

# GUARDIAN ANGEL 2.0: A TELEMEDICINE SERVICE FOR CHILDREN WITH HOME MECHANICAL VENTILATION

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The use of telemedicine has been rapidly increasing in the last few years. Telemonitoring and televisit services proved effective at homecare. The telemedicine project “Guardian Angel” was started in 2014 and then updated in 2019 in the pediatric hospital Santobono-Pausilipon in Naples carries out telemonitoring and televisit activities on home-ventilated pediatric patients. It was improved using an innovative quality measurement approach [1]. Here are presented the quality by design approach to implement new technologies, an innovative workflow, and the introduction of measurement indices for structure – process – clinical outcome useful to measure the global quality of the telemedicine service.

## 1. INTRODUCTION

Telemedicine can be identified as using Information and Communication Technologies (ICT) to provide medical assistance and services [2]. This health-related service has been rapidly growing during the last decade, in particular since COVID-19 outbreak, which complicated doctor-patient physical interactions [3]. During this time, e-health between patient and doctor has been a key factor in the patient workflow [4–65].

The use of telemedicine for a home-ventilated patient is proved to be effective in vital signs remote monitoring, having advantages for both the patients and the doctors, reducing clinical access of patients and home visits by clinical practitioners while keeping high-intensity care and reducing the burden of the family of the patient [7, 8]. Moreover, videoconferencing systems devoted to e-health are useful for easy communications between medical practitioners and the patient-caregiver [9, 10].

Even with the value of the clinical services offered through telemedicine [11, 12], there is a lack of quality management approaches for their design. Elsewhere indices to measure clinical outcomes [13], technological aspects [14], and service assessment [15] are reported. Poor is oriented to a globally quality approach [1].

The paper considers a real telemonitoring service for home ventilated pediatric patients at the Pediatric Hospital Santobono Pausilipon (Santobono) in Naples (*i.e.* “Guardian Angel”) implemented in its first version in 2014. During these years emerged the need to increase the efficiency of the service and up-to-date technologies. Moreover, it was evident that in the design of innovative clinical pathways technology-based [16], using a quality assessment measurement framework founded on structure – process – outcome [17, 18] is useful for the quality by design approach.

Starting from previous work [1], this paper aims to put in evidence the value of a quality by design methodology for innovative telemedicine service, showing the improvement of the project, presenting new data on patients’ characteristics, and giving a set of process indicators currently under study due to the innovative approach in the design.

## 2. MATERIALS AND METHODS

### 2.1. QUALITY APPROACH TO TELEMEDICINE DESIGN

The implementation of the innovative telemedicine service for home-ventilation “Guardian Angel” followed this workflow [10]:

- definition of all requirements (organizational, legal and technological);
- definition of operative procedures;
- implementation of the operative procedures;
- optimization of the entire process following plan-do-check-act cycle.

The last point of this workflow allowed having continuous improvement of the strengths and filling the organizational and/or technological criticalities of the telemedicine clinical service appeared during the real use.

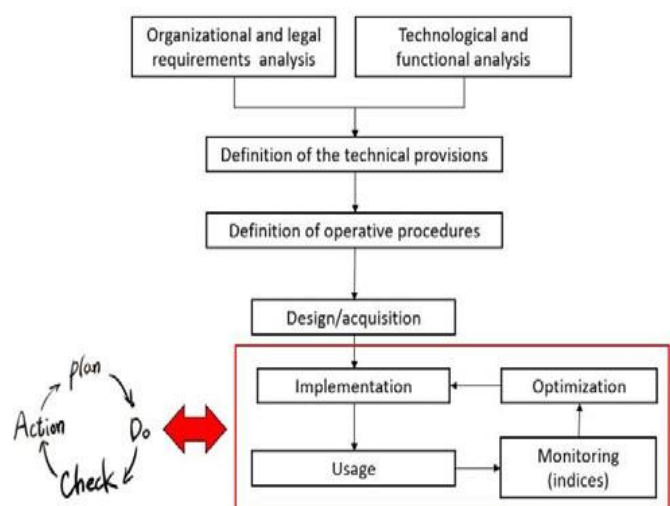


Fig. 1 – Implementation and PDCA workflow.

After implementing the quality management workflow, a quality measurement approach was taken. This consists of the identification and measurement of the components of quality in both the structure and the process of the project to obtain the desired outcome to be measured as well. The analysis included several aspects on a technical level,

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evaluating the adequacy of the telemedicine service and the resources used to carry it out, and quality interaction level, estimating the suitability of the clinical workflow [19]. Once evaluating both the structure and the process indicators, the obtained outcomes are compared to the desired ones.

## 2.2. CLINICAL SERVICE

The first version of “Guardian Angel” was designed in 2014 at Pediatric Hospital Santobono Pausilipon (Santobono) in Naples. It is the most important pediatric hospital in the south of Italy, with 400 beds distributed in 21 specialties [10]. The telemedicine project belongs to the Department of Intensive Care for children with severe disabilities vegetative states and home care, which assists patients in home mechanical ventilation, living in different Local Health Units (ASL) in Campania Region (Fig. 2). The organization required one clinician as responsible for the telemedicine service, providing the monitoring of ventilation parameters, the setting of critical alarms. Nurses gave continuous assistance to patients thanks to televisit service, and a group of nurses that provided home visits to check patients’ status and to carry out care activities. The service was implemented with personal assistance as the project was financed by Archbishop and the faithful of Catholic Diocese of Naples.

In this early version, telemonitoring was implemented with telemetry devices for data collection and a GPRS Transmitter, which was directly connected to the ResMed Elisee 150 pulmonary ventilator. Teleassistance was carried out with video calls operated through a tablet equipped with a SIM card. This project was later discarded for clinical use because of too many critical issues, such as missing network coverage and lack of cooperation from caregivers. This led to a deep analysis of requirements referred to each stakeholder. So, according to the approach described above and, using new technologies both hardware and software, the new telemedicine project “Guardian Angel 2.0” was designed, and implemented in October 2019.



Fig. 2 – Local Health Units (ASL) distribution in the Campania region.

## 2.3. TECHNOLOGIES AND WORKFLOW

Following the same functionalities, the “Guardian Angel” telemedicine project has seen remarkable improvements since 2019.

From an organizational point of view, the project is set as the previous version, seeing one responsible clinician and a group of nurses carry out telemonitoring and teleassistance services. Before implementing new components, according to the quality by design approach, all stakeholders

participated in the design phase implemented in UML (Fig. 3). From a technological point of view, the pulmonary ventilator Resmed – Astral 150 and an additional SpO<sub>2</sub> sensor are used. These are given to the hospital in a full-risk contract, providing continuous device software updating and, eventually, ventilator replacement.

The telemonitoring service is applied by using the web-based platform “Airview” by Resmed®. The service consented to collect clinical data from the pulmonary ventilator and store them in a cloud. The doctor can then check critical ventilation parameters for every patient, such as respiratory rate, humidity rate, tidal volume, ventilation time, SpO<sub>2</sub>, and leakage, and evaluate the mechