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Study Visit no.8

Pomorskie Voivodeship, Gdańsk, Poland

Teledialysis: The First Northeast Italy Experience of Telehealth in Peritoneal Dialysis

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Partner n. 06

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The current and future landscape of dialysis

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Willem Kolff



Belding Scribner



FROM «MIRACLE» TO «MAINSTREAM»



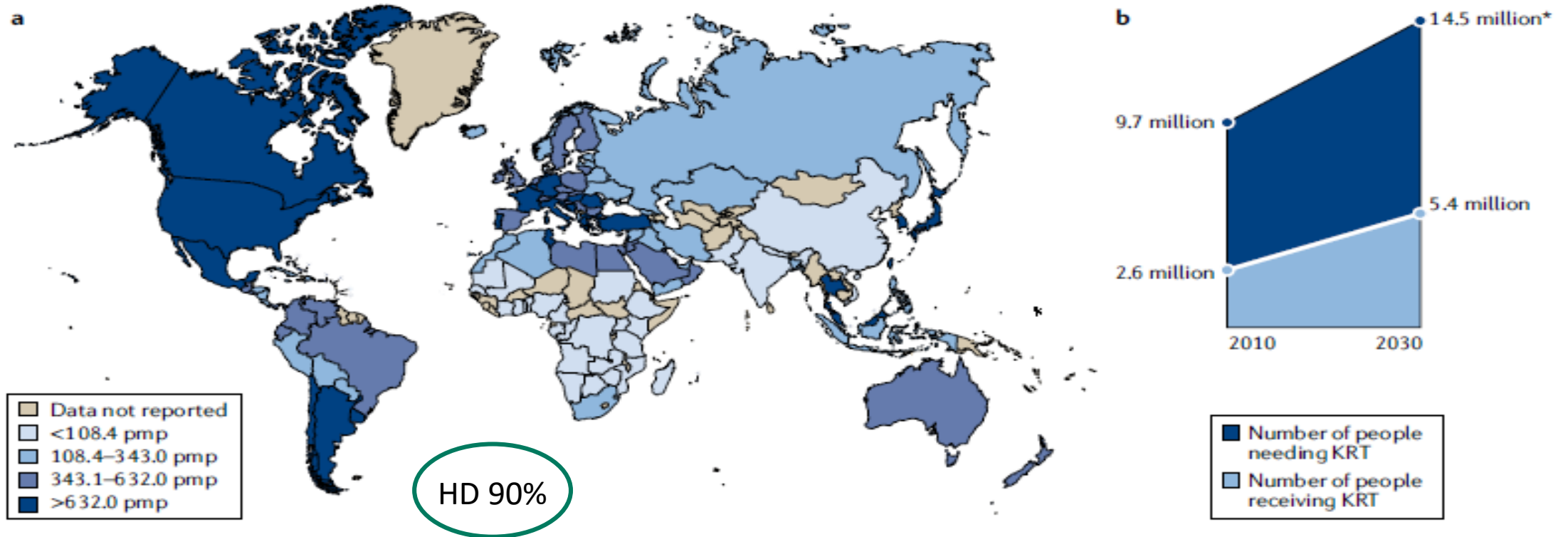
HEMODIALYSIS TRANSPLANT PROGRAM

Criteria for Acceptance

1. Adult <50 yr. of age
2. Renal disease near terminal stage
3. Absence of other disabling disease
4. Emotional stability & cooperativeness
5. Available kidney donor
6. Accessibility to "Dialysis Center"

Slide, Dr. William Johnson

FROM «MAINSTREAM» TO «MIRACLE» ?



Current and projected prevalence of kidney failure requiring kidney replacement therapy

Patient priorities

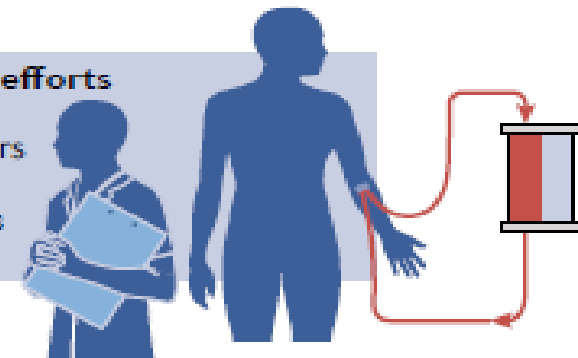
- Physical symptoms (fatigue, insomnia, cramps, pain)
- Mood symptoms (depression, anxiety, frustration, wash-out)
- Rehabilitation priorities (ability to work, ability to travel, impact on family and friends, mobility)

Top-down efforts (by government agencies, societies, NGOs, etc.)

- Regulatory considerations
- Reimbursement and other financial incentives
- Guidance on product development and clinical end points
- Support for comprehensive kidney care strategies
- Policy considerations

Bottom-up efforts

- Patients
- Researchers and innovators



The goal

- Low-cost options
- Miniaturized devices for greater mobility (wearable, portable, implantable)
- Greener, water-efficient technology
- Technology that more closely mimics kidney function
- Better toxin removal
- Improved mortality and morbidity
- Improvements in physical and mood symptoms
- Robust, safe, complication free

KRT: 5-7% of total Health-care budgets

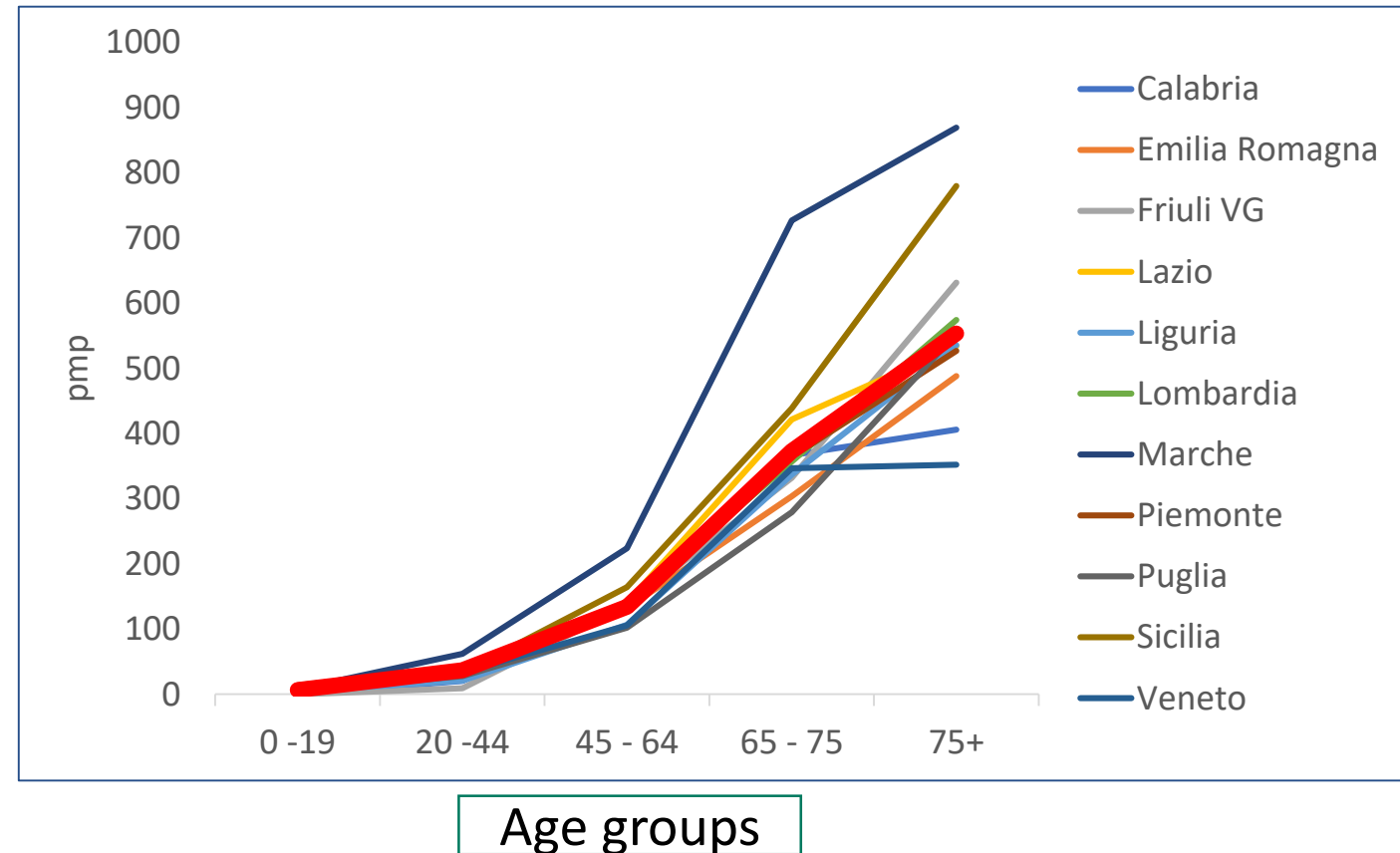
BUT

ESKD: affects only 0.1-0.2% of total population

Nephrology in 2023: An Overview of Italy

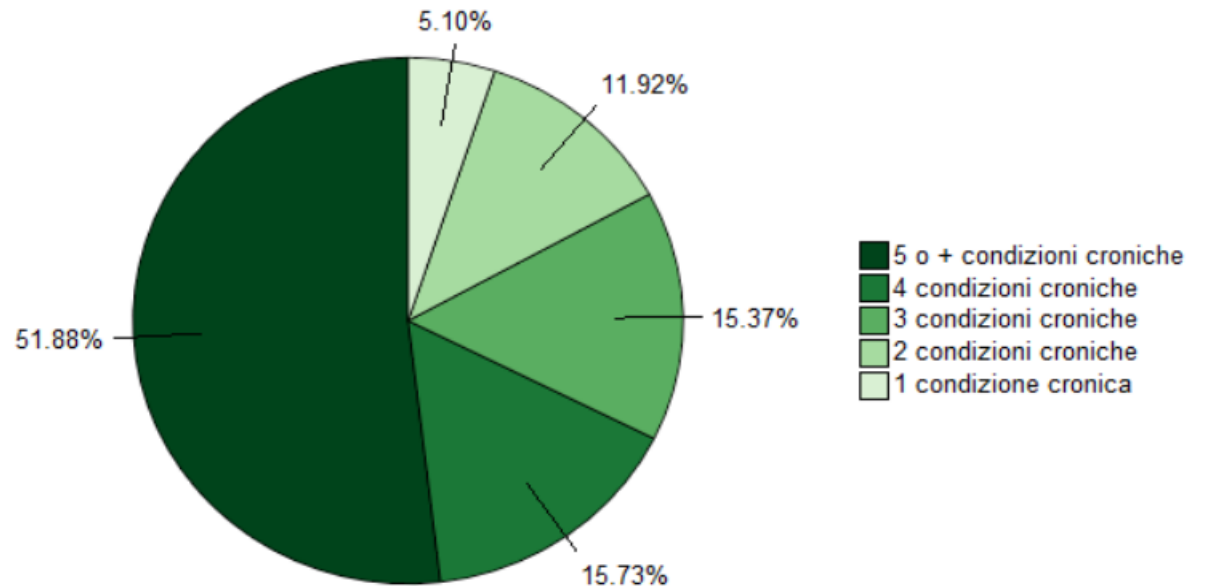
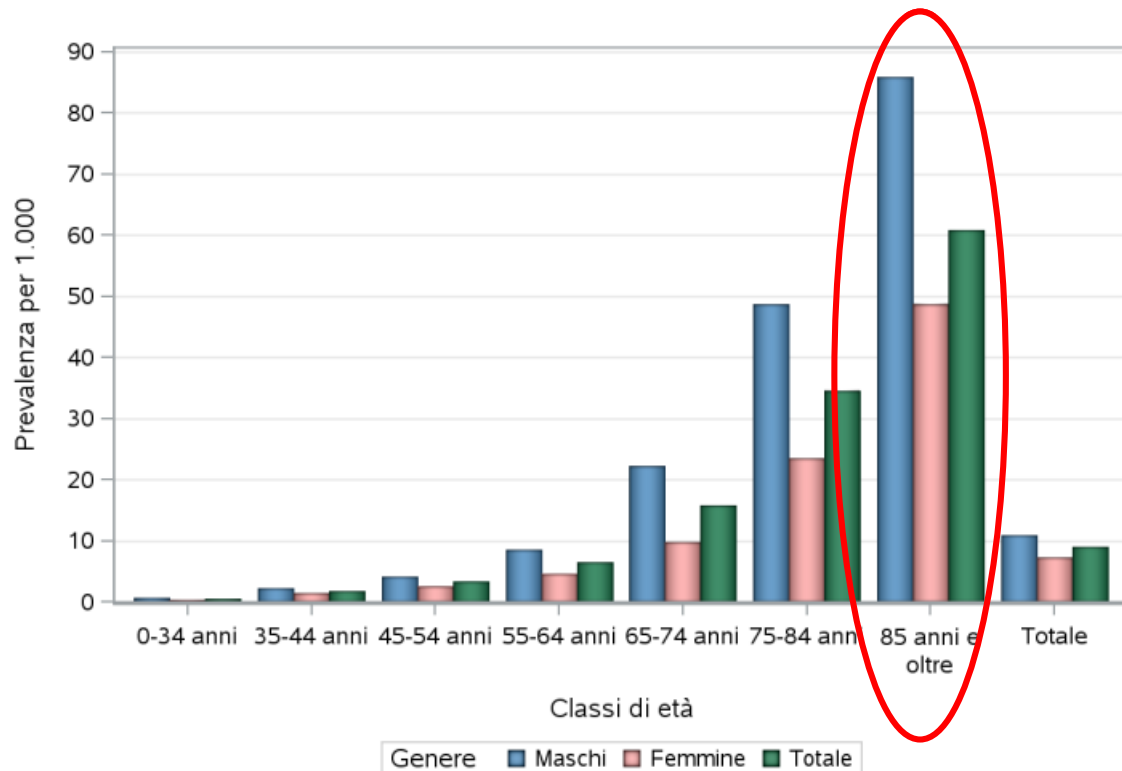


"In Italy, more than 45,000 individuals are undergoing chronic dialysis treatment, equivalent to 788 per million population, while over 8,500 new patients start dialysis each year, corresponding to 160 per million population. Among these, those aged over 70 and over 80 years accounted for 55% and 20% respectively in 2019."



EPIDEMIOLOGY

- Increase in the average age of the general population. 45,476 individuals affected by chronic kidney disease in the Veneto region, with prevalence increasing over the years. 83% have 3 or more associated comorbidities → poor survival rates and inadequate quality of life. Hypertension and type II diabetes are the most common coexisting conditions.



Chronic conditions: require continuous care, resource allocation, and integration of healthcare and social services."

Italian Ministry of Health - National Plan for Chronic Diseases

Objectives of the Plan:

- **Improve the management of chronic diseases** in compliance with scientific evidence.
- Ensure the **appropriateness of healthcare services**.
- Promote the **sharing of Diagnostic-Therapeutic Care Pathways (PDTA)**.
- **List of prioritized chronic diseases** based on epidemiological relevance, severity, disability, healthcare and economic burden, and difficulties in accessing treatment

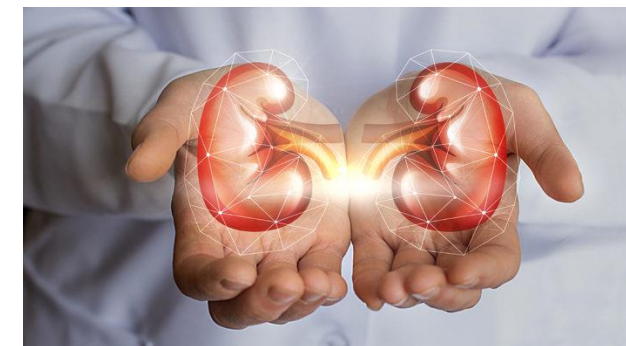
Chronic rheumatic diseases

Chronic kidney diseases and renal insufficiency

Chronic intestinal diseases

Chronic cardiovascular diseases

Neurodegenerative diseases



National Plan for Chronic Diseases

Key Challenges in Chronic Kidney Disease (CKD)

- Excessive reliance on unplanned, emergency dialysis initiation;
- Limited availability and integration of **peritoneal dialysis and home hemodialysis programs**;
- **Suboptimal utilization of telemedicine and digital health technologies for remote patient monitoring and management ;**
- Insufficient coordination between nephrology care units and dialysis facilities, leading to fragmented patient care.



«Tailored» Dialysis Therapy

Self-sufficient Patient: Home Dialysis



Elderly, Self-sufficient Patient: Home Dialysis or Dialysis in Nursing Homes or Day Care Centers (Social Aspects)

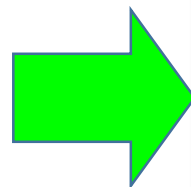


Partially Self-sufficient Patient: Peritoneal Dialysis (PD) or Home Hemodialysis (HDD) with Caregiver Support and the use of Telemedicine in Nephrology and Teledialysis

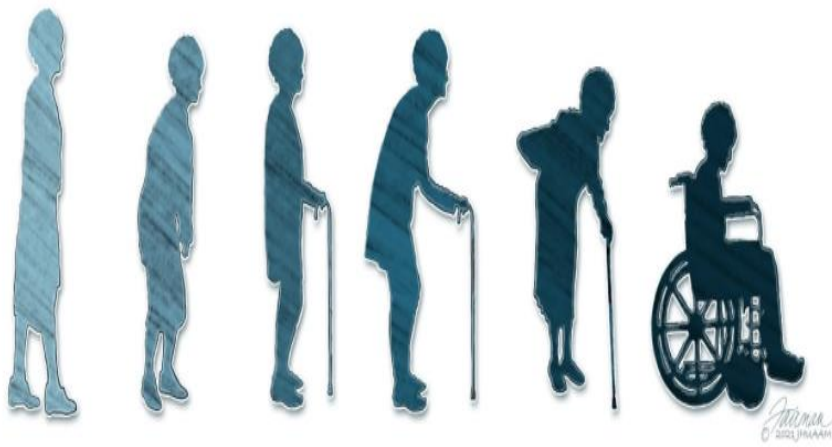


Non-self-sufficient Patient, without Caregiver, Unstable/Critically Ill: In-Hospital Hemodialysis





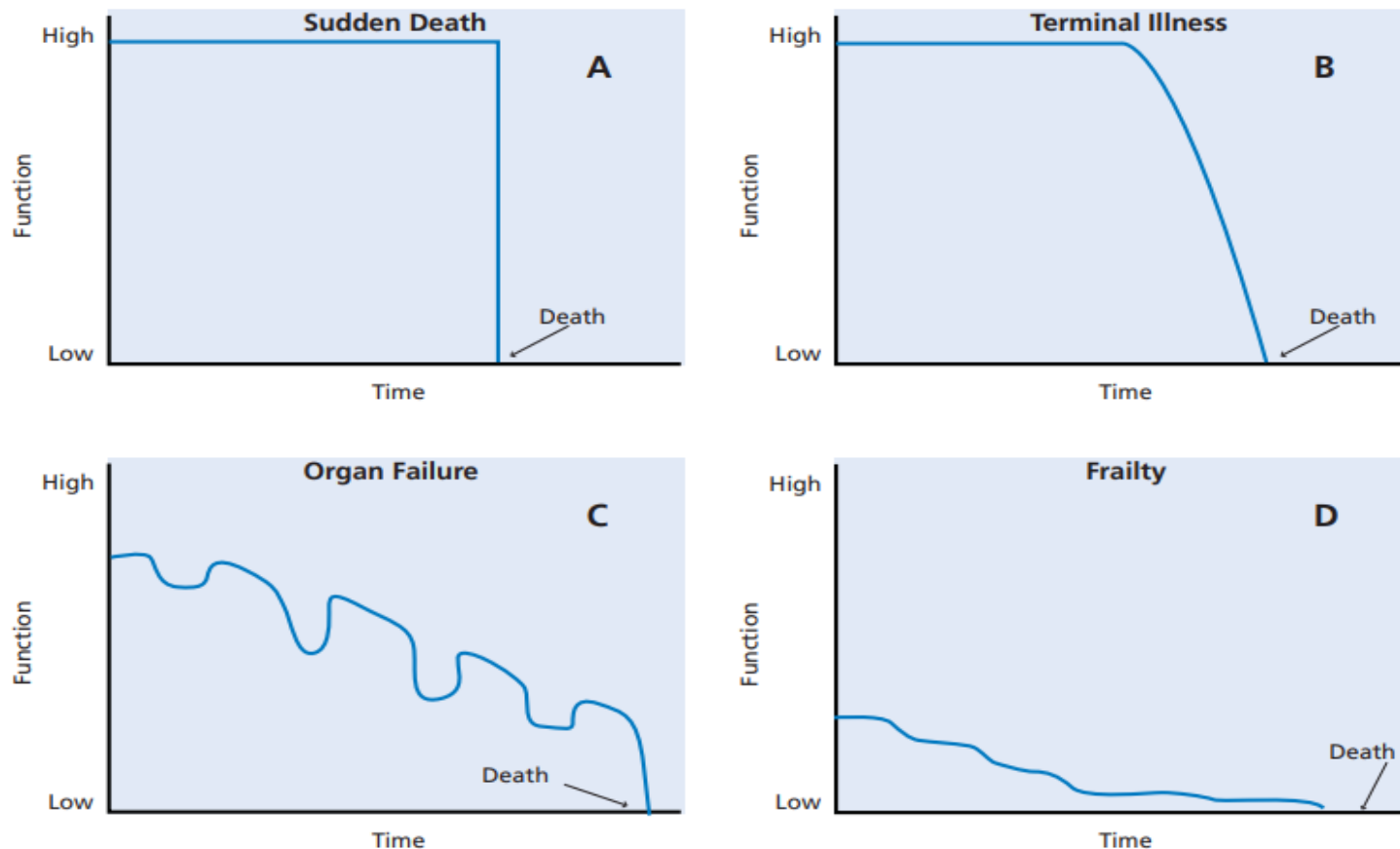
Advanced age;
Multiple associated comorbidities;
Malnutrition;
Cognitive impairment;
Reduced functional autonomy;
Subjects with repeated hospitalizations



Under these conditions, RRT is associated with limited survival, even lower than that of many types of cancer, and with a decline in quality of life and loss of functional autonomy.

Pathways Project: Development of a Multimodal Innovation To Improve Kidney Supportive Care in Dialysis Centers

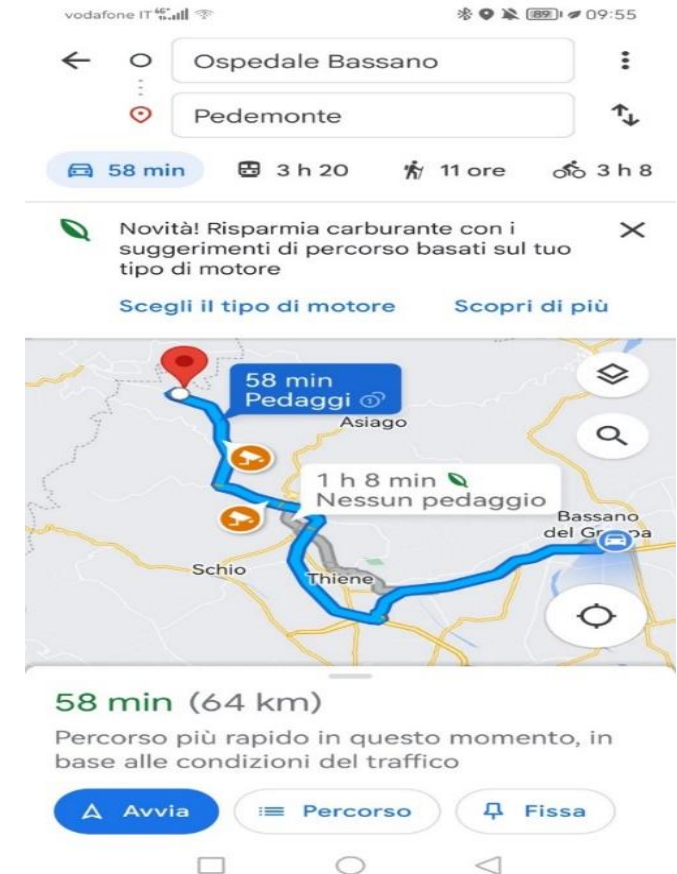
Disease Trajectory



Palliative RRT

CKD «D Pattern» Elderly

Nephrology Services in the AULSS7 Pedemontana Region



District Population: 180,040; **District 2 Population:** 186,389; **Total:** 366,429
Distances: Up to 64-71 km to reach the hospital

Nephrology Activities 2021: AULSS7 Pedemontana

Outpatient Clinic (N. Pts)

3 Hospitals

Bassano del Grappa

Santorso

Asiago

Bassano del Grappa: (3,308)

Santorso: (3,274)

Asiago: (194)

Hemodialysis: (169) [Bassano + Santorso + Asiago]



Pre-Dialysis Clinic: (127)

Glomerular Disease Clinic: (141)

Peritoneal Dialysis Clinic: (43)

Transplant Clinic: (86)

Kidney Stone Clinic: (142)

Vascular Access Clinic: (41)

Total: 7,525 patients

111 Transplant patients followed by other healthcare authorities: 68

Pediatric nephrology patients: 41

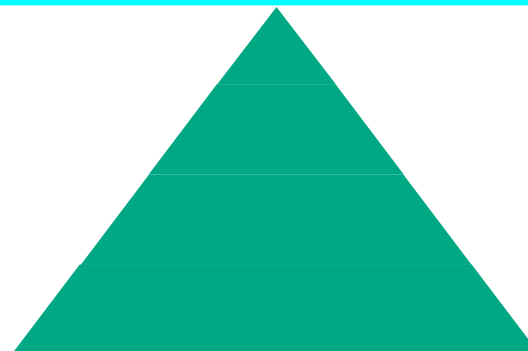
Economic Analysis : Comparative Analysis in Hemodialysis VS Peritoneal Dialysis

COSTS	Session Cost €			Monthly Cost €	
Direct Costs	Bic-HD	APD		Bic-HD	APD
Physicians (h)	30,00	2,00		463,75	106,00
Nurses (h)	28,75	1,53		212,45	86
Laboratory, Equipments, Supplies	62,67	15,33		819,09	510
Trasports*	52	2		650	50
Total	171,76	20,53		2.232,90	616,00
Indirect Costs		-			
Water Treatment and Microbiology	19,57	-		254,43	0
Patient Cost					
Loss of workdays	3	NO			
TOTAL	191,33	20,53		2487,33	722,00

TECHNOLOGIES



RESOURCES



WHAT HINDERS THE PRESCRIPTION OF PERITONEAL DIALYSIS?

1. Patients' fear of being inadequate in learning how to manage home treatment (fear of failure);
2. The perception of receiving lower quality and less effective care;
3. Concern about not receiving adequate medical supervision;
4. Fear that home treatment will burden the family.



Nephrologists prescribe home dialysis infrequently because they fear that patients may underestimate certain symptoms and fail to contact the center promptly, or because they fear not having the tools to assess patients' adherence to the treatment

Telemedicine

Definition according to the WHO:

A method of delivering healthcare services using innovative technologies, which does not replace traditional healthcare, but provides a set of tools aimed at improving effectiveness, efficiency, and appropriateness.

REMOTE MONITORING

- allows for the supervision of patients from a distance through regular interactions with healthcare professionals, combined with the sharing of clinical data collected by the patient..

TELECONSULTATION

- is a medical act in which a healthcare professional remotely interacts with one or more other physicians to agree on the continuation of the diagnostic-therapeutic pathway.

TELEMONITORING

- allows for the real-time detection and remote transmission of vital signs and clinical parameters.

TELEASSISTENCE

- s a professional act that relies on remote interaction between the healthcare professional and the patient or caregiver through a video call.

Telemedicine: National and Regional Guidelines

The use of telemedicine tools is defined by guidelines issued by the Ministry of Health and approved by the "State-Regions Conference." On October 27, 2020, the "National Guidelines for the Provision of Telemedicine Services" were published.



On September 21, 2022, new ministerial guidelines were published and approved for "technological innovation and digital transition." These documents define the various aspects of telemedicine services and propose a classification of these services according to different areas of application (Official Gazette - November 2, 2022).



Telemedicine

Based on current knowledge, telemedicine applications can be useful, if not crucial, for certain healthcare objectives.

Here are the main ones:

PREVENTION	<ul style="list-style-type: none"> • Tool for primary, secondary, and tertiary prevention. Telemedicine can be utilized both in screening activities and in the type of prevention aimed at individuals who already have conditions that require long-term monitoring.
DIAGNOSIS	<ul style="list-style-type: none"> • Move diagnostic information instead of the patient,” for example, by facilitating the ability of a physician working in Spoke centers to connect with Hub centers for a second opinion from other specialists.
THERAPY	<ul style="list-style-type: none"> • Remote healthcare assistance, particularly in cases of chronic conditions. It allows for the ongoing evaluation of therapeutic options and the progression of the clinical status of patients who require long-term care.
MONITORING	<ul style="list-style-type: none"> • The ability to remotely monitor the patient with real-time parameters or to complement clinical evaluation retrospectively.

Expected benefits driving the development and adoption of telemedicine models, techniques, and tools in chronic disease management

Equity of Access to Healthcare	Equity of access and the availability of qualified healthcare in remote areas can be greatly enhanced through the use of telemedicine.
Continuity of Care and Improved Quality of Assistance	Telemonitoring can improve the quality of life for chronic patients through self-management solutions and remote monitoring, also aimed at early hospital discharge.
Improved Effectiveness, Efficiency, Appropriateness	It reduces risks related to complications, decreases hospital admissions and optimizes the use of available resources. Timely information enables the measurement of healthcare processes using outcome indicators.
Costs Optimization and expenditure control	Streamlining of social and healthcare processes , which can have a significant impact on cost containment, reducing healthcare expenditures, waiting lists, and other associated burdens.
Contribution to economy	Telemedicine and e-health represent one of the most innovation-driven sectors in the industry.

Our Experience

The main goal was to **increase the use of peritoneal dialysis** among dialysis patients, reducing the incidence of patients undergoing hemodialysis and minimizing drop-out rates from the method.

Objectives:

Training: To provide personalized and flexible remote teaching to patients or caregivers on the correct execution of dialysis procedures and wound care.

Assistance (Virtual Partner): To offer support in case of questions or guidance on specific procedures.

Remote Visits: To intensify the monitoring of patients with complex clinical conditions or those with difficulties accessing the center for regular check-ups.

Our Experience: Materials and Methods



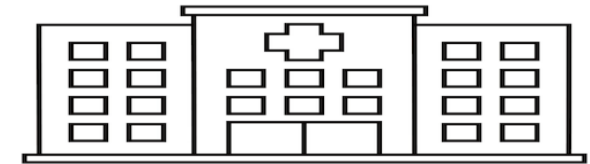
TOTEM: The remote station consists of a self-supporting and portable structure that connects to the internet in a “plug and play” mode, using either fixed or mobile connectivity.

CHARACTERISTICS

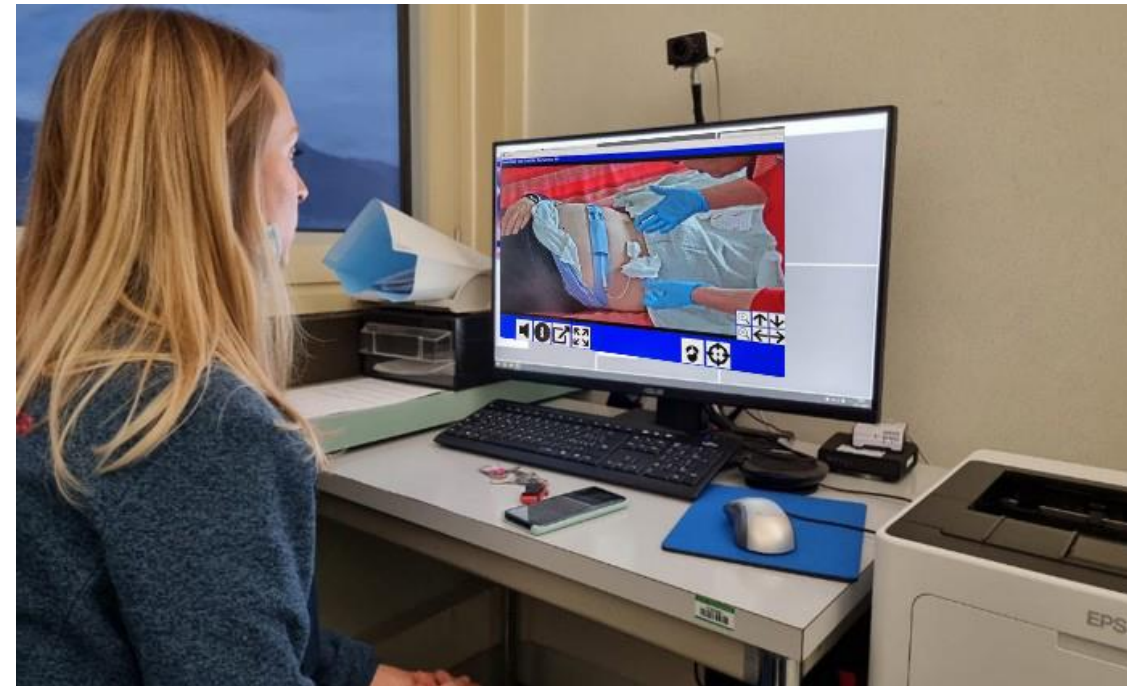
- Transportable self-supporting structure;
- High-performance camera;
- 15' touch screen monitor;
- Speakerphone;
- internal router;
- plug-and-play system;
- simple call answering;



ET-8000

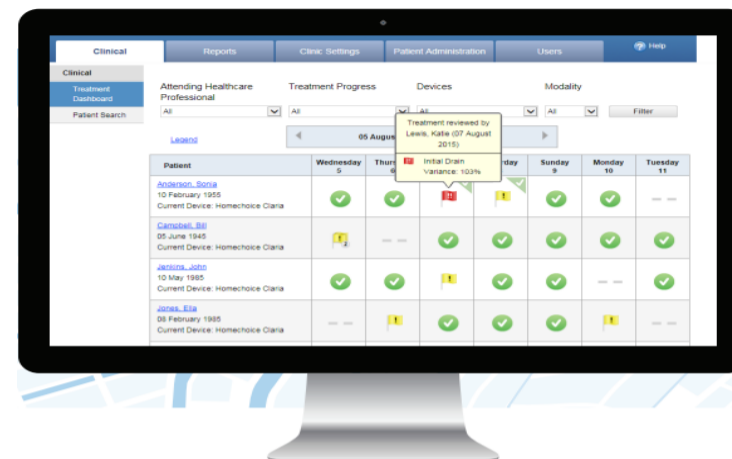


CONTROL STATION: Located at the site where healthcare personnel perform remote care and assistance operations. It consists of a desktop computer with a high-resolution monitor and a dedicated camera.

