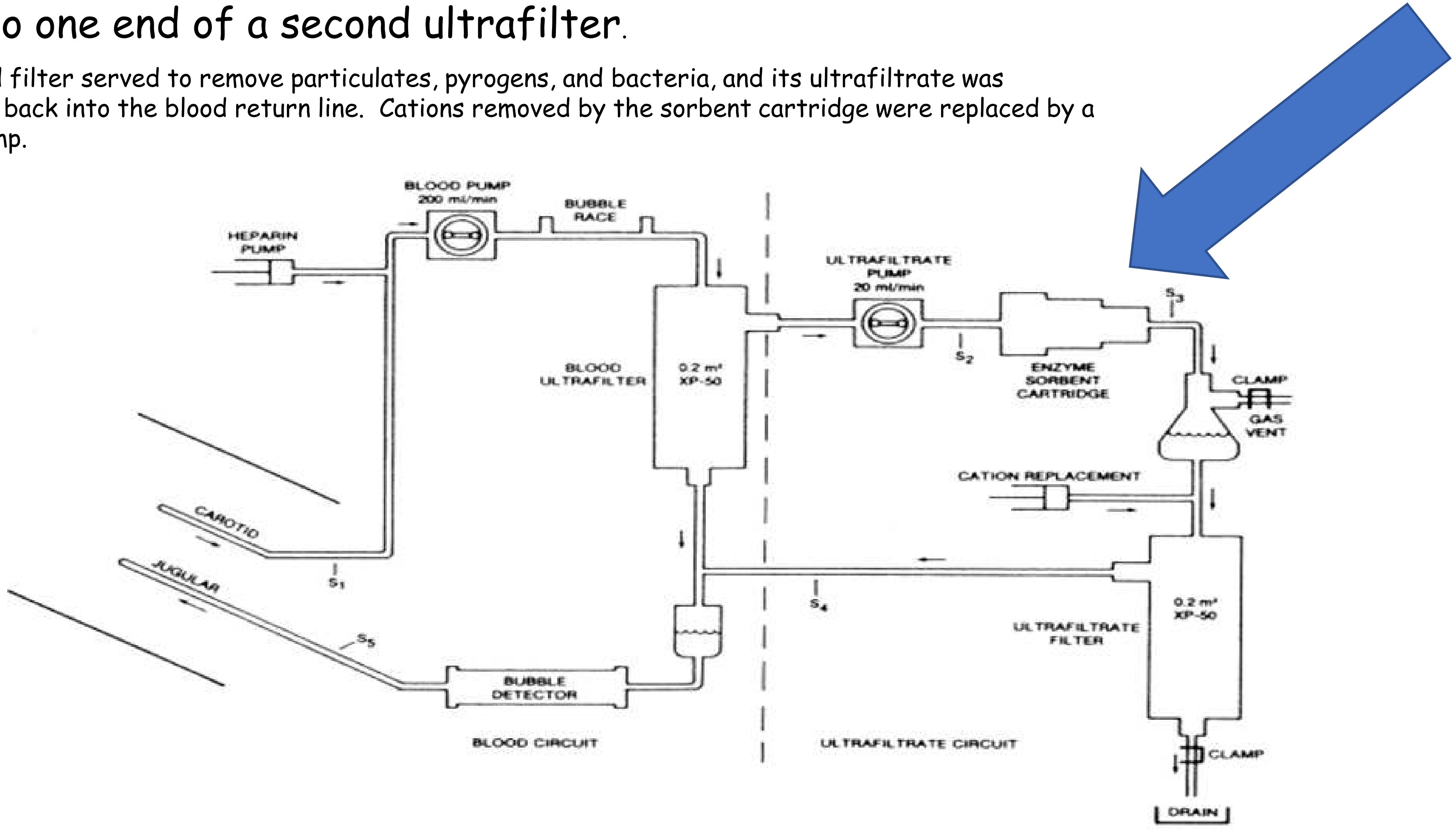
If a more efficient urea adsorber were developed, then a small cartridge of adsorbent could be used in conjunction with a small volume of fluid to form a system of low weight and volume, particularly if the solution and adsorbent were changed at intervals. If this system were coupled with a small dialyser and a pump to circulate the fluid, the system might appear as shown in highly idealized form in Figure 4

Blaney TL, Lindan O, Sparks RE. Adsorption: a step forwards to a wearable artificial kidney. Trans Am Soc Artif Intern Organs ***1966****;12:7- 12*

Sorbent regeneration of ultrafiltration - Henderson

The ultrafiltrate was then pumped through <u>the REDY cartridge</u> and into one end of a second ultrafilter.

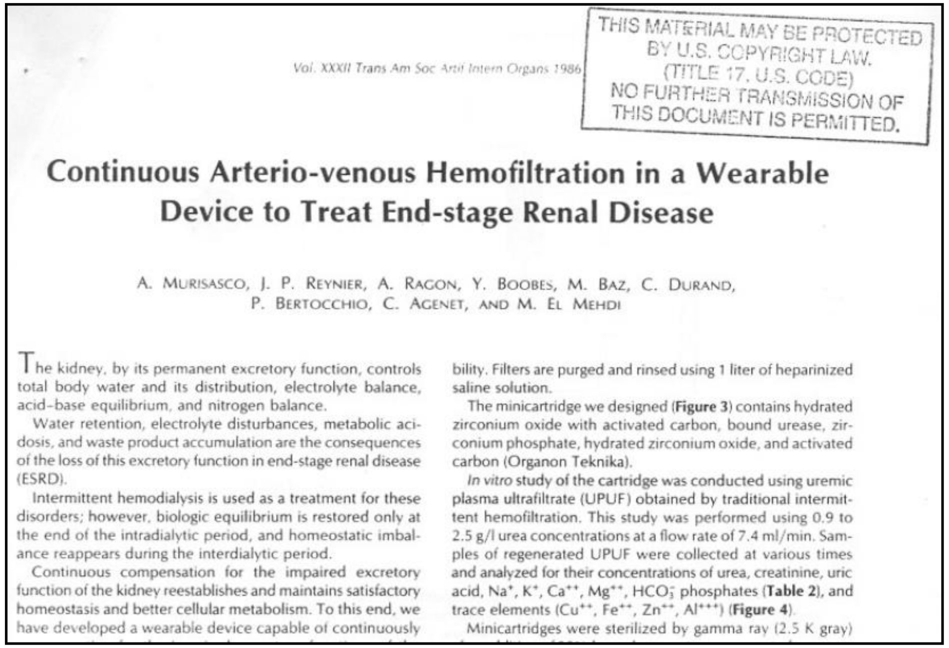
The second filter served to remove particulates, pyrogens, and bacteria, and its ultrafiltrate was introduced back into the blood return line. Cations removed by the sorbent cartridge were replaced by a syringe pump.



Henderson LW, Parker HR, Schroeder JP, et.al. Continuous low flow hemofiltrationwith sorbent regeneration of ultrafiltrate. Trans Amer Soc Artif Intern Organs1978; 24: 178-84.

Sorbent regeneration of ultrafiltration - Murisasco

The device was designed to <u>mimic the normal excretory functions of the nephron</u>: <u>glomerular filtration, tubular reabsorption, and urine eliminations</u>. The system was consisted of a hemofilter, sorbent cartridge, two pumps, microfilter, and a minisyringe for the continuous heparin injection


Vol. XXXII Trans Am Soc Artif Intern Organs 1986

Continuous Arterio-venous Hemofiltration in a Wearable Device to Treat End-stage Renal Disease

A. Murisasco, J. P. Reynier, A. Ragon, Y. Boobes, M. Baz, C. Durand, P. Bertocchio, C. Agenet, and M. El Mehdi

The kidney, by its permanent excretory function, controls total body water and its distribution, electrolyte balance, acid–base equilibrium, and nitrogen balance.

Water retention, electrolyte disturbances, metabolic acidosis, and waste product accumulation are the consequences of the loss of this excretory function in end-stage renal disease (ESRD).

Intermittent hemodialysis is used as a treatment for these disorders; however, biologic equilibrium is restored only at the end of the intradialytic period, and homeostatic imbalance reappears during the interdialytic period.

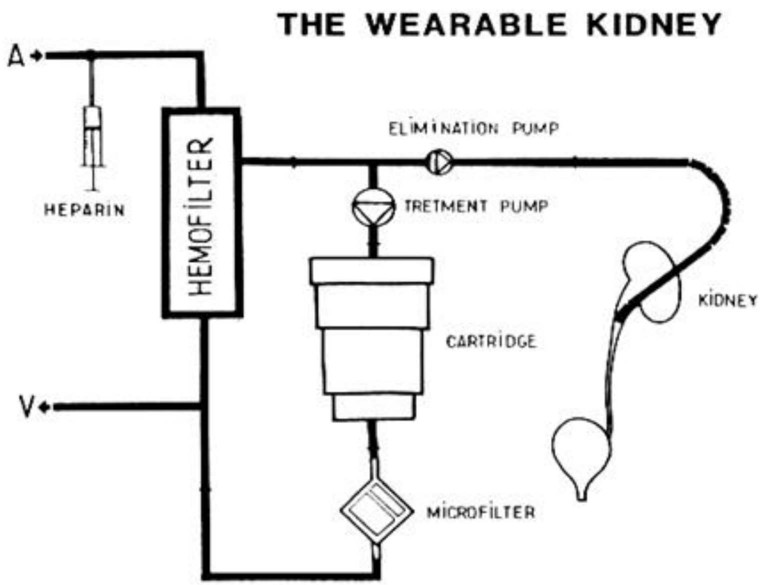
Continuous compensation for the impaired excretory function of the kidney reestablishes and maintains satisfactory homeostasis and better cellular metabolism. To this end, we have developed a wearable device capable of continuously

bility. Filters are purged and rinsed using 1 liter of heparinized saline solution.

The minicartridge we designed (**Figure 3**) contains hydrated zirconium oxide with activated carbon, bound urease, zirconium phosphate, hydrated zirconium oxide, and activated carbon (Organon Teknika).

In vitro study of the cartridge was conducted using uremic plasma ultrafiltrate (UPUF) obtained by traditional intermittent hemofiltration. This study was performed using 0.9 to 2.5 g/l urea concentrations at a flow rate of 7.4 ml/min. Samples of regenerated UPUF were collected at various times and analyzed for their concentrations of urea, creatinine, uric acid, Na^+, K^+, Ca^{++}, Mg^{++}, HCO_3^- phosphates (**Table 2**), and trace elements (Cu^{++}, Fe^{++}, Zn^{++}, Al^{+++}) (**Figure 4**).

Minicartridges were sterilized by gamma ray (2.5 K gray)



Murisasco A, Reynier JP, Ragon A et al. Continuous arterio-venous hemofiltration in a wearable device to treat end-stage renal disease. Trans. Am. Soc. Artif. Intern. Organs 32(1), 567–571 (1986).

PD with dialysate regeneration approaches

Continuous ambulatory peritoneal dialysis: the major objectives were to see if continuous ambulatory peritoneal dialysis would provide:

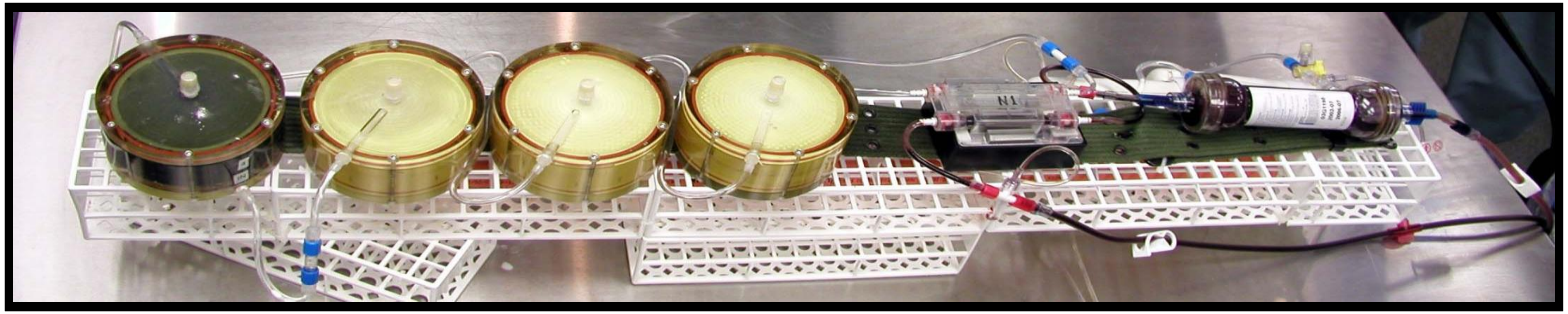
[1] acceptable control of serum chemistries by usual criteria,

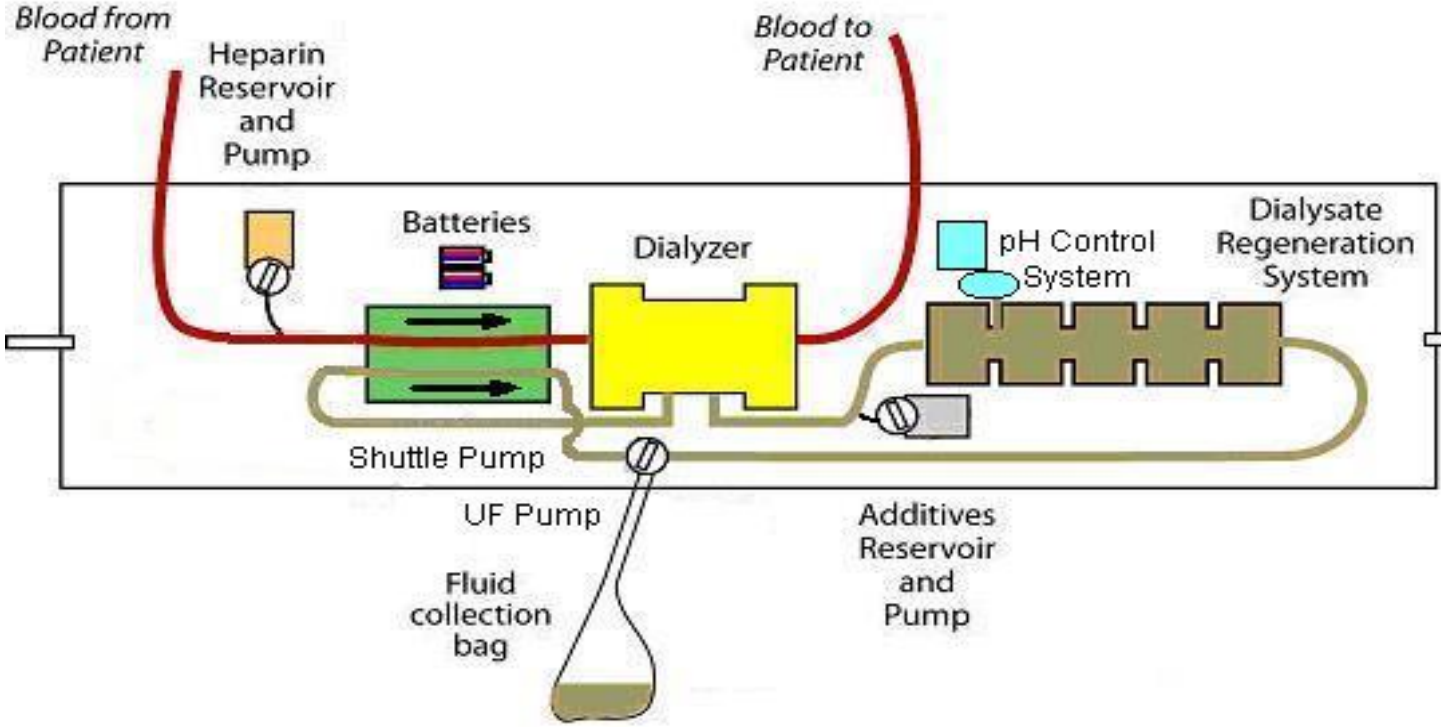
[2] adequate removal of sodium and water,