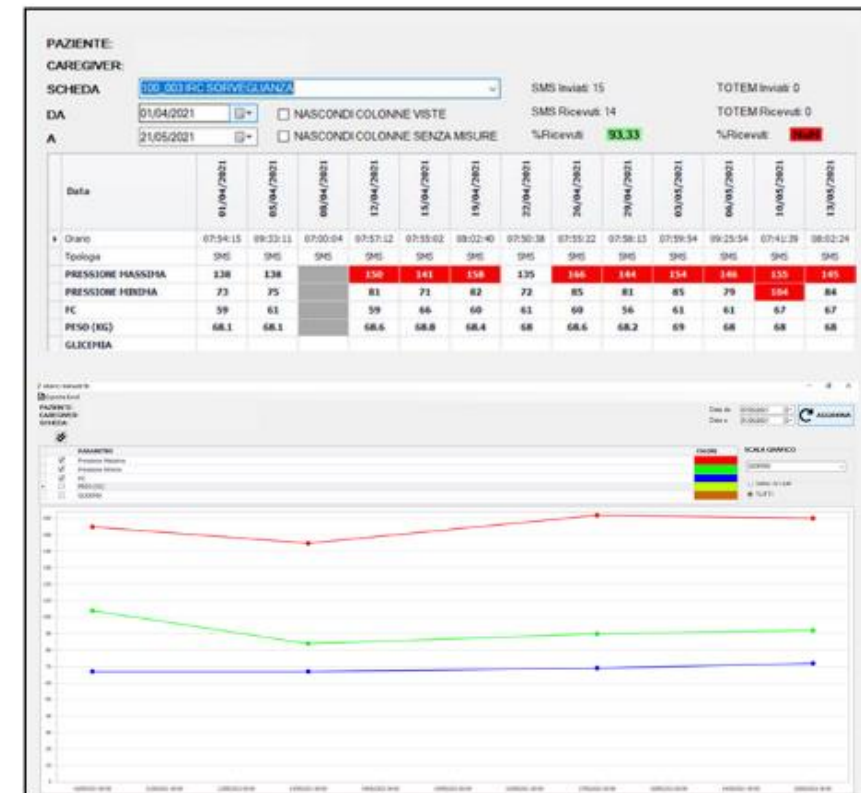


INFORMATICS CONTROL CENTER: Allows for monitoring, assistance, and online updates of the entire network implemented with the TESI eViSuS® system. - A web platform integrated with APD devices enabling remote management of home dialysis.

SHARESOURCE (BAXTER): Provides visibility into the progress of the prescribed automated dialysis therapy, allows for adjustments, and monitors patient adherence to the dialysis treatment



eViSuS® BIOCARE: Collection of clinical parameters through questionnaires sent via SMS/APP to the patient/caregiver, subsequently gathered in a dashboard that allows quick and intuitive visualization of the monitored patients' status.



PROACTIVE MANAGEMENT

CORRECTIVE MANAGEMENT

PREVENTIVE MANAGEMENT

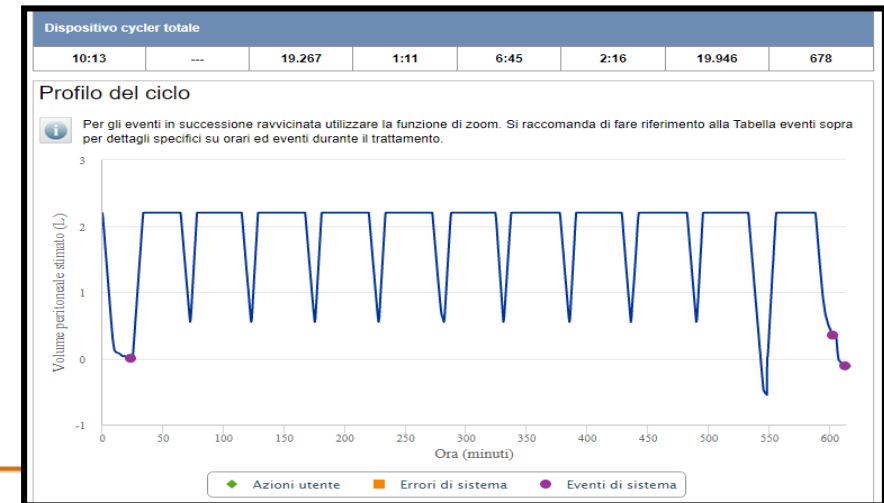
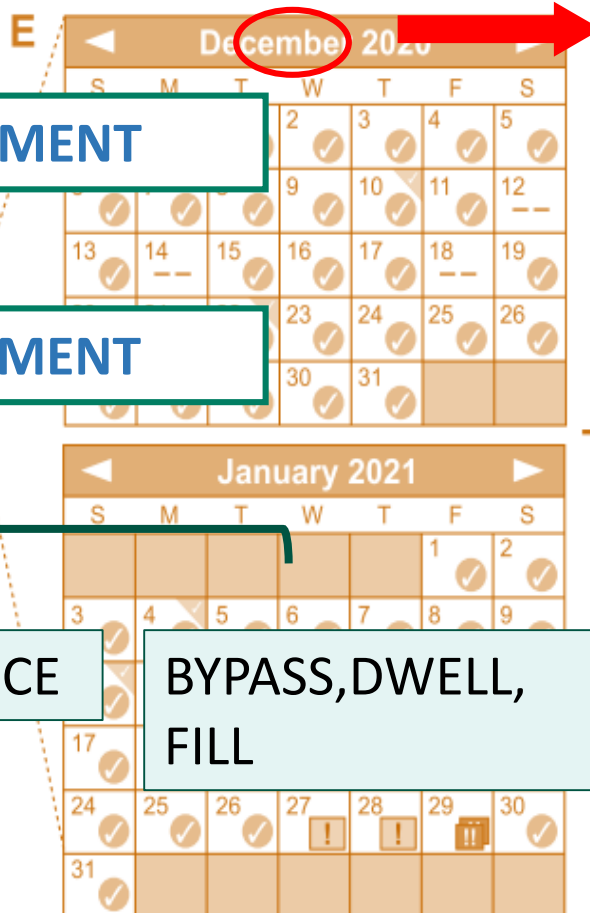
ULTRAFILTRATION