[3] tolerable protein losses

[4] a low prevalence of peritonitis with episodes responsive to therapy with continuing continuous ambulatory peritoneal dialysis

The Wearable Artificial Kidney (V1.1)





Activated charcoal

Urease

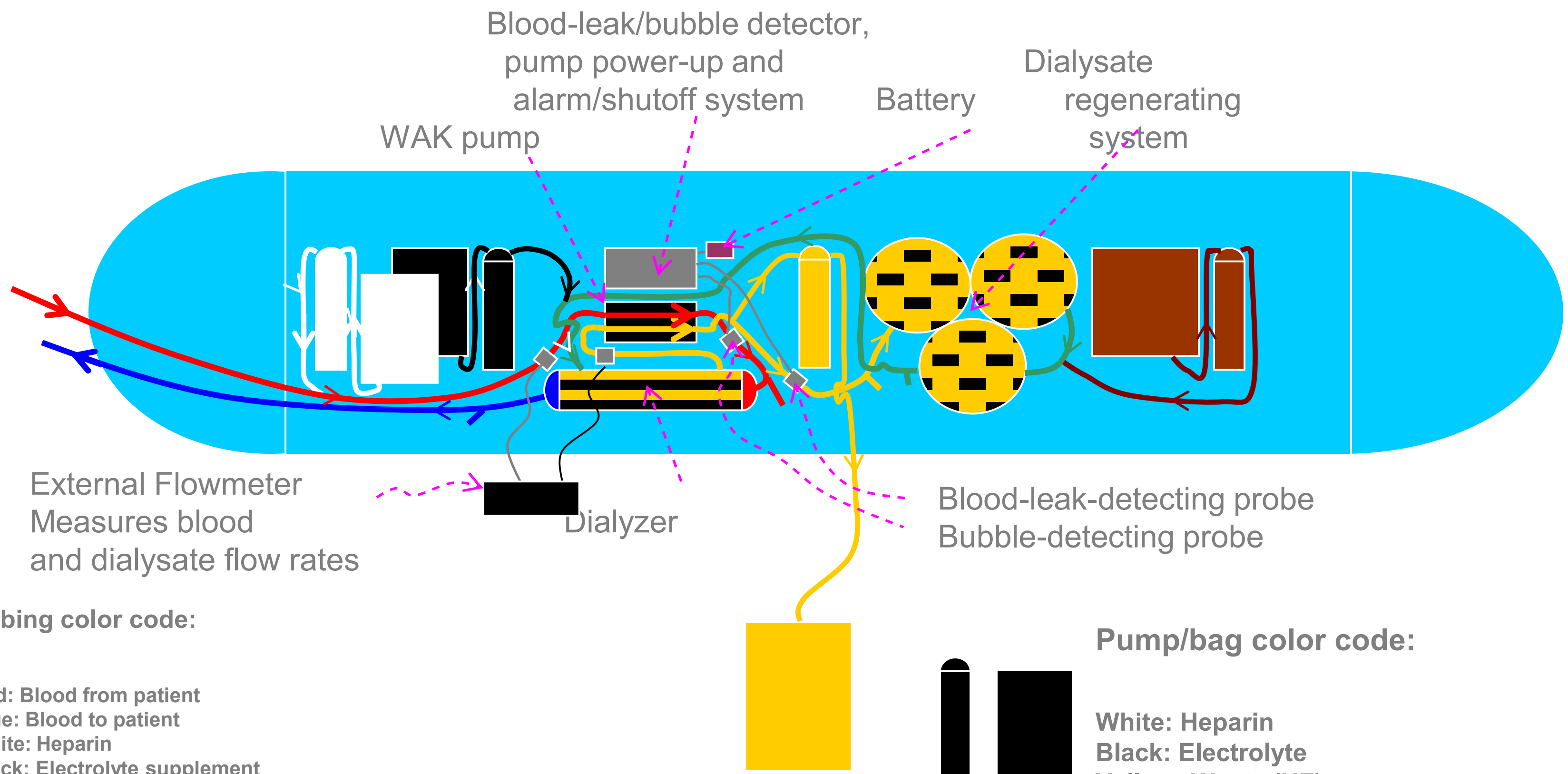
Zirconium phosphate

Hydrated zirconium oxide

Activated charcoal

The Wearable Artificial Kidney V1.2

US Patent No. 6,960,179 and other patents pending.



Tubing color code:

Red: Blood from patient
Blue: Blood to patient
White: Heparin
Black: Electrolyte supplement
Yellow: Dialysate to regenerating system
Brown: Bicarbonate
Green: Dialysate from regenerating system

Electronics/cables are shown in gray

Pump/bag color code:

White: Heparin
Black: Electrolyte
Yellow: Waste (UF)
Brown: Bicarbonate

Backfiltration: Past, Present and Future

Armando Vazquez Rangel · Jeong Chul Kim ·
Manish Kaushik · Francesco Garzotto · Mauro Neri ·
Dinna N. Cruz · Claudio Ronco

Department of Nephrology, San Bortolo Hospital and International Renal Research Institute
Vicenza (IRRIV), Vicenza, Italy

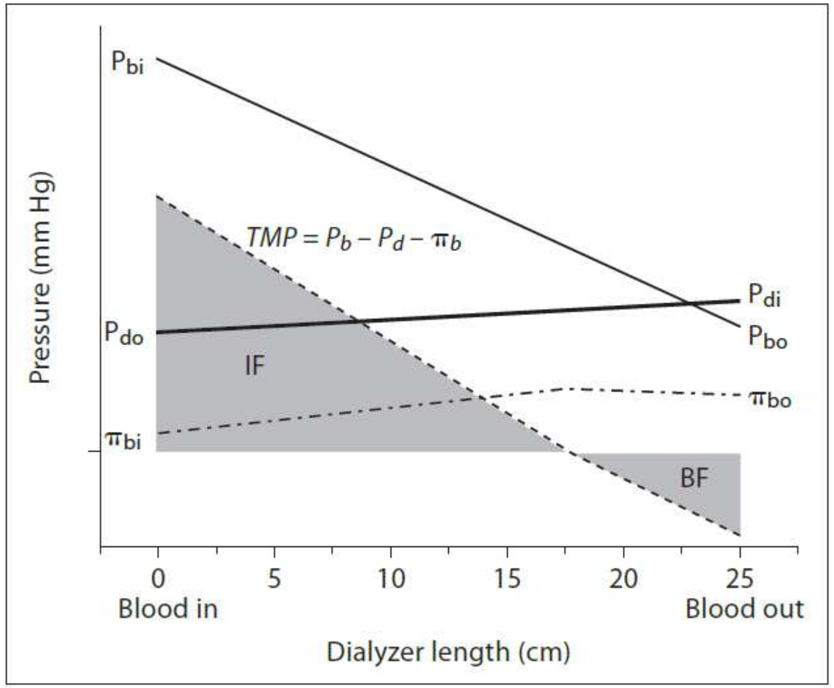
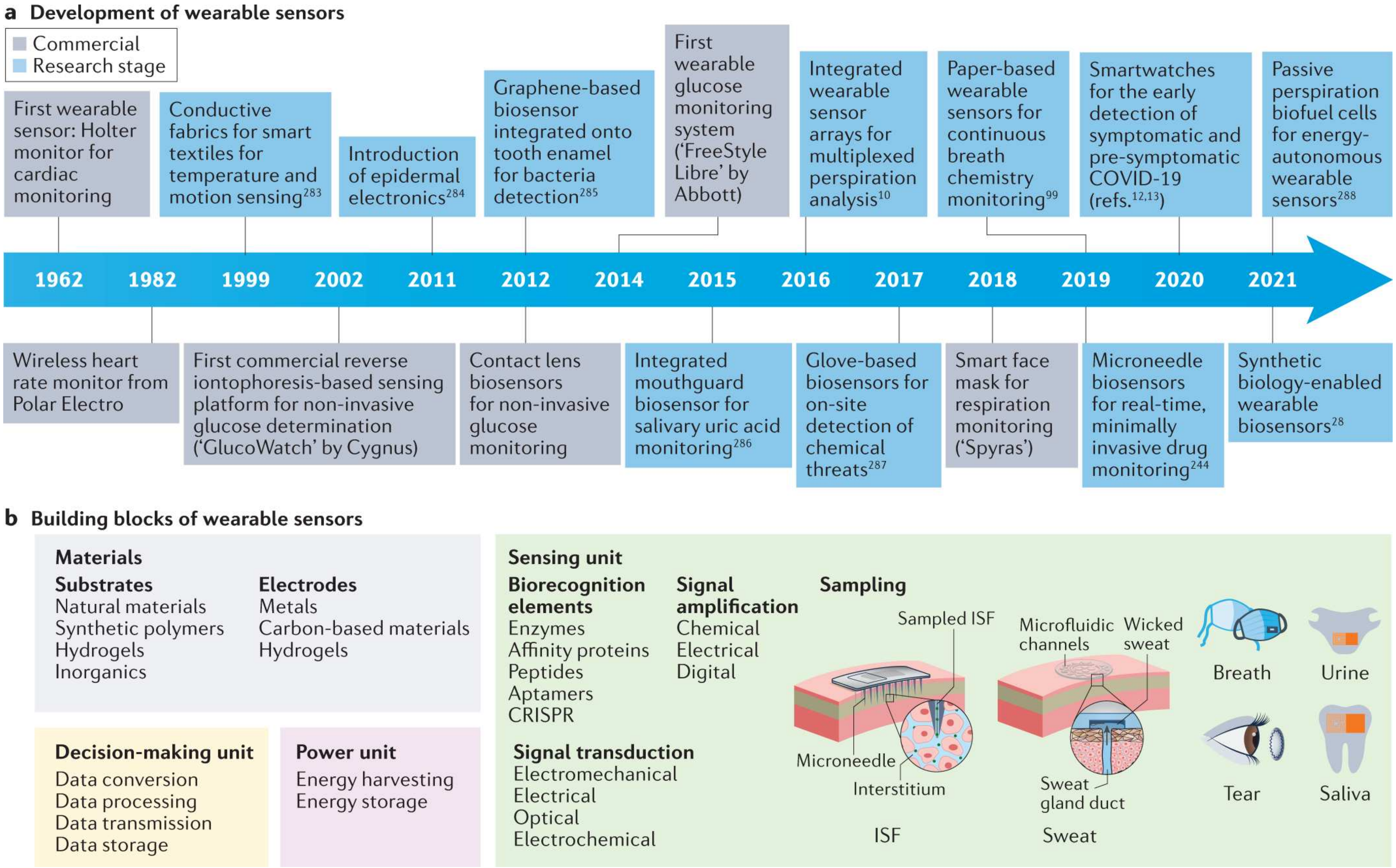
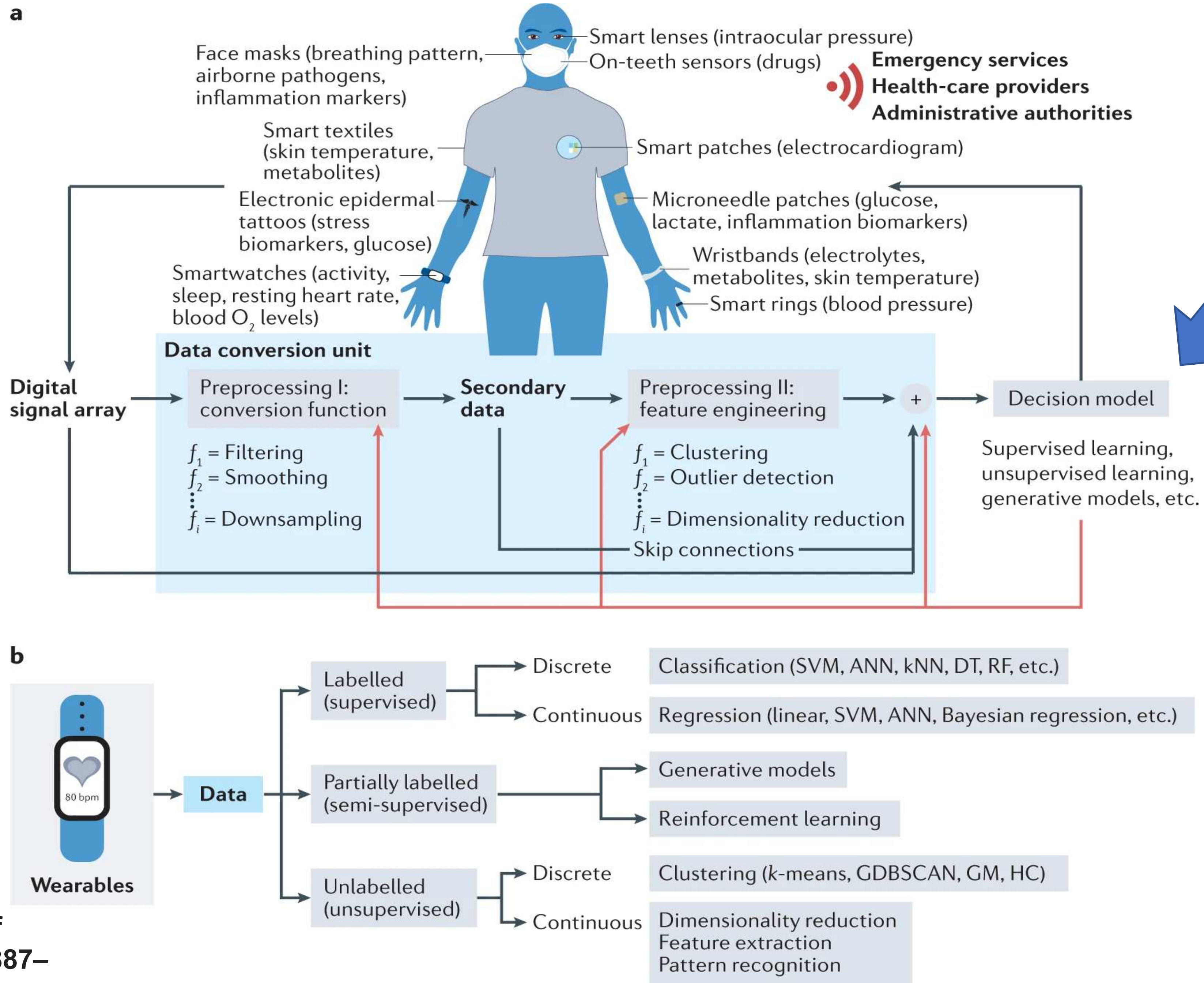


Fig. 1. Pressure profiles along the dialyzer contributing to internal filtration (IF) and backfiltration (BF). TMP = Transmembrane pressure; P_{bi} = inlet hydrostatic blood pressure; P_{bo} = outlet blood pressure; P_{di} = inlet hydrostatic dialysate pressure; P_{do} = outlet dialysate pressure; π_{bi} = inlet oncotic blood pressure; π_{bo} = outlet oncotic blood pressure.