COMPLIANCE

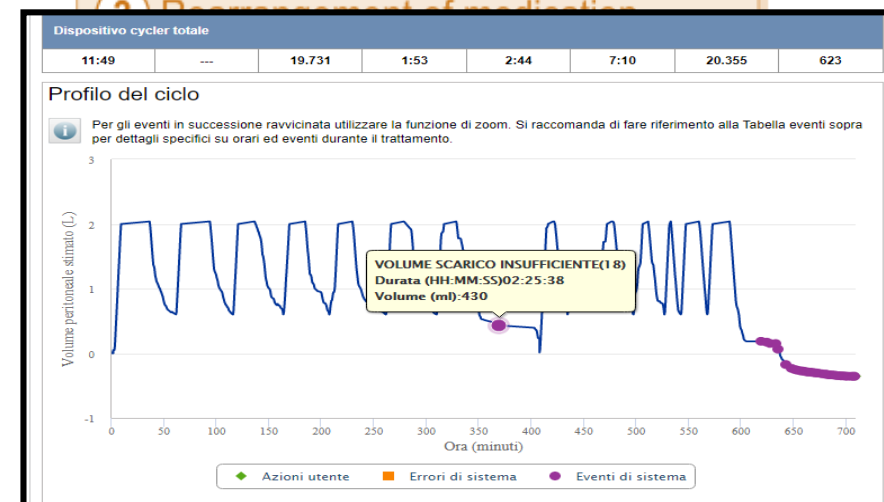
BYPASS, DWELL,
FILL

Cloud

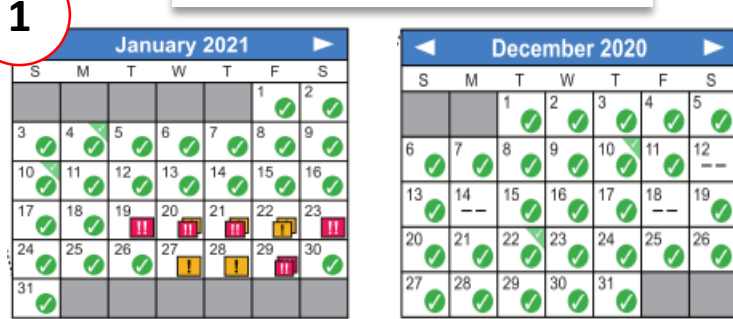
C



and motivation



TELEMONITORING



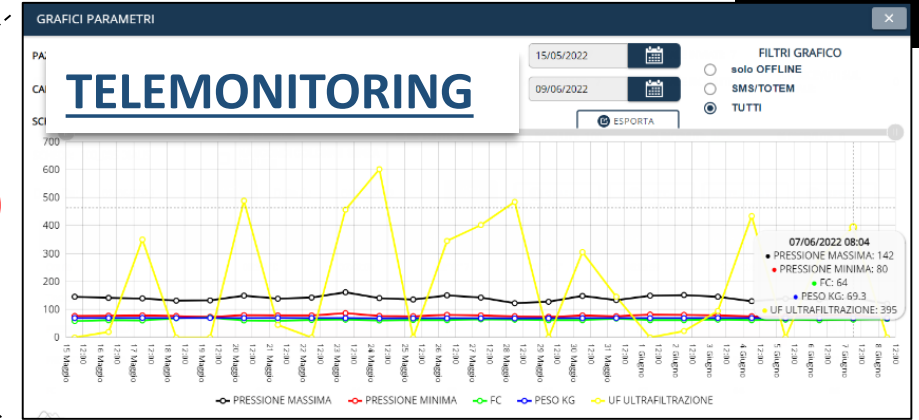
CLOUD



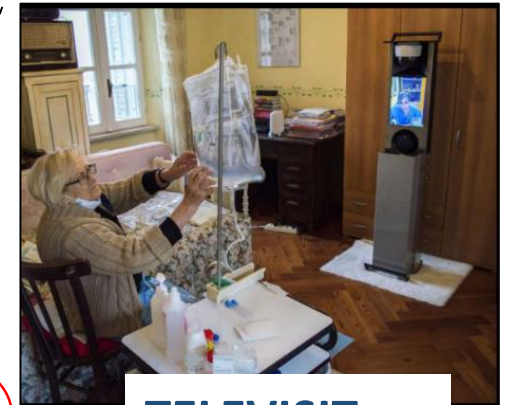
TOTO M



2



3



TELEVISIT



Ricetta Elettronica: Accordi con il CUP di Istituire una Agenda Dedicata. Viene indicata come Visita Nefrologica di controllo- Inserendo nel quesito diagnostico «Telemedicina». Viene rendicontata con la tariffa Visita Nefrologica di Controllo-89.01 B; Eu 14,25

Trattamento dei dati sensibili: L'azienda AULSS7 è titolare del trattamento e rispettando i criteri di accountability previsto dall'articolo 5, par 2 del Regolamento Europeo in materia di dati sensibili ha adottato tramite il CED comportamenti proattivi alla protezione della privacy. Delega del Fornitore

Consenso Informato: Tutti i pazienti hanno firmato il consenso informato dove sono state esplicitate la natura e il tipo di assistenza e la modalità di gestione dei dati personali

Pilot Study: Patient Population

- Daily monitoring of PD sessions via Sharesource/Biocare for 4-6 weeks/pts
- Clinical evaluations conducted with the eVISUS system to assess catheter site, PD effluent color, and to provide real-time guidance for PD training.
- A 24-month study involving 37 consecutive APD patients (26 male, 11 female) with an average age of 73 years.
- A total of 403 Teledialysis sessions were conducted with an average duration of 26 minutes per session.

Results

Pts (N)	37 (28M, 11F) 73 aa
TeleDialysis Session (n)	403
Exit-Site Infection (n)	4
Tunnel Infection (n)	2
Peritonitis (n)	1
Emergency room access (n)	0
Hospital admission (n)	1
Conversion to in-person medical visit	1

TELEDIALYSIS: ADAPTABILITY

TD-Caregiver: Patients requiring caregiver support for peritoneal dialysis (PD).

TD-Clinic: Patients requiring constant monitoring/support.

TD-Training: Training.

TD-Transport: Patients living far from the dialysis center.

TD-RSA: Residential care facilities.

TD-Teleconsultation: Consultations with other specialists (e.g., wound care specialist).

Teledialysis vs Hemodialysis

- Telemedicine applied to Peritoneal Dialysis (APD) has shown promising benefits in clinical outcomes and resource optimization.

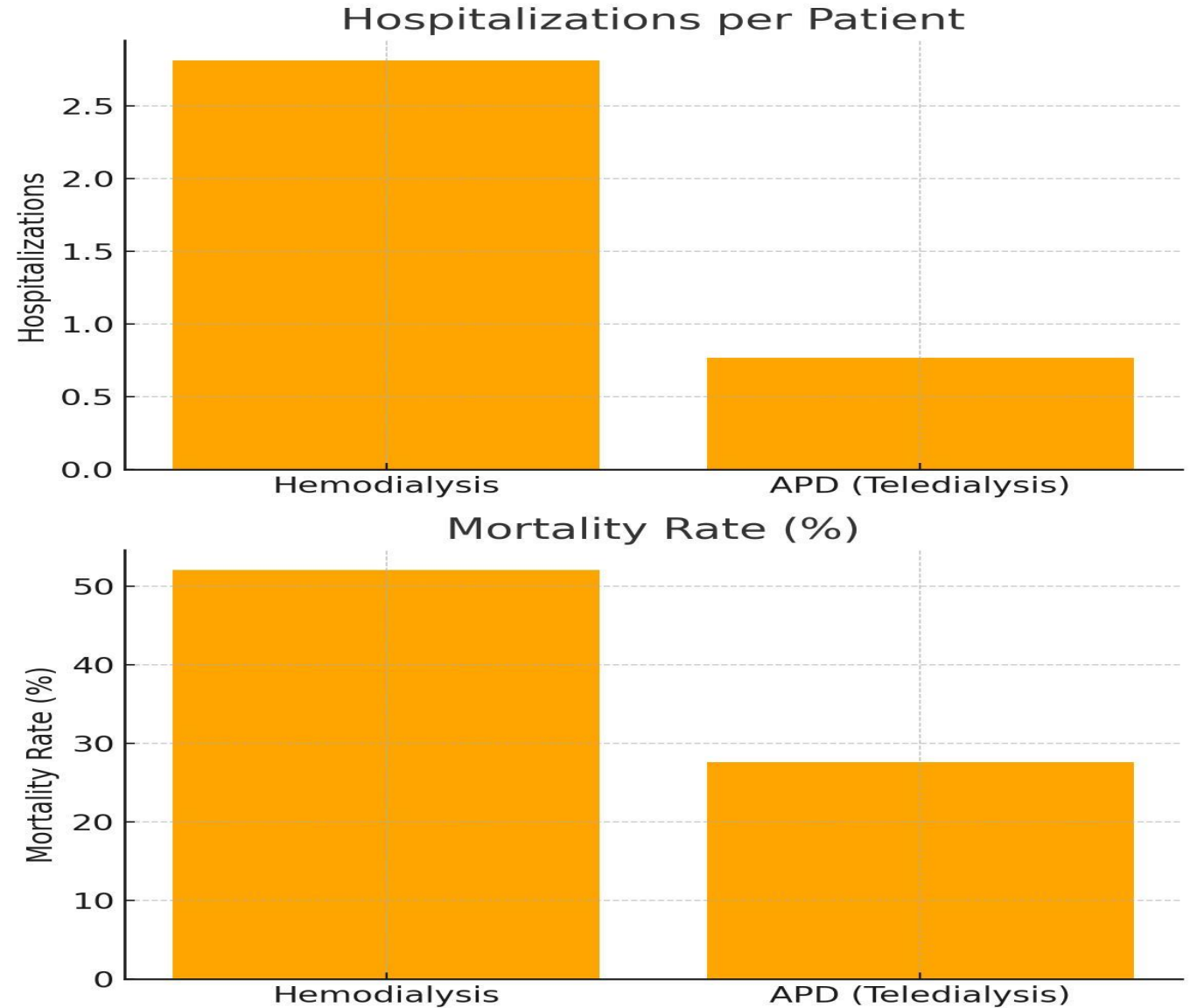
Objective:

- To compare patients on PD with teledialysis support versus conventional in-center Hemodialysis (HD), focusing on hospitalizations and mortality.

Methods:

- - Retrospective analysis over 3 years
- - 37 PD patients in teledialysis program vs 73 incident HD patients
- - Tools used: Sharesource® platform + eVISUS Totem system

- - Hospitalizations/patient:
0.77 (APD) vs 2.81 (HD)
- - Mortality rate:
27.6% (PD) vs 52.05% (HD)
- - Total hospitalizations:
34 (APD) vs 132 (HD)
- - Total deaths:
16 (APD) vs 38 (HD)