Ates, H.C., Nguyen, P.Q., Gonzalez-Macia, L. *et al.* End-to-end design of wearable sensors. *Nat Rev Mater* **7**, 887–907 (2022)

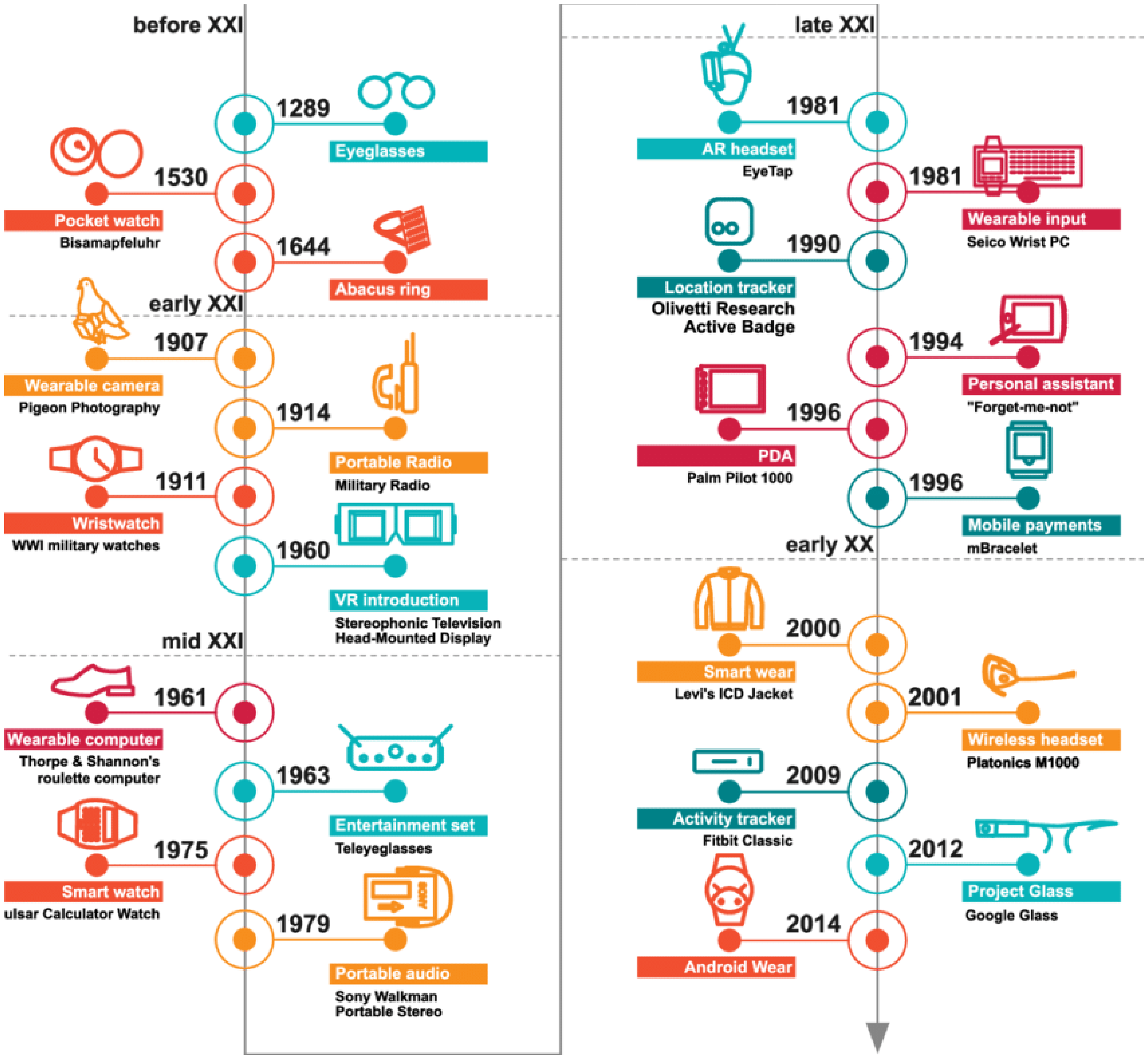


links between the measured signals and physiological status

Overview of data-driven methods. Post-processing of big data to explore the complex links between the measured signals and physiological status of individuals is possible with machine learning algorithms.

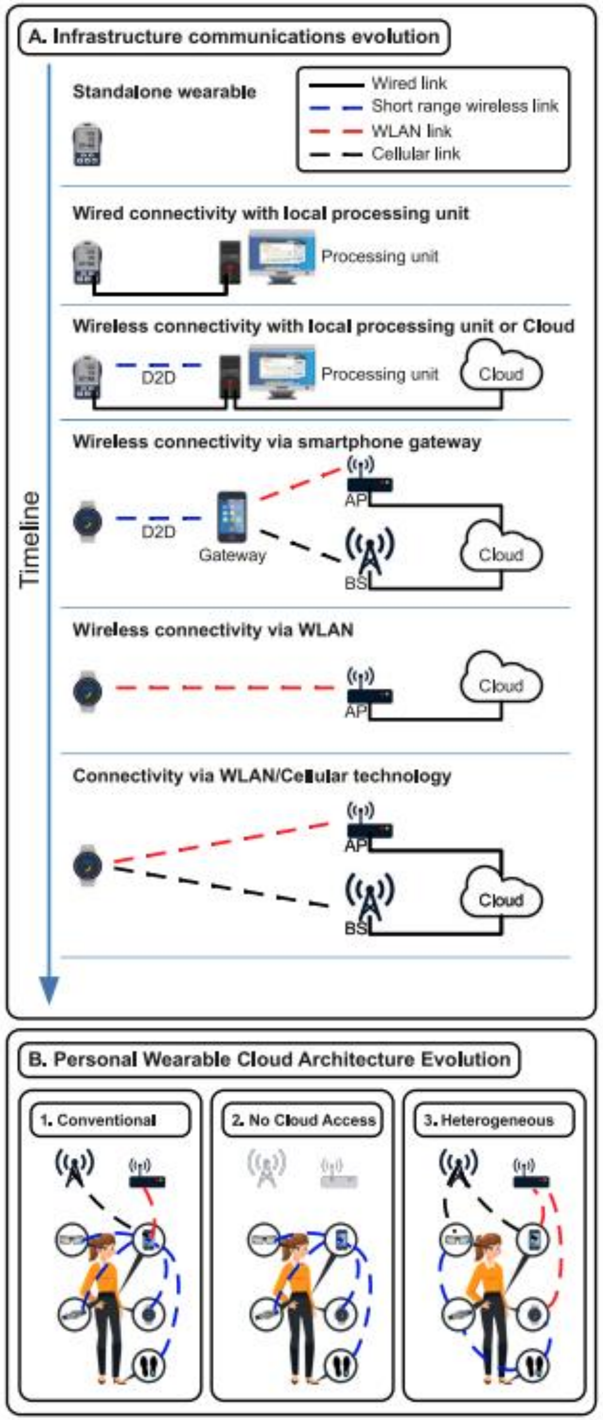
Ates, H.C. *et al.* End-to-end design of wearable sensors. *Nat Rev Mater* 7, 887–907 (2022)

Milestone of wearable device evolution



Wearable device enable the integration of smart connectivity

Fig. 4. Classification of wearable devices based on the on-body location.



mHealth- coinvolgimento attivo del paziente

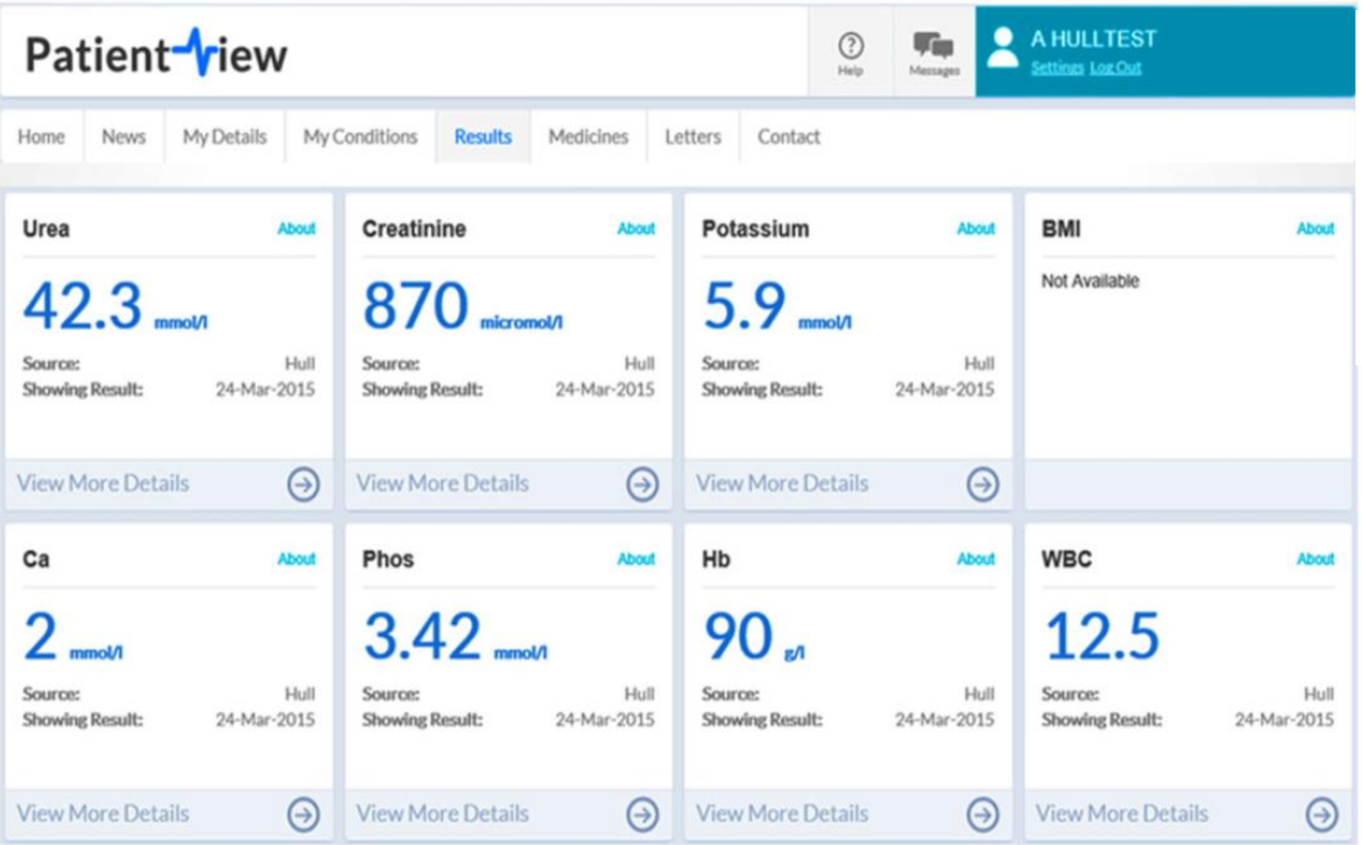


FIGURE 5: RenalPatientView™—screenshot with laboratory results (fictitious patient) from [86] (open access licence).

CKJ REVIEW

The role of patient portals in enhancing self-care in patients with renal conditions

Adil M. Hazara[1,2], Katherine Durrans[3] and Sunil Bhandari[1,2]

[1]Department of Renal Medicine, Hull University Teaching Hospitals NHS Trust, Hull, UK, [2]Hull York Medical School, University of Hull, Hull, UK and [3]Department of Nutrition and Dietetics, Hull University Teaching Hospitals NHS Trust, Hull, UK

Correspondence to: Adil M. Hazara; E-mail: adilhazara@nhs.net

E' necessario munire i pz di tools che li metta in grado di reagire al cambiamento delle proprie condizioni

The care of patients with long-term conditions such as CKD can be enhanced if they are actively engaged in the management of their condition. Increasing patient knowledge, seeking their participation in decision making and equipping them with tools that enable them to monitor and react to changes in their condition could lead to improved outcomes and prevent complications associated with long-term conditions

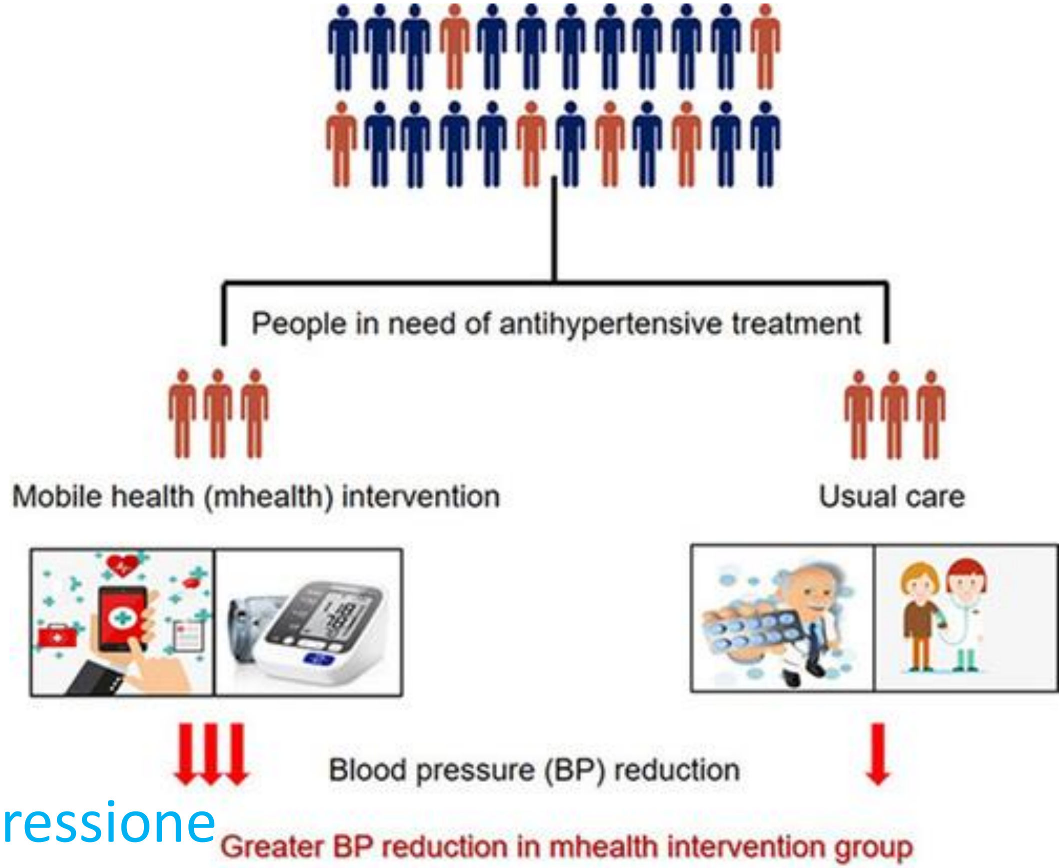
Interactive Mobile Health Intervention and Blood Pressure Management in Adults

A Meta-Analysis of Randomized Controlled Trials

Xiaomei Lu, Huijun Yang, Xue Xia, Xiangfeng Lu, Jinchun Lin, Fangchao Liu and Dongfeng Gu

Originally published 22 Jul 2019 | https://doi.org/10.1161/HYPERTENSIONAHA.119.13273 | Hypertension. 2019;74:697–704

Other version(s) of this article



Supporto con mobile health -> riduzione pressione

eHealth Aderenza alla terapia TAKE-IT

The TAKE- IT trial assessed the efficacy of a multimodal intervention to promote medication adherence

that incorporated patient input in the eHealth component.

The TAKE- IT intervention **significantly improved medication adherence compared with the control group**.

This finding demonstrates that involving patients as stakeholders to individualize eHealth interventions and meet patient needs can improve outcomes.

Foster, B. J. et al. A randomized trial of a multicomponent intervention to promote medication adherence: the Teen Adherence in Kidney Transplant Effectiveness of Intervention Trial (TAKE- IT) Am. J. Kidney Dis. ***72****, 30–41 (2018).*

applied sciences

MDPI

Article

Self-Reporting Technique-Based Clinical-Trial Service Platform for Real-Time Arrhythmia Detection

Heejin Kim [1], Ki Young Huh [2], Meihua Piao [3], Hyeongju Ryu [4], Wooseok Yang [1], SeungHwan Lee [2] and Kyung Hwan Kim [5,*]

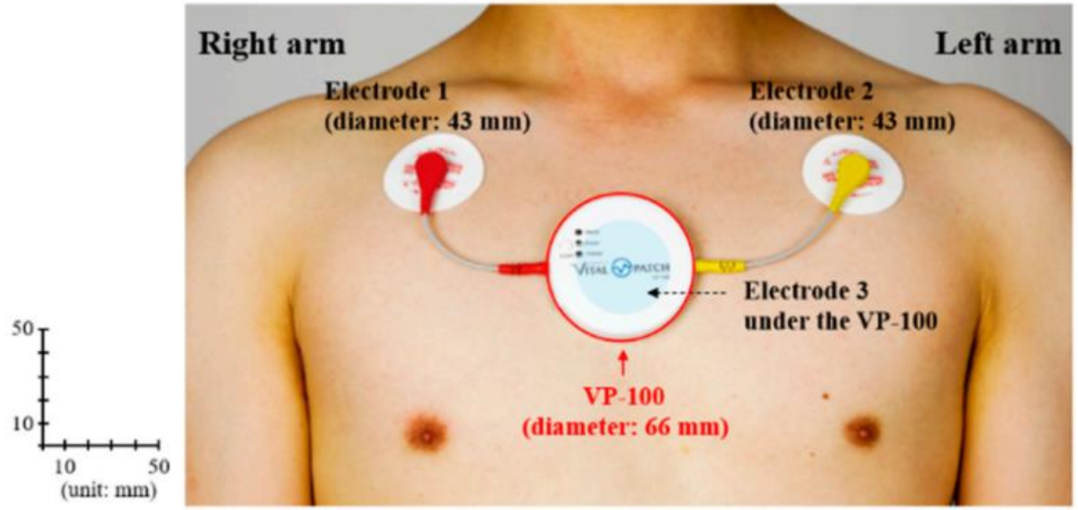


Figure 1. Placement of the VP-100 on the chest of a human volunteer.

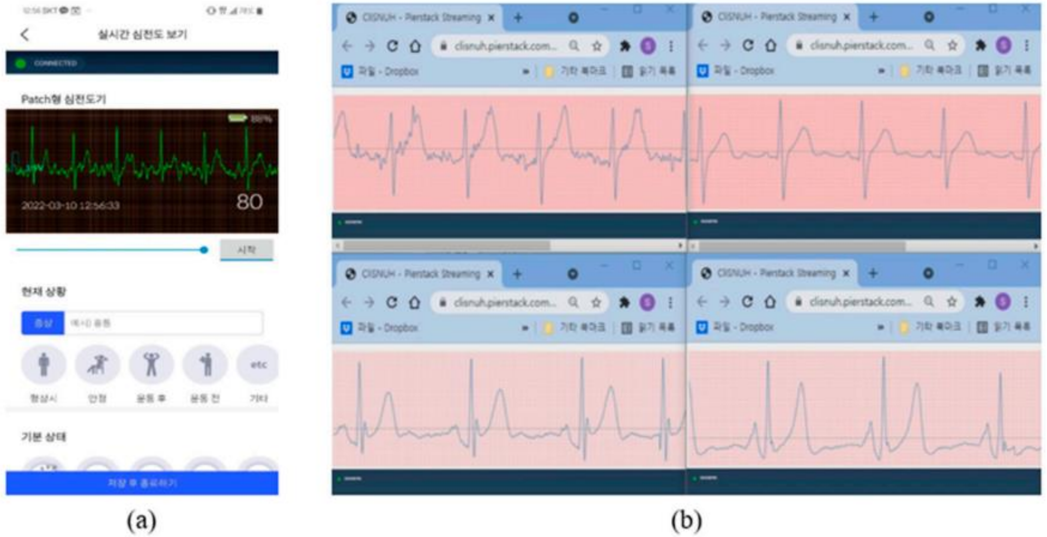


Figure 4. Real-time ECG obtained from healthy volunteers: (**a**) Single-channel ECG on the mobile app; (**b**) Streamed ECG data of four participants in real-time on the web client.

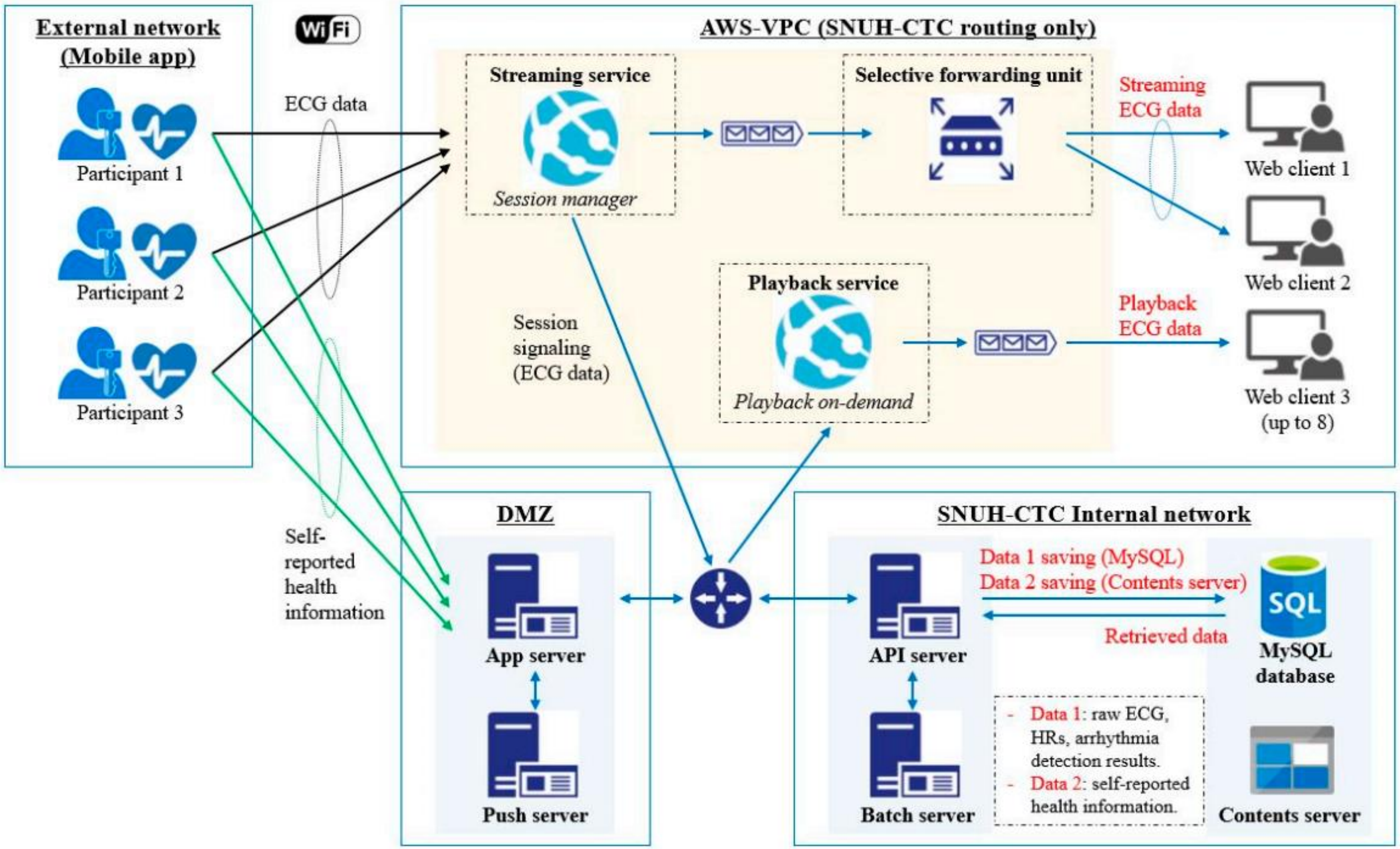
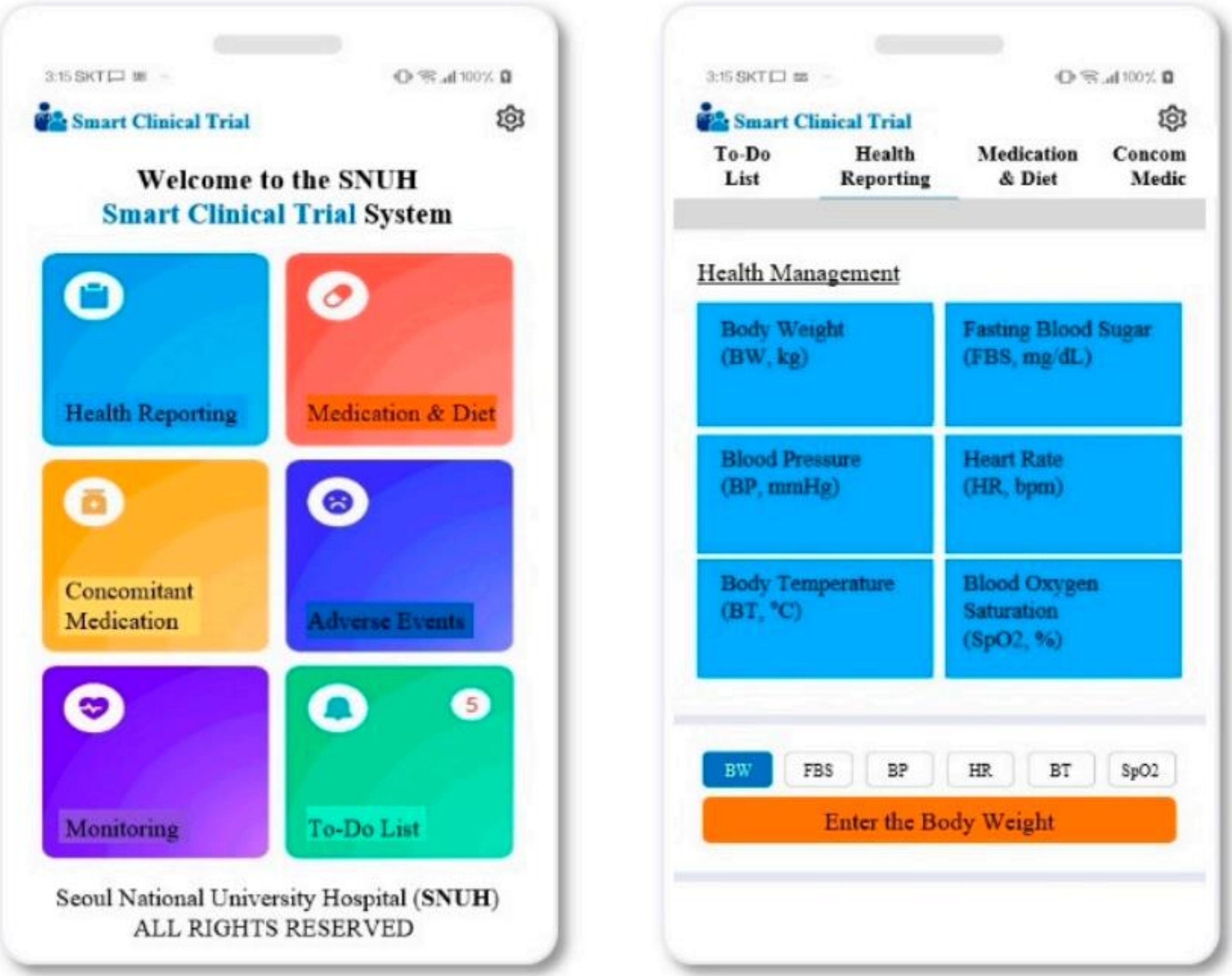
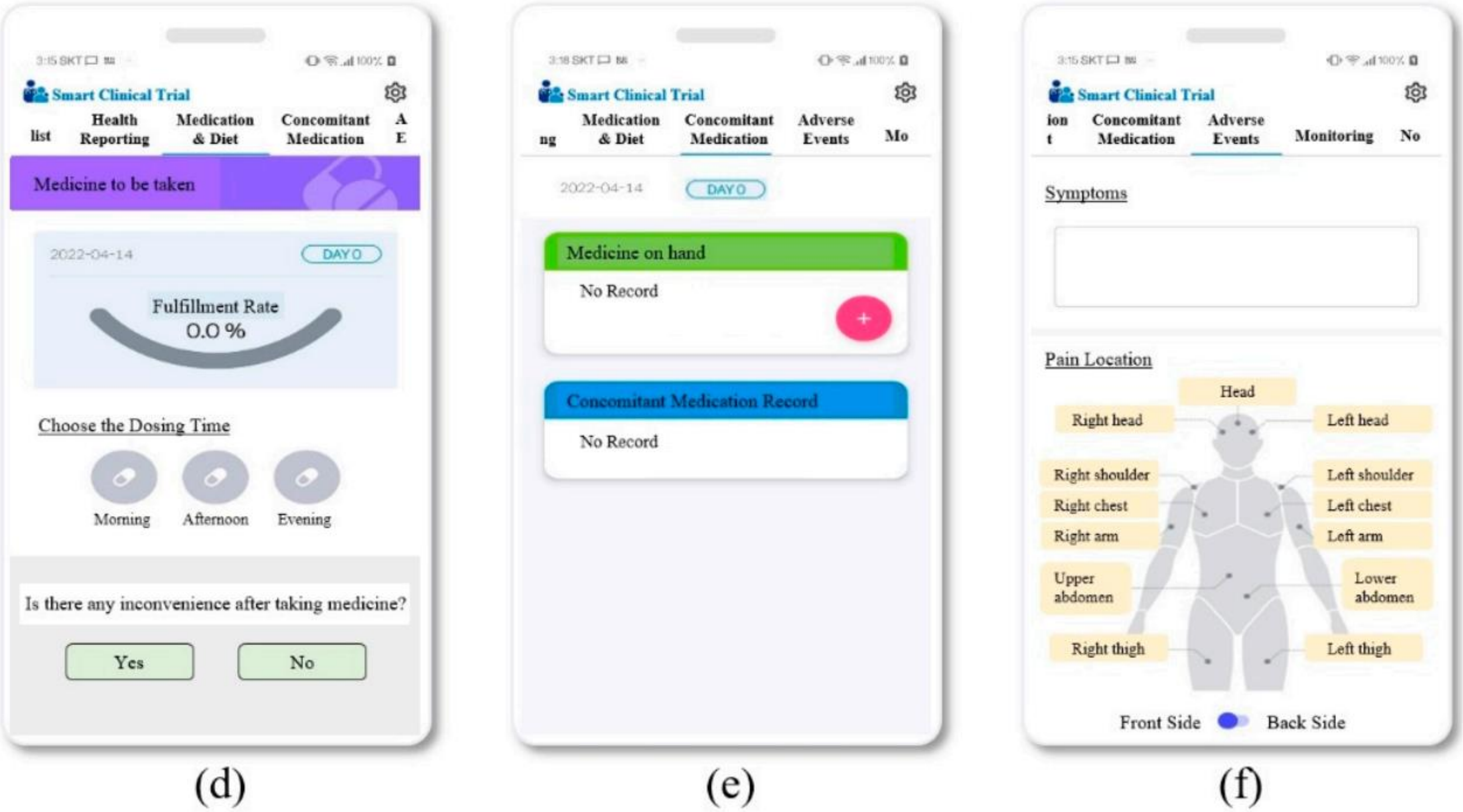