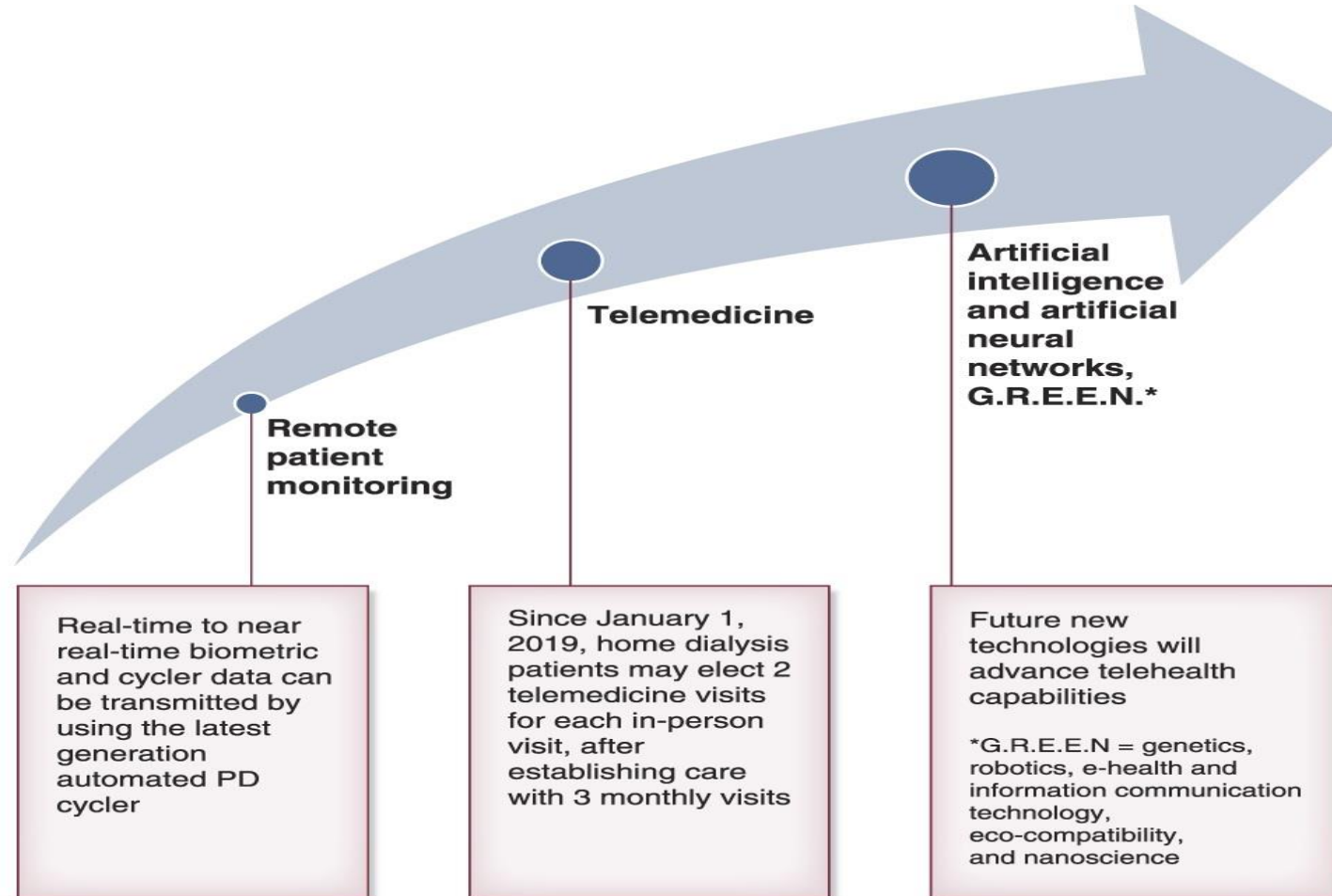


Limitations

Dysfunctional Connection: Technical tests - IT Department.

- **Cybersecurity:** IT Department/Clinical Engineering/Encrypted data.
- **Difficulty in patient/operator IT access (Digital Divide):** Technological education/training.
- **Privacy and Data Management:** Prior patient consent, explicit agreement for data use (including for research purposes).
- **Loss of human contact:** Maintain 1-2 in-person visits per year.
- **Diagnostic error:** Preselection/“Therapeutic agreement” for conversion to an in-person visit.
- **Time-consuming procedure:** Connection issues, unavailability of caregiver or documentation: IT Department/Patient selection.

Perspective



Effect of Remote and Virtual technology on Home dialysis Lew S, et al CJASN 19; 1330-1334, 2024

MACHINE LEARNING

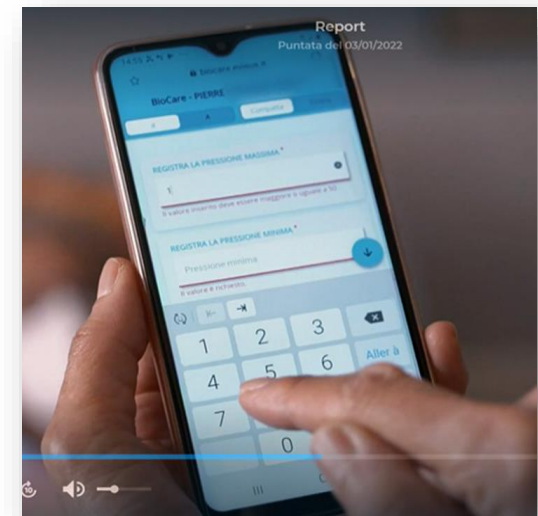
The use and development of computer systems capable of learning and adapting without following explicit instructions, using algorithms and statistical models to analyze and draw inferences from patterns in the data



CLUSTERING ALGORITHMS

Using specific clustering algorithms, it is possible to identify the presence of groups of similar data, which can then be correlated with another set of events and advance towards a predictive phase.

For example: all patients living in rural areas respond to therapy differently.

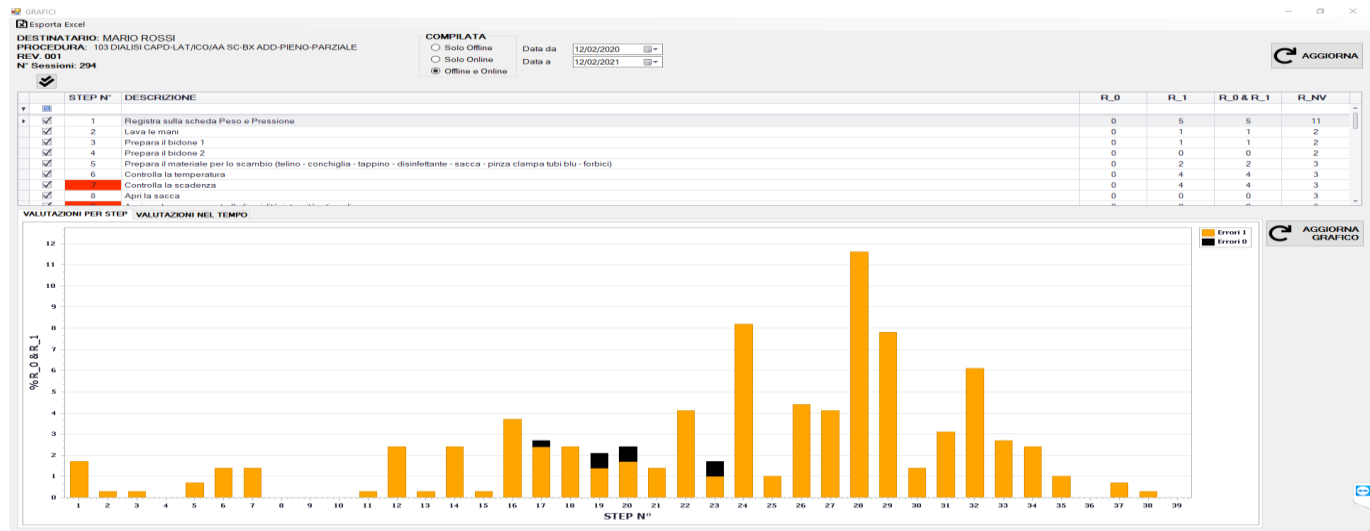
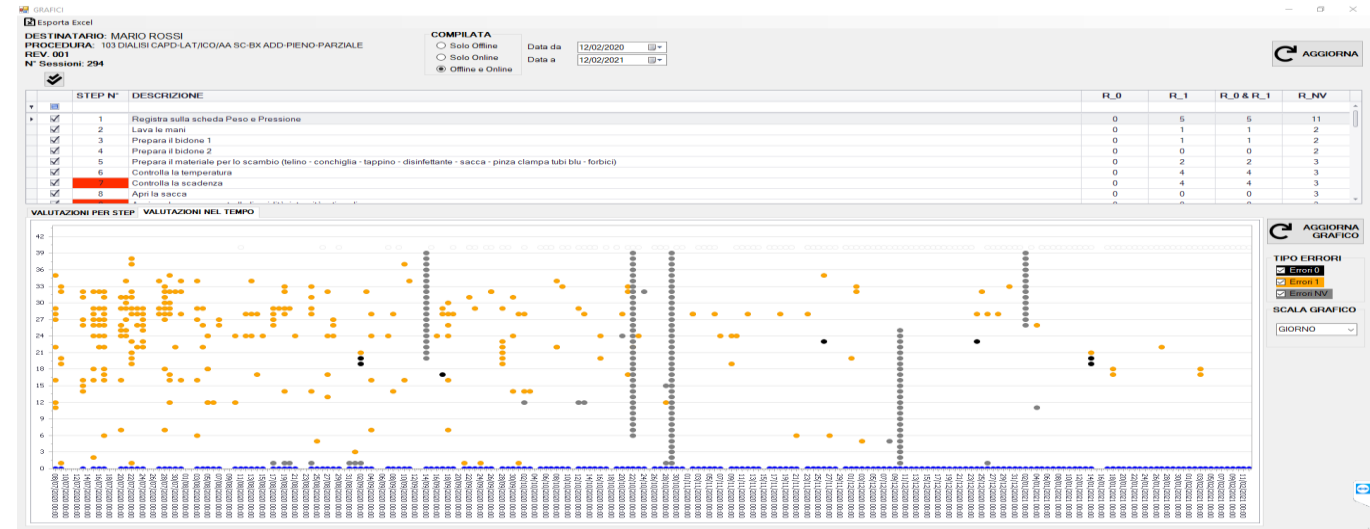


TIME SERIES ANALYSIS – “EXPERT SYSTEM”

Time series analysis is a technique that deals with statistical data ordered over time.