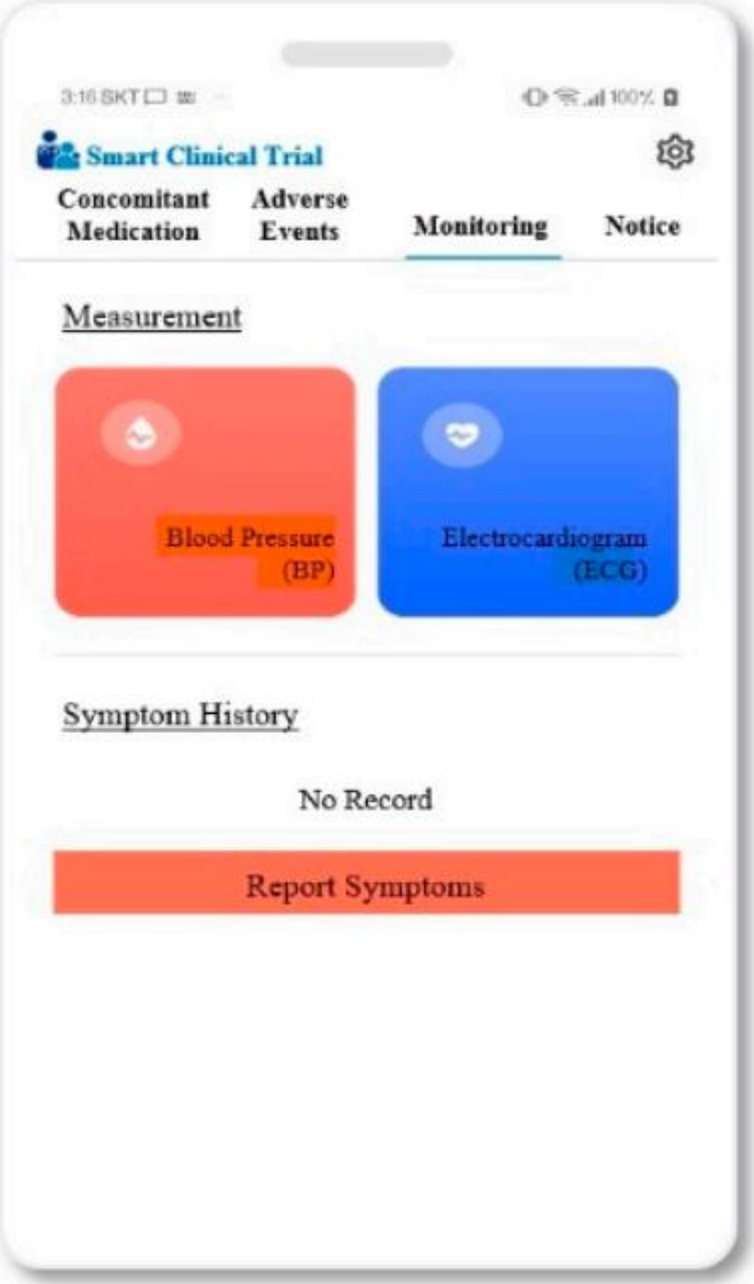
Figure 3. Entire network structure and connection configuration.


Smart Clinical Trial
Welcome to the SNUH
Smart Clinical Trial System
Health Reporting
Medication & Diet
Concomitant Medication
Adverse Events
Monitoring
To-Do List
5
Seoul National University Hospital (SNUH)
ALL RIGHTS RESERVED
Smart Clinical Trial
To-Do List
Health Reporting
Medication & Diet
Concom Medic
Health Management
Body Weight (BW, kg)
Fasting Blood Sugar (FBS, mg/dL)
Blood Pressure (BP, mmHg)
Heart Rate (HR, bpm)
Body Temperature (BT, °C)
Blood Oxygen Saturation (SpO2, %)
BW
FBS
BP
HR
BT
SpO2
Enter the Body Weight

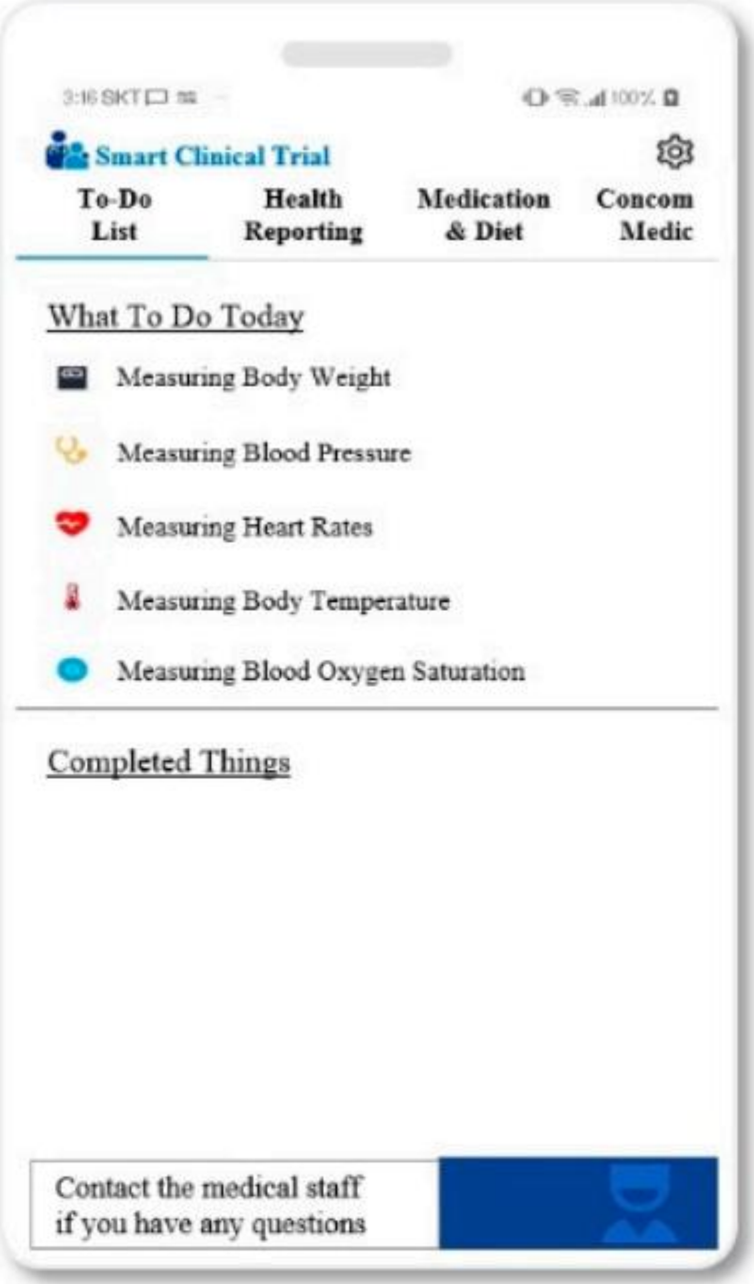
(b) (c)



(**d**) medication and diet; (**e**) concomitant medication; (**f**) adverse events;



(g)
monitoring



(h)
To do list

Analisi delle urine domiciliare utilizzando uno smartphone

Dipping at home: Is it better, easier and more convenient? A feasibility and acceptability study of a novel home urinalysis using a smartphone application

{Graphical Abstract}

HYPOTHESIS: The novel app will have high rates of acceptance among patients and caregivers.

DESIGN & OUTCOMES:

103 Children (5-21 yrs.)
47 Glomerular disease
48 Non-Glomerular
8 Kidney transplant

App Download

Home urine test by Caregiver or Child > 12

Survey comparing app vs. standard of care*

Patient satisfaction of current practice and Healthy.Io home urinalysis smartphone app

Satisfaction Level	Current Practice*	Healthy.io app	Significance
Very Satisfied	15% (15)	81% (84)	P<0.0001
Satisfied	25% (26)	17% (17)	
Neutral	55% (57)	2% (2)	
Dissatisfied	5% (5)	0% (0)	

*Home albustics, in clinic urine testing or lab drop off

CONCLUSION: The Healthy.Io home urine testing app received very high rates of satisfaction among patients and caregivers compared to current practice and holds great potential to enhance patient-centered care.

Levy Erez et al. 2022

Pediatric Nephrology
Journal of the International Pediatric Nephrology Association
IPNA

sensors

MDPI

Article

Real-Time Internet of Medical Things System for Detecting Blood Leakage during Hemodialysis Using a Novel Multiple Concentric Ring Sensor

Hsiang-Wei Hu [1,2], Chih-Hao Liu [3], Yi-Chun Du [1,4], Kuan-Yu Chen [2], Hsuan-Ming Lin [5] and Chou-Ching Lin [1,6,*]

Figure 9. An example of the micro-leakage chart in the clinical trial. A tiny amount of blood infiltrated into a small area emphasized in a direction. The multi-ring design is better than a multiple point-type design for the estimation of leaked blood volume.

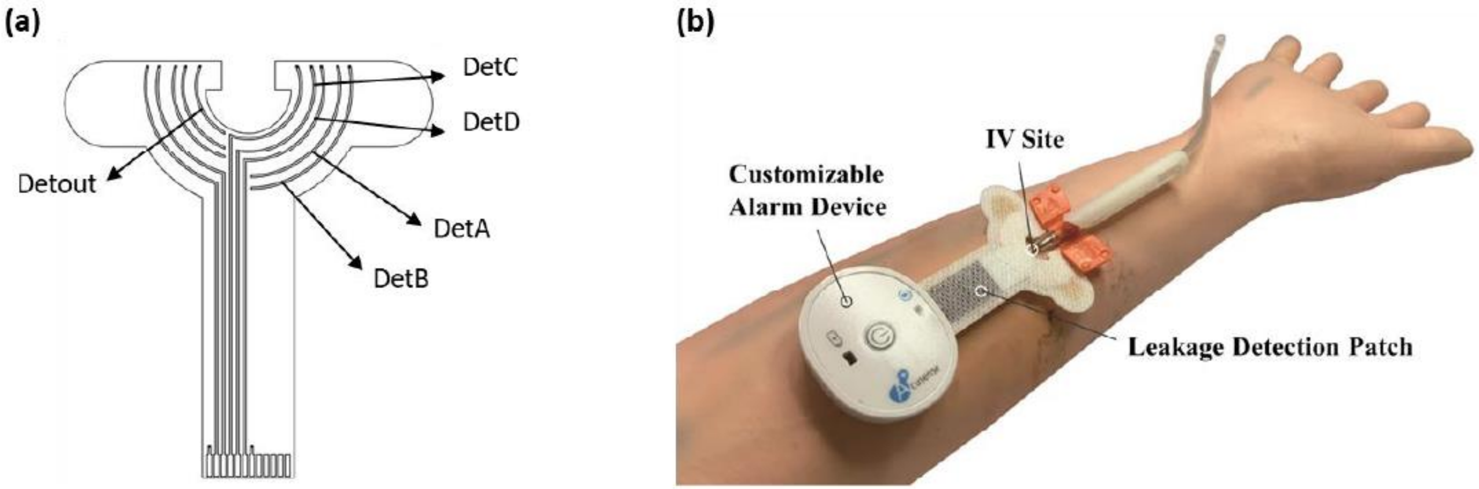


Figure 1. Sensor patch layout and the in vitro setup for testing the device. (**a**) Sensor patch layout. The cross-ring design architecture from the inside out was designed to detect leakage from all directions. (**b**) The performance of the leakage-detection patch was tested on a prosthetic arm with other parts of the detection device.

Smart Multi-frequency Bioelectrical Impedance Spectrometer for BIA and BIVA Applications

Rene Harder[1,2] **[Graduate Student Member IEEE]**, **André Diedrich**[2,3] **[Member IEEE]**, **Jonathan Whitfield**[3], **Maciej S. Buchowski**[4], **John B. Pietsch**[5], and **Franz Baudenbacher**[2]

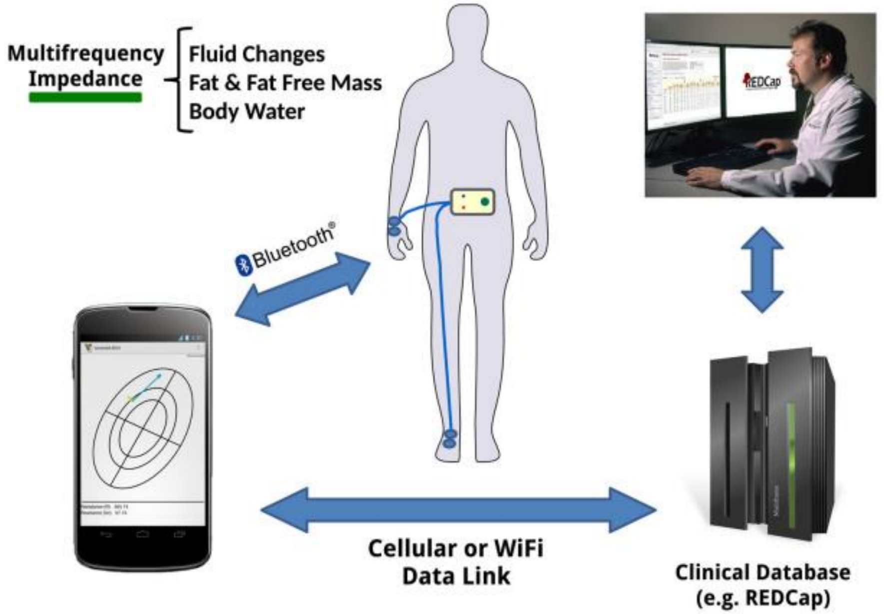


Figure 1.
Concept of smart multi-frequency impedance spectrometer tethered to a smart phone and data transfer to a data server to facilitate immediate feedback from health care provider or aggregation of impedance measurements across multiple studies in a clinical database.

Figure 2.
Wireless multi-frequency impedance spectrometer (left) used for bioelectrical impedance vector analysis (BIVA) in a rugged dust and water protected (IP 54) enclosure and snap on lead wires for easy and robust electrode attachment. Mobile application running on Nexus 7 tablet computer (right) that displays multiple BIVA measurements and allows for tracking of patient progress, patient management and data export.

Journal of
Clinical Medicine

MDPI

Article

Can Dialysis Patients Identify and Diagnose Pulmonary Congestion Using Self-Lung Ultrasound?

Eyal Schneider [1,*], Netta Maimon [1,*], Ariel Hasidim [1], Alla Shnaider [2], Gabrielle Migliozzi [1], Yosef S. Haviv [2], Dor Halpern [1], Basel Abu Ganem [3,4] and Lior Fuchs [1,5]

This study aims to evaluate the feasibility and accuracy of a self-lung ultrasound study conducted by hemodialysis (HD) patients to detect pulmonary congestion, with and without artificial intelligence (AI)-based automatic tools.

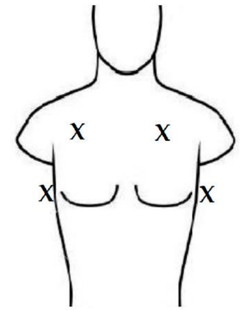
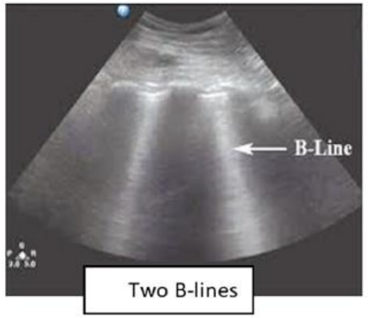
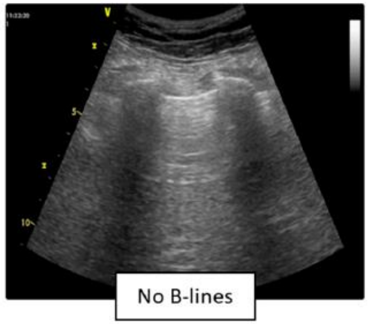


Figure 2. Researchers' scan locations.





Dialysis patients can self-scan their lungs with good anatomical precision
When using an AI-based counting application, accurate B-line counts are comparable to an expert's count on clips taken by researchers.

We believe this study sheds light on the **potential for using home US devices to detect PC**, allowing patients to take a more active role in their medical care.

biomedicines

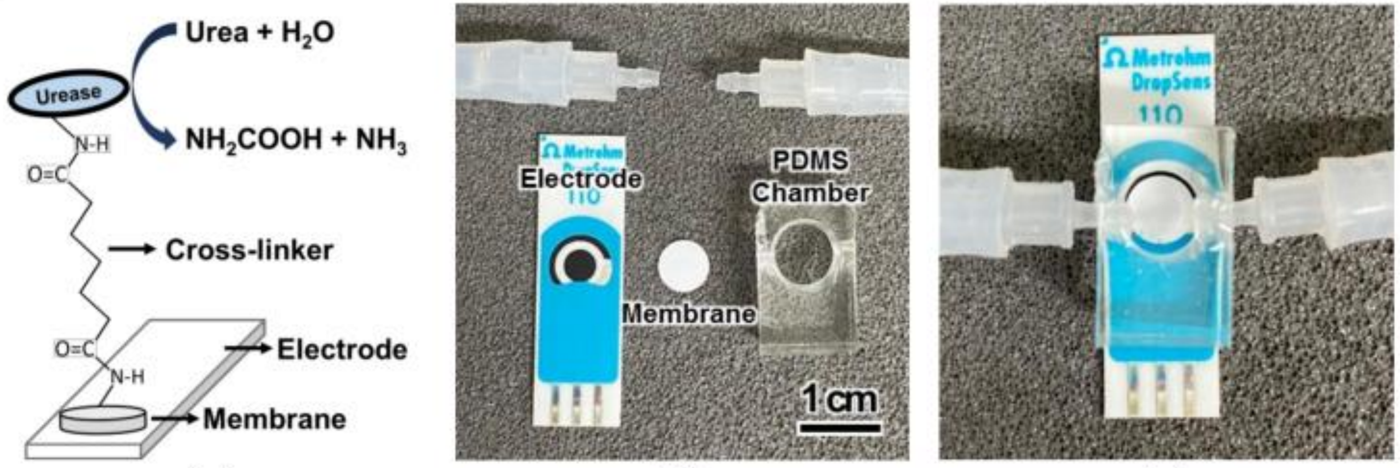
MDPI

Article

Efficient Portable Urea Biosensor Based on Urease Immobilized Membrane for Monitoring of Physiological Fluids

Jee Young Kim [1,2], Gun Yong Sung [1,2,3] and Min Park [1,2,3,*]

1 Cooperative Course of Nano-Medical Device Engineering, Hallym University, Chuncheon, Gangwon-do 24252, Korea; jyoung@hallym.ac.kr (J.Y.K.); gysung@hallym.ac.kr (G.Y.S.)
2 Integrative Materials Research Institute, Hallym University, Chuncheon, Gangwon-do 24252, Korea
3 Major in Materials Science and Engineering, Hallym University, Chuncheon, Gangwon-do 24252, Korea
* Correspondence: minpark@hallym.ac.kr



(a) (b) (c)

Figure 1. Schematic diagram of (**a**) the configuration of the urease-immobilized membrane; the configuration of the fluidic compartment of the urea biosensor (**b**) before and (**c**) after assembly.

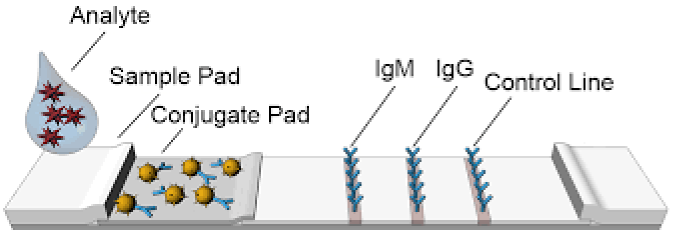
CKJ REVIEW

Point-of-care testing technologies for the home in chronic kidney disease: a narrative review

Richard Bodington [1], Xenophon Kassianides [2] and Sunil Bhandari [2]

[1]Sheffield Kidney Institute, Northern General Hospital, Sheffield, UK and [2]Department of Renal Research, H
Royal Infirmary, Hull, UK

Point-of-care testing (POCT): analisi di campioni di pazienti a fianco/vicino al paziente.

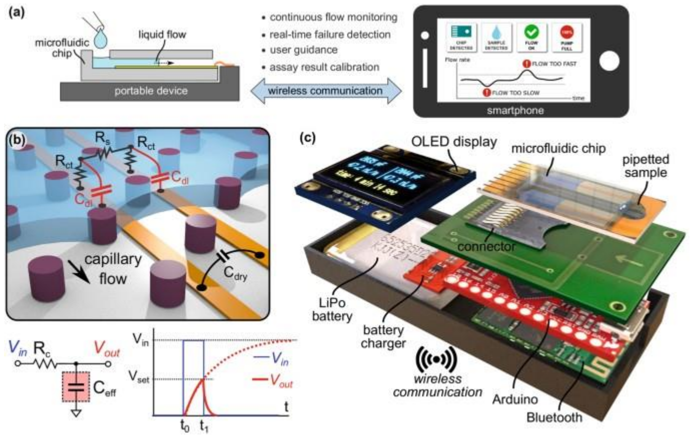


Lateral Flow Assay

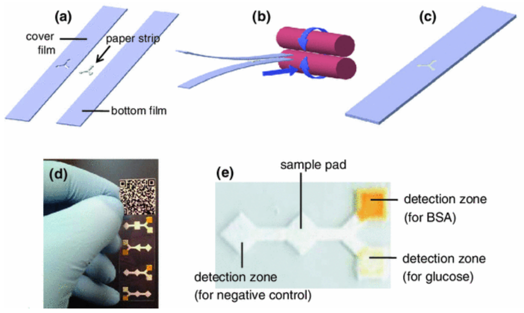
World Health Organization

Caratteristiche POC

Conveniente
Sensibile
Specifico
Facile da usare
Rapido e robusto
Senza attrezzature
Consegnabile agli utenti finali

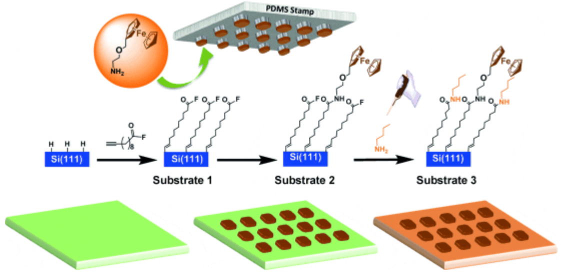


Chip-based microfluidics (lab-on-a-chip)

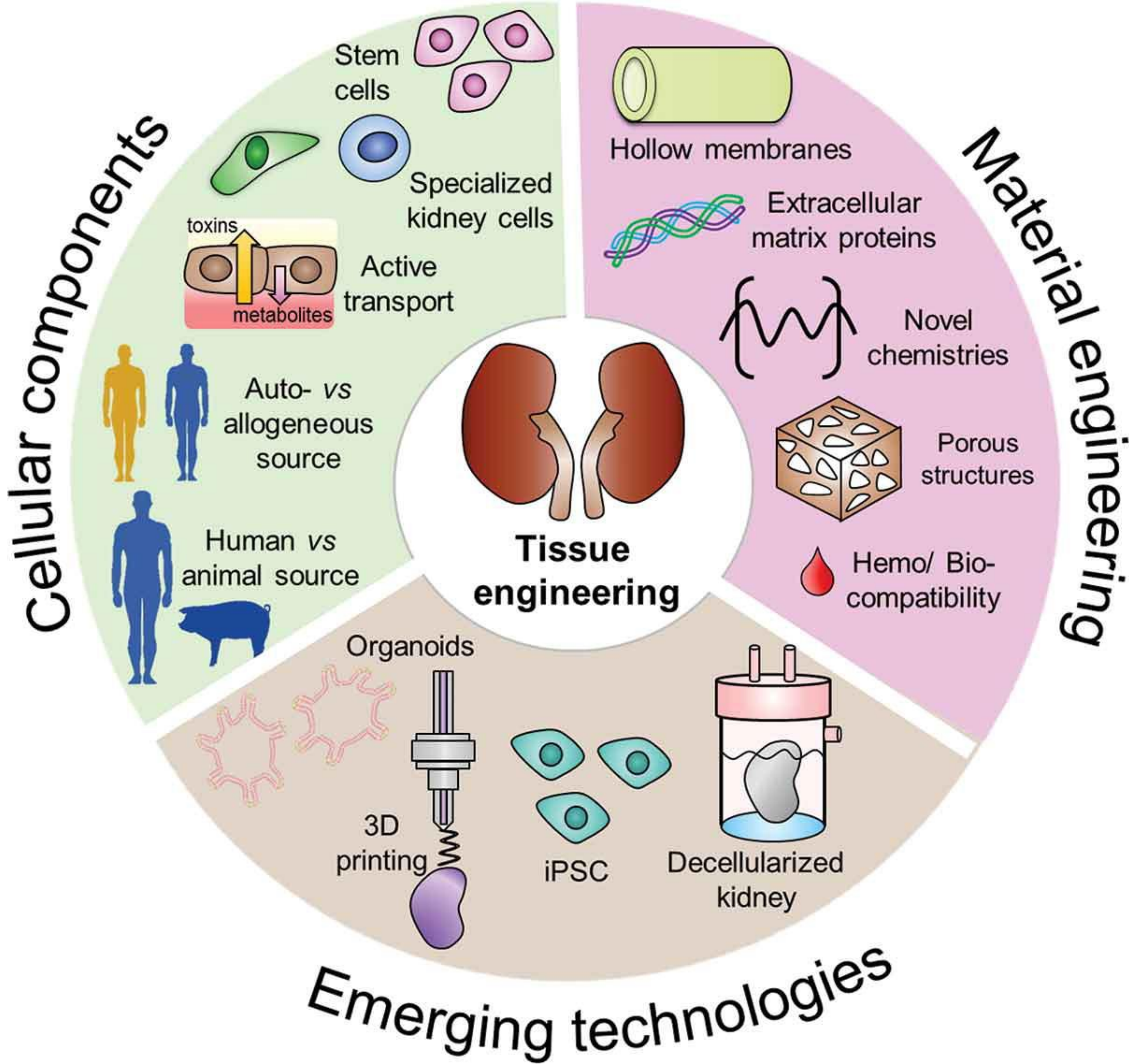


Paper-based analytical devices IPAD

Dipsticks



Microcell-based devices



Taylor & Francis
Taylor & Francis Group

Expert Review of Medical Devices

ISSN: 1743-4440 (Print) 1745-2422 (Online) Journal homepage: https://www.tandfonline.com/loi/ierd20

From portable dialysis to a bioengineered kidney

Maaike K. van Gelder, Silvia M. Mihaila, Jitske Jansen, Maarten Wester, Marianne C. Verhaar, Jaap A. Joles, Dimitrios Stamatialis, Roos Masereeuw & Karin G. F. Gerritsen

I tre filoni che possono migliorare la

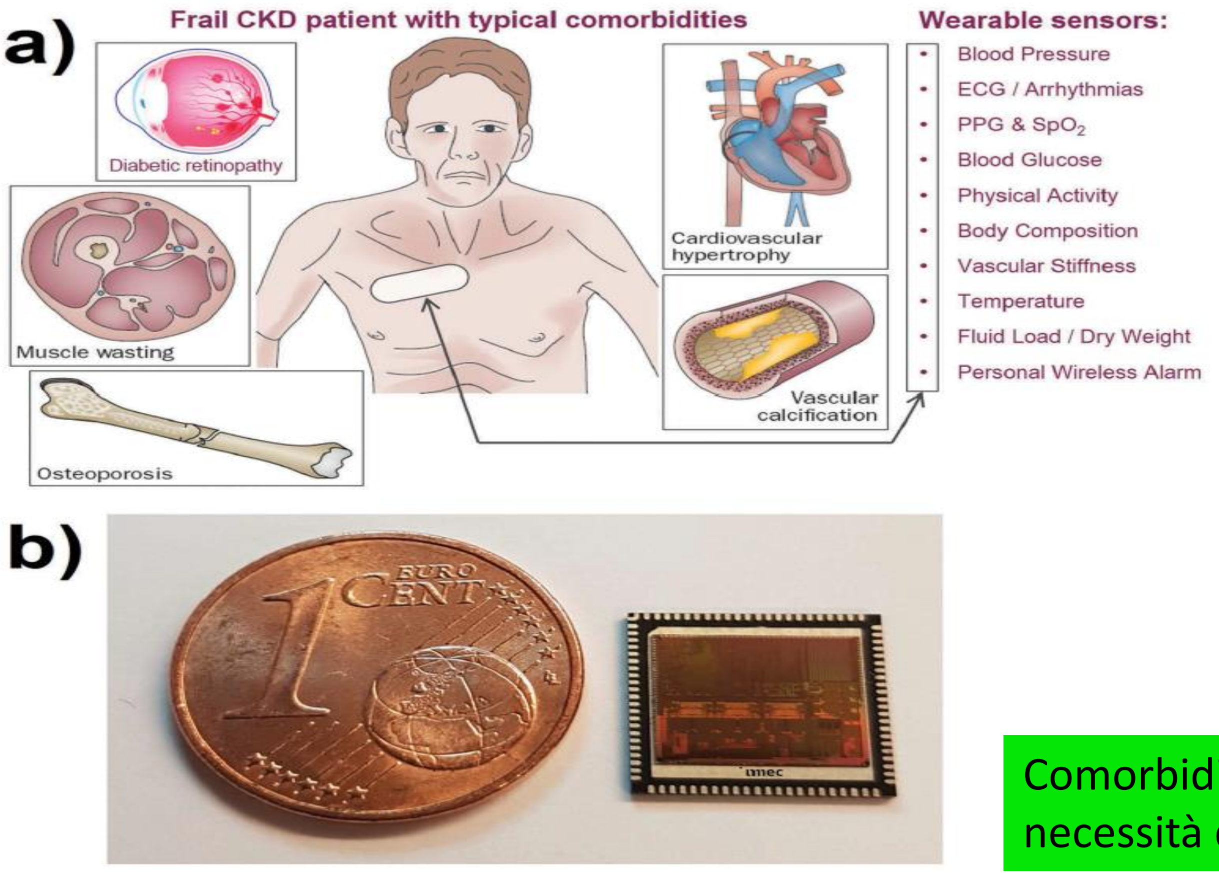
- Componenti cellulari
- Ingegnerizzazione dei materiali
- Tecnologie emergenti

EXPERT REVIEW OF MEDICAL DEVICES, 2017
VOL. 14, NO. 7, 505–519
https://doi.org/10.1080/17434440.2017.1342533

REVIEW

Wearable sensors: can they benefit patients with chronic kidney disease?