It is possible to identify trends in historical data and/or make predictions about future data.

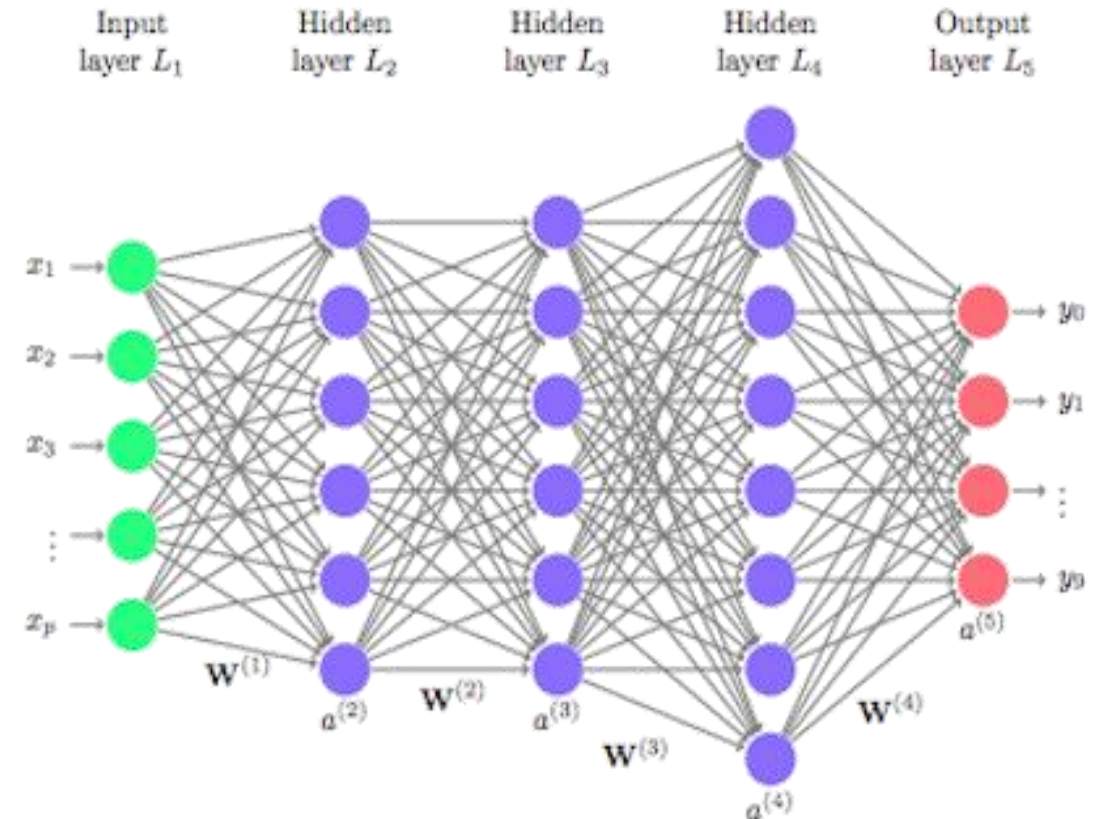
For example, predicting how long training will take for a specific type of user.



NEURAL NETWORK - IMAGING ANALYSIS

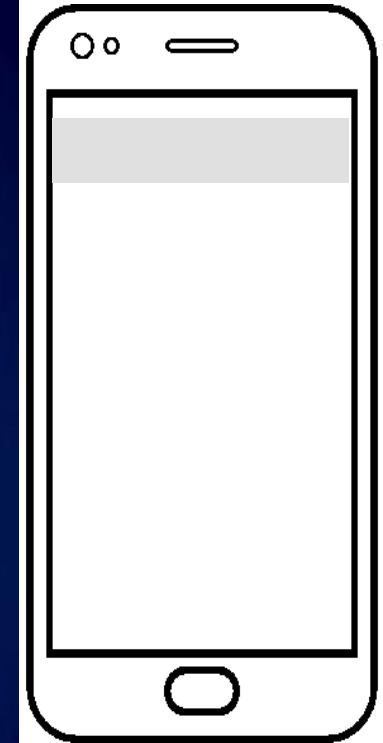
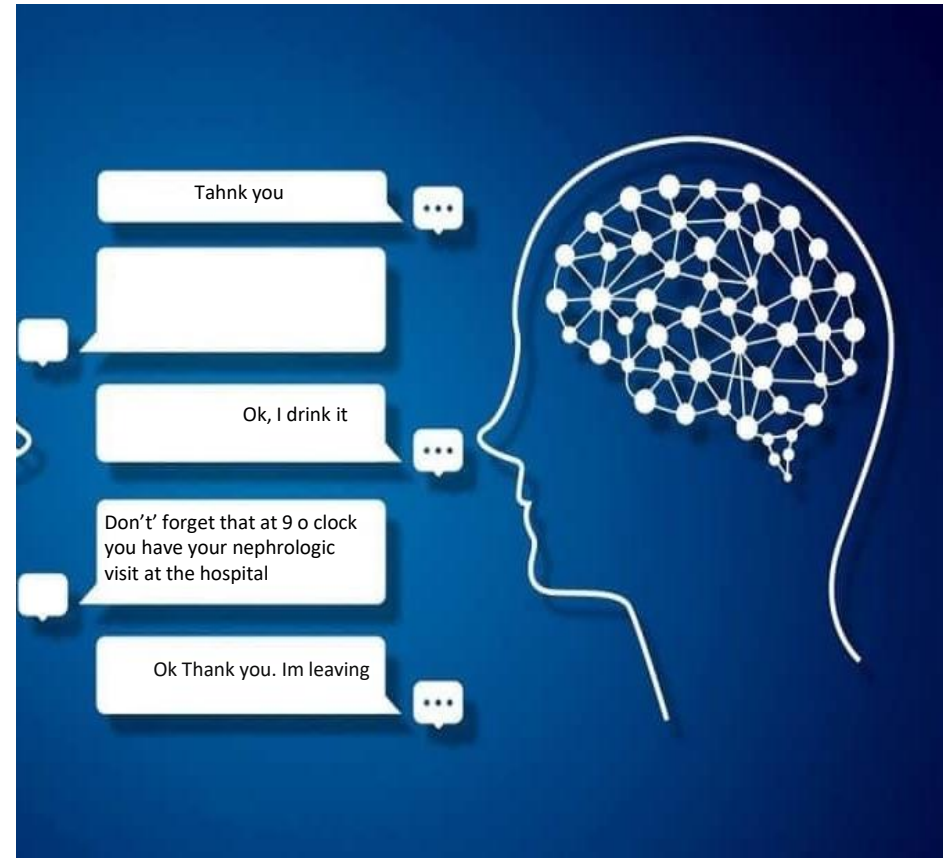
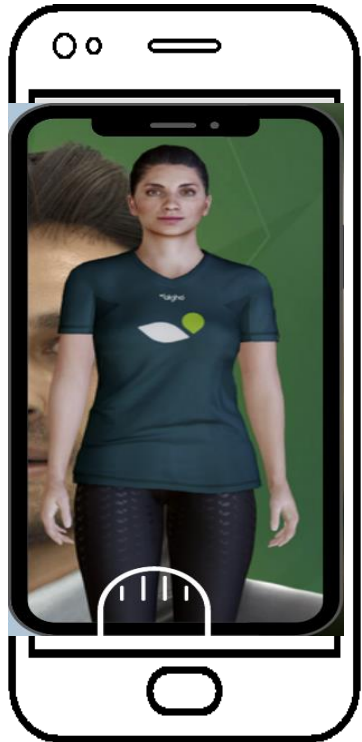
Photograph Analysis with DEEP LEARNING to Identify Potential Infections/Irritations at the Peritoneal Catheter Exit Site

- The computation passes through multiple layers composed of small components.
- The weight of each component is determined using a virtual training system with real data.



INTEGRATED IMPLEMENTATION (NLP)

Virtual Assistant 3d with BioCare



Conclusions

- Teledialysis proved to be safe, reliable, and easy to use for our patients.
- The program facilitated integration between the hospital and community, providing a new care pathway.
- Technology can enhance PD programs and help patients overcome barriers to treatment.
- Improves the clinical management of the patient;
- Reduces hospitalizations and Emergency Room visits;
- Promotes monitoring of health status and quality of life;
- Increases efficiency in resource and healthcare team management;
- Provides better adherence to dialysis therapy;

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