Fokko Pieter Wieringa[a,b], Natascha Juliana Hendrika Broers[b], Jeroen Peter Kooman[c], Frank M. Van Der Sande[c] and Chris Van Hoof[a,d]



Pressione BPM
ECG
SpO2
Glucosio
Attività fisica
Body composition
Stifness vascolare
Temperatura
Sovraccarico Fluidi
Allarmi WiFi personalizzati

Comorbidità associate ai pazienti CKD e la necessità di sviluppare sensori portatili

Figure 4. (a) Monitoring opportunities for wearable devices in CKD management, illustration adapted and modified (with permission) from Kooman *et al* [35]. (b) Example of a modern system-on-chip (SoC) with on-board digital signal processing and multi-parameter monitoring capability for several days on a single (2.9–4.5V) battery charge. On-board measurement modalities: 3 ECG channels, PPG (2 photodetector & 4 LED channels), galvanic skin response (GSR), multi-frequency bio-impedance (BIO-Z) channels, and 3 reconfigurable analog channels (e.g. for EEG, EMG). Shown is an 7x8mm unpackaged bare chip laid on top of a 10x10mm packaged chip (photo imec).

eHealth – Home monitoring devices

A randomized trial that included 601 patients with CKD found that an eHealth intervention that used home monitoring devices to obtain biometric data (for example, blood pressure and weight) and deliver multidisciplinary care

Crowley, S. T. et al. Targeting access to kidney care via telehealth: the VA experience. Adv. Chronic Kidney Dis. ***24****, 22–30 (2017).*

reduce mortality
hospitalization rates
emergency department visits
nursing home admissions

NO

**when compared with usual care*

- 91% of participants completed 1 year of follow-up
- 14.2 completed virtual visits
- 14.9 blood pressure measurements per month and
- used the educational modules on 5.8 days per month

Multiple other studies have reported high participant satisfaction with kidney eHealth interventions for a variety of reasons, including ease of use, low burden and increased frequency and quality of interactions with health- care staff

Stevenson, J. K. et al. eHealth interventions for people with chronic kidney disease. Cochrane Database Syst. Rev. ***8****, CD012379 (2019)*

Cochrane
Library

Cochrane Database of Systematic Reviews

eHealth interventions for people with chronic kidney disease (Review)

Stevenson JK, Campbell ZC, Webster AC, Chow CK, Tong A, Craig JC, Campbell KL, Lee VWS

A Cochrane review of randomised controlled trials of electronic health in chronic kidney disease including dialysis found **limited evidence of advantage** other than possible benefits for dietary sodium intake and fluid management.

Stevenson JK, Campbell ZC, Webster AC, et al. *eHealth interventions for people with chronic kidney disease.*

Cochrane Database Syst Rev 2019; 8: CD012379.

Cuff- less blood pressure devices based on pulse transit time have been found to correlate with oscillometric measurements in research settings, but the **accuracy depends on posture and the devices require frequent calibration**

Park, S. H., Zhang, Y., Rogers, J. A. & Gallon, L. Recent advances of biosensors for hypertension and nephrology. *Curr. Opin. Nephrol. Hypertens.* **28**, 390–396 (2019).

Many wearable devices will require additional validation before clinical use. Clinicians and patients must remain vigilant about the potential for errors, particularly if eHealth tools are used in place of traditional monitoring without full validation.

Second, patients with kidney disease have complex needs that can make remote monitoring via eHealth tools less suitable than traditional face- to- face care. Certain aspects of the physical exam, such as examination of catheter exit sites, may be difficult to perform via video consultation. The physical presence of the provider may also be reassuring and comforting for patients with emotional distress4,5

CE

Per ottenere il marchio CE non servono indagini cliniche

FDA CLEARED

FDA valuta i dati clinici di registri / studi

RESEARCH

OPEN ACCESS

CrossMark
click for updates

Comparison of rates of safety issues and reporting of trial outcomes for medical devices approved in the European Union and United States: cohort study

Thomas J Hwang,[1,3] Elisaveta Sokolov,[2] Jessica M Franklin,[3] Aaron S Kesselheim[3]

BMJ: first publis

BMJ 2011;342:d2748 doi: 10.1136/bmj.d2748 (Published 14 May 2011) Page 1 of 6

FEATURE

MEDICAL DEVICES

Europeans are left to their own devices

When it comes to medical devices, Europeans seem to get a worse deal than US patients. **Deborah Cohen** and **Matthew Billingsley** compare the regulatory systems

36.6 mesi in meno per avere l'autorizzazione al commercio In Europa

2.9 volte in più le segnalazione di incidenti in Europa

REGULATIONS

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

(Text with EEA relevance)

BMJ 2011;342:d2748 doi: 10.1136/bmj.d2748 (Published 14 May 2011)

FEATURE

MEDICAL DEVICES

Europeans are left to their own devices

When it comes to medical devices, Europeans seem to get a worse deal than US patients. **Deborah Cohen** and **Matthew Billingsley** compare the regulatory systems

Medical device regulation in Europe – what is changing and how can I become more involved?

Cardiovasc Intervent Radiol (2019) 42:1272–1278
https://doi.org/10.1007/s00270-019-02247-0

CIRSE

Check for updates

REVIEW

New European Regulation for Medical Devices: What Is Changing?

Nicolas Martelli[1,2] · Déborah Eskenazy[2] · Carole Déan[3] · Judith Pineau[1] · Patrice Prognon[1] · Gilles Chatellier[4] · Marc Sapoval[3,5,6] · Olivier Pellerin[3,5,6]

Clin Orthop Relat Res (2020) 00:1-3
DOI 10.1097/CORR.0000000000001154

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

Editorial

Published online: 29 January 2020

Guest Editorial: New Medical Device Regulation in Europe: A Collaborative Effort of Stakeholders to Improve Patient Safety

Emmanuel Thienpont MD, MBA, PhD, Gianluca Quaglio MD, PhD, Theodoros Karapiperis PhD, Per Kjaersgaard-Andersen MD, PhD

2020 → 2021

FDA CLEARED

FDA valuta i dati clinici prima di autorizzare

CE

Per ottenere il marchio CE SEVIRANNO dati clinici

(4) Al fine di migliorare la salute e la sicurezza è opportuno rafforzare profondamente alcuni elementi chiave dell'attuale approccio normativo, quali la supervisione degli organismi notificati, le procedure di valutazione della conformità, le indagini cliniche e la valutazione clinica, la vigilanza e la sorveglianza del mercato, e introdurre nel contempo disposizioni che garantiscano la trasparenza e la tracciabilità dei dispositivi medici.


European Commission

Is your software a

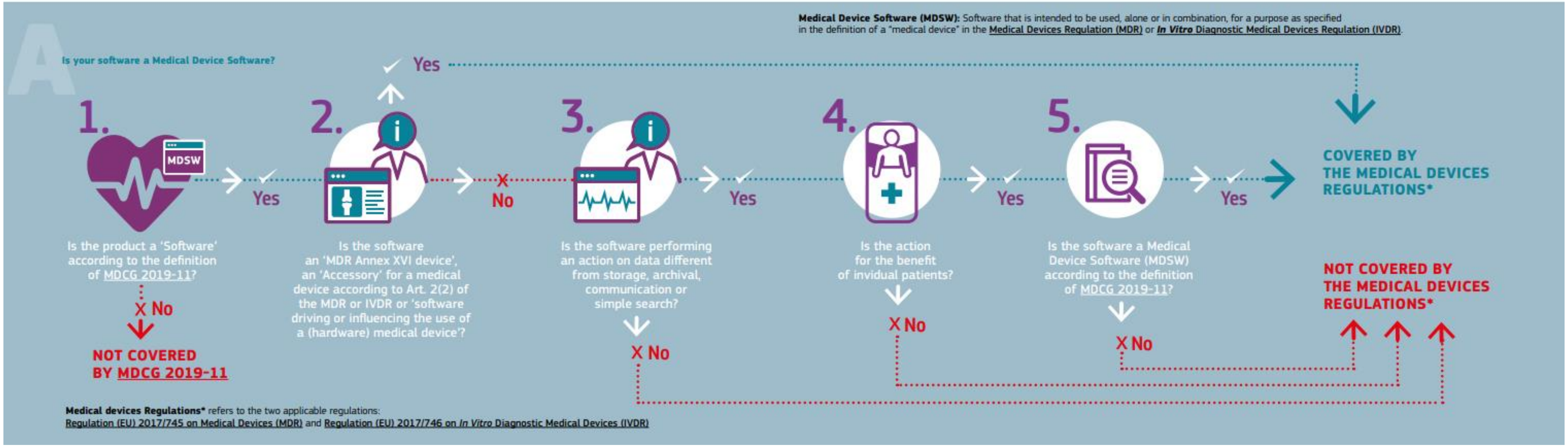
Medical Device?

MDCG 2019-11

Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR

October 2019

Decision steps to assist qualification of Medical Device Software (MDSW)



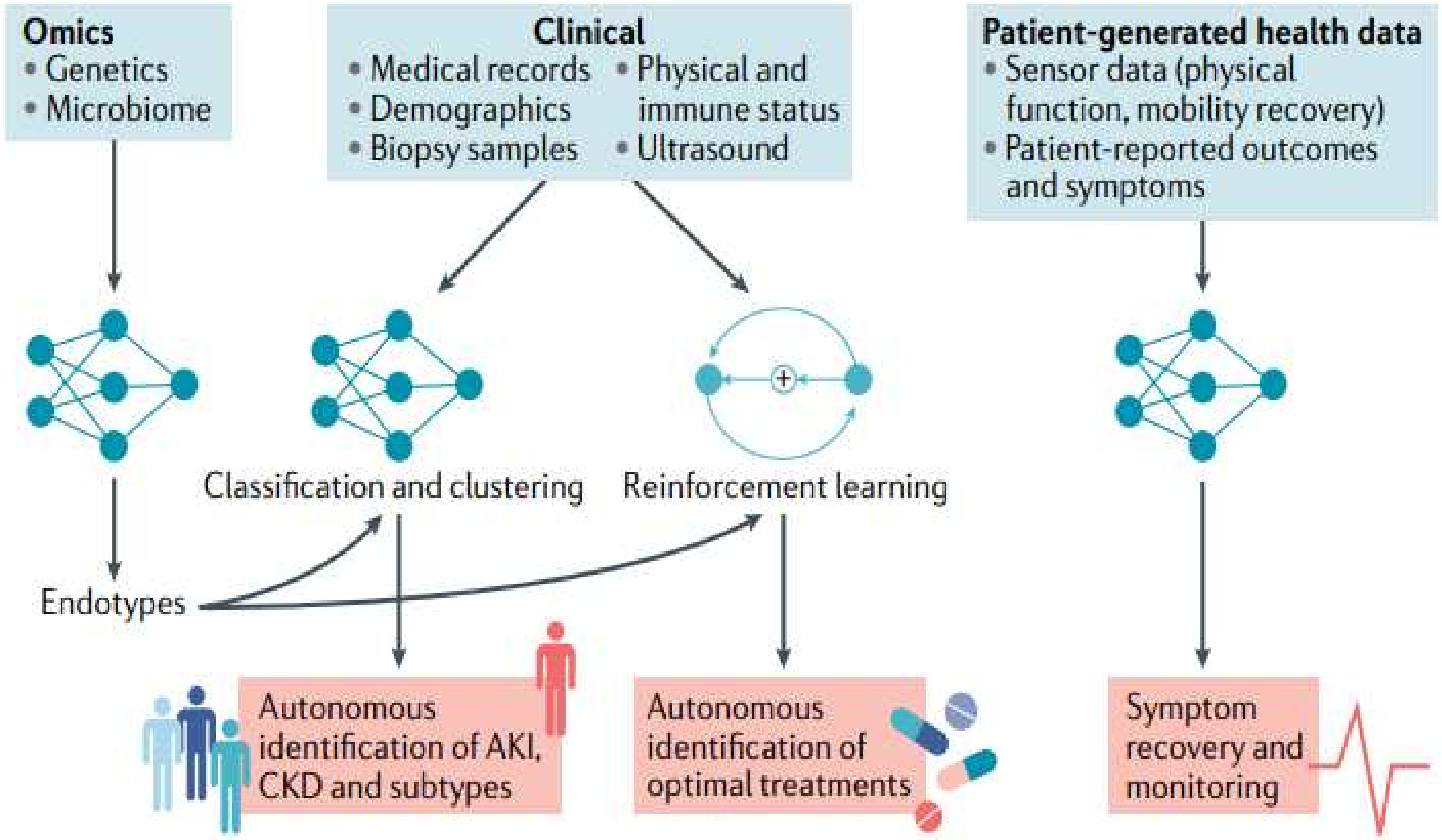


Fig. 1 | **A conceptual framework for the future use of artificial intelligence in nephrology.** A variety of omics, clinical and patient-generated health data can power artificial intelligence algorithms for improving the diagnosis and prognostication of acute kidney injury (AKI) and chronic kidney disease (CKD). Omics data can be used to characterize endotypes, which together with clinical information can be used for identification of AKI, CKD and their subtypes and optimal treatments. Patient-generated health data obtained from wearable sensors and mobile health applications also can be helpful for monitoring symptoms and recovery, thus providing a comprehensive pipeline for diagnosis, treatment and recovery monitoring.

nature reviews nephrology

ARTIFICIAL INTELLIGENCE IN NEPHROLOGY IN 2019

Artificial intelligence approaches to improve kidney care

Parisa Rashidi and Azra Bihorac

Omica, dati clinici e dati generati dalle cure, possono alimentare algoritmi di intelligenza artificiale per migliorare la DIAGNOSI e la PROGNOSI di AKI e CKD.

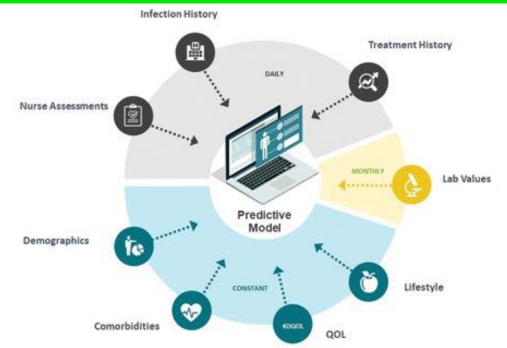
Dati generati dai sensori e mHealt possono migliorare cure, diagnosi e trattamenti

Intelligenza Artificiale – predizione peritoniti

September 03, 2019 | 10 min read SAVE

How artificial intelligence impacts the treatment of kidney disease

E’ stato sviluppato un modello per predirre, nei pazienti in PD, quelli a rischio di sviluppare **peritoniti**



AI in home dialysis

For home therapy, we have developed an ML model to predict patients on PD who are at risk of developing peritonitis in the next month.

AI in vascular access

Renal Research Institute, a specialized research team with expertise in computational biomedicine and data analytics, is working on an AI-based classification model in collaboration with Azura Vascular Care, a network of outpatient vascular and ambulatory surgery centers, to detect and diagnose arteriovenous fistulae aneurysm (AVFA) stages in the United States (defined by an expansion of the intimal, medial and adventitial layers of the vessel wall to a diameter of more than 18 mm)

AI per rilevare e diagnosticare l'aneurisma delle fistole arterovenose

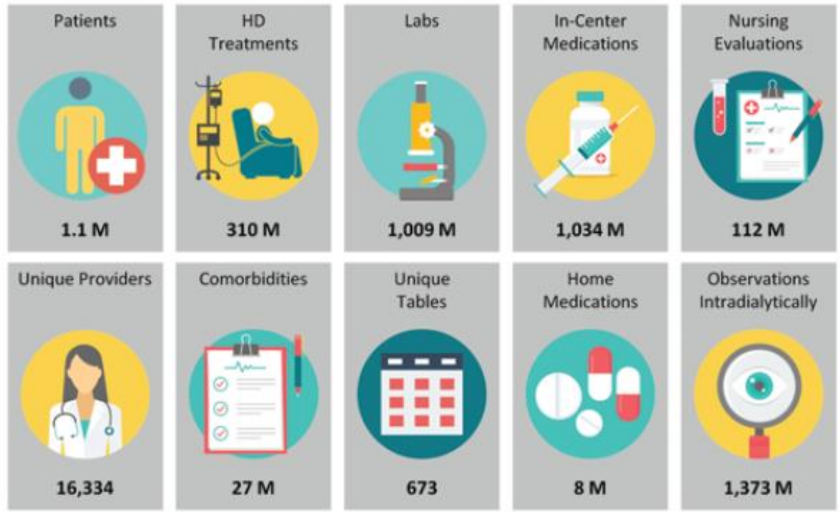


Figure 3: Data collected at an LDO of a large integrated kidney disease care organization in North America (as of June 2018) are shown. This LDO has a vast amount of clinical data collected from more than 1.1 million patients.

GUIDANCE DOCUMENT

Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

Draft Guidance for Industry and Food and Drug Administration Staff

APRIL 2022

Download the Draft Guidance Document   Read the Federal Register Notice

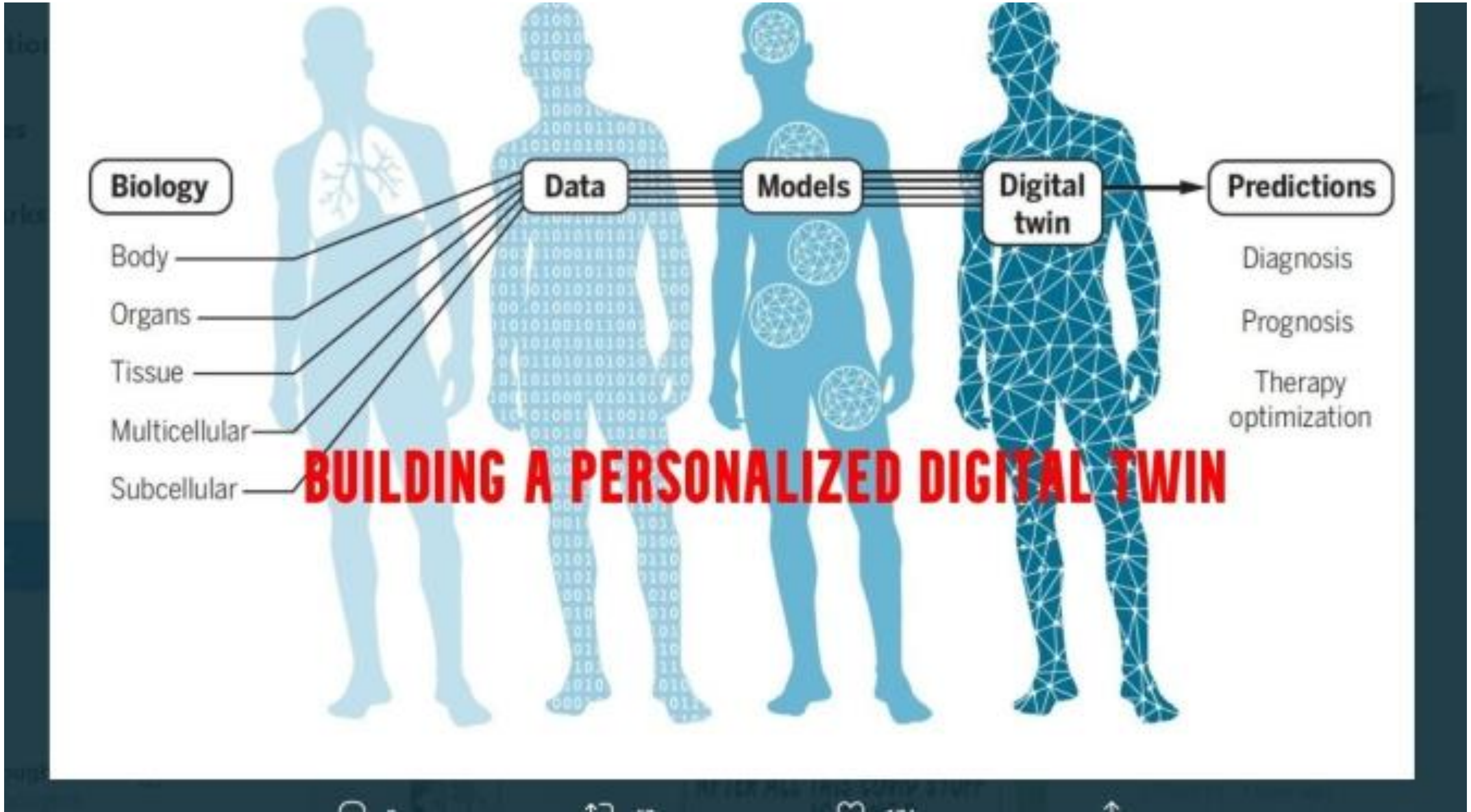
Draft

EU AI Act: first regulation on artificial intelligence

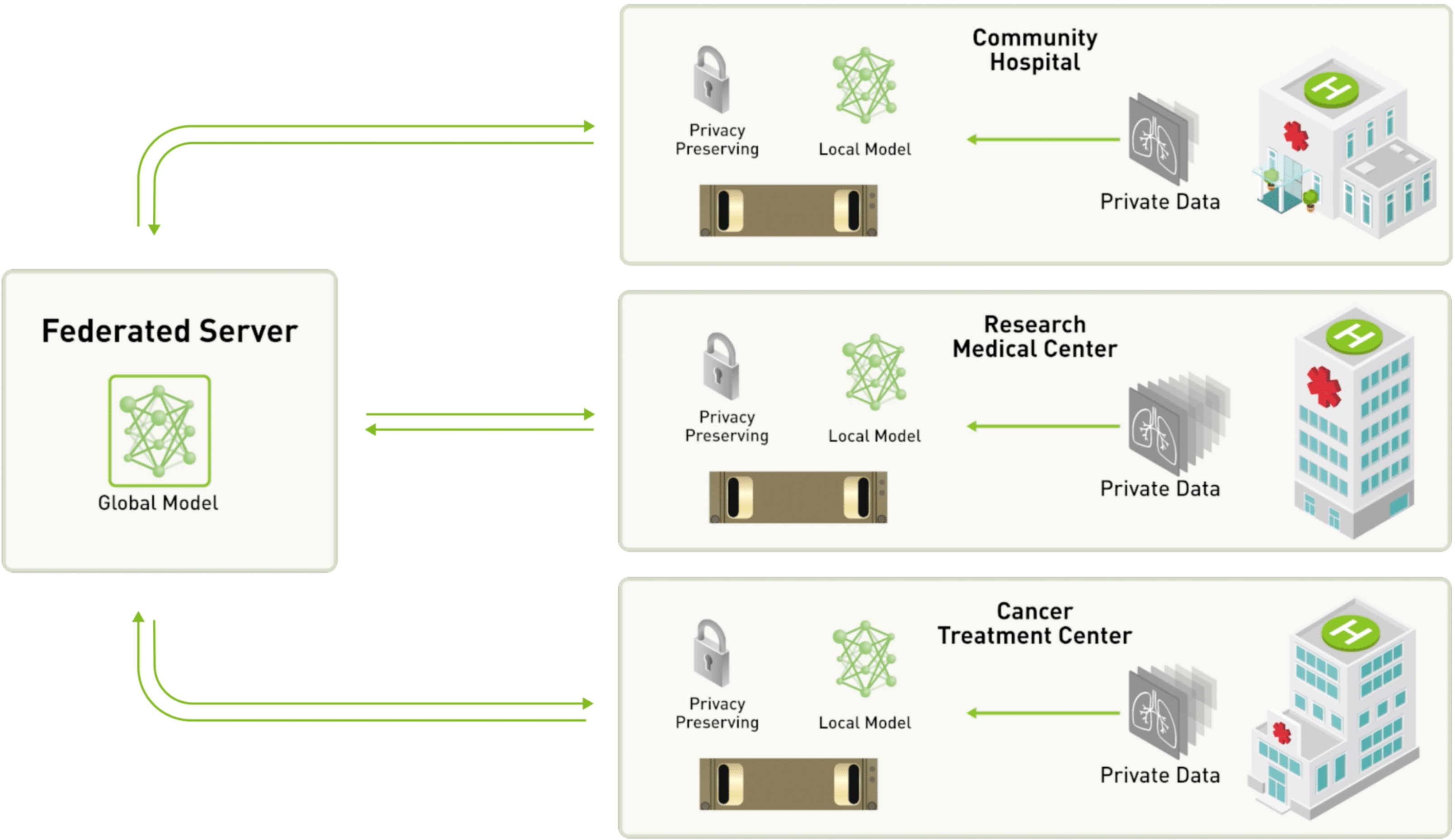
The use of artificial intelligence in the EU will be regulated by the AI Act, the world's first comprehensive AI law. Find out how it will protect you.

Published: 08-06-2023 • Last updated: 19-12-2023 - 11:45

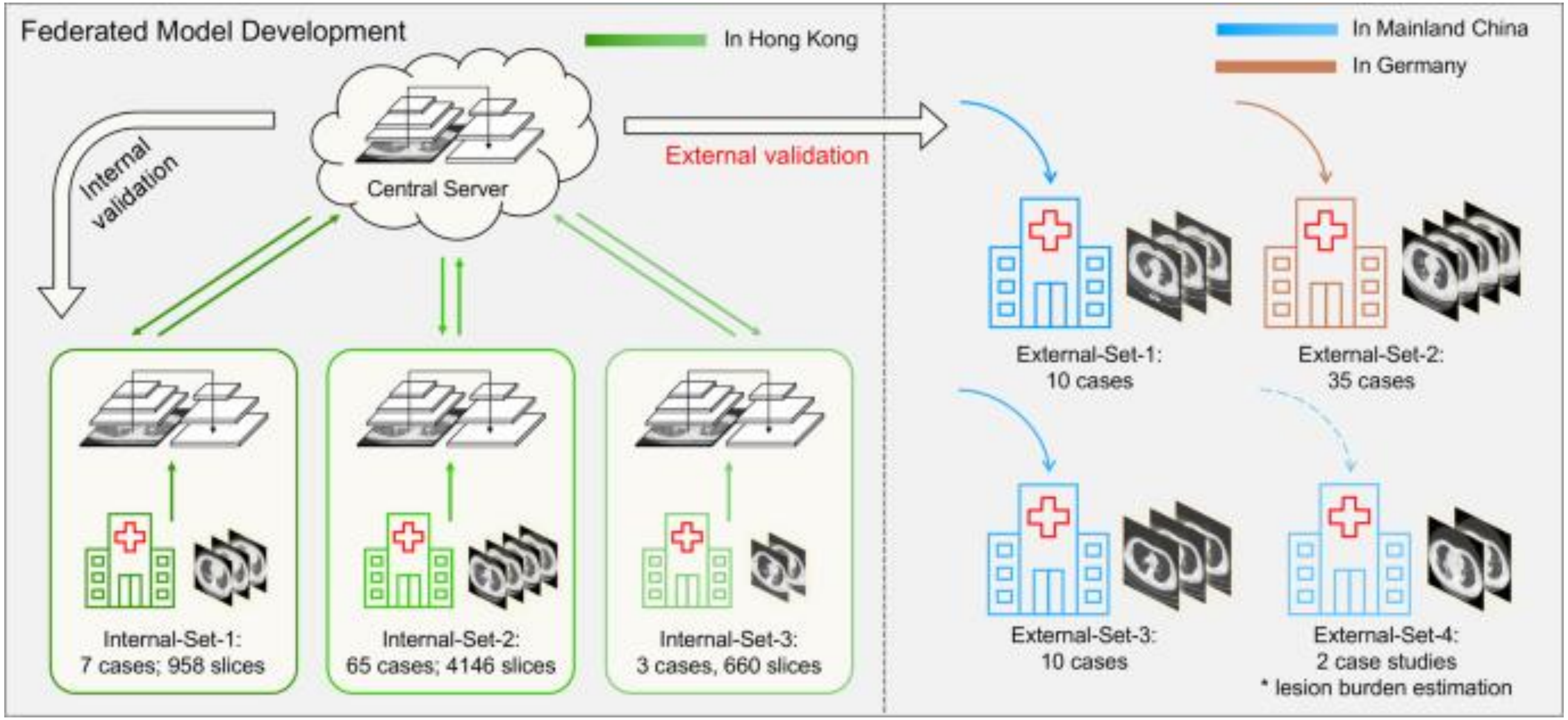
Digital Twin



FEDERATE LEARNING



Federated deep learning for detecting COVID-19 lung abnormalities in CT: a privacy-preserving multinational validation study



Overview of our AI scheme to develop a privacy-preserving CNN (convolutional neural networks**)-based model for detecting CT abnormalities in COVID-19 patients with a multinational validation study.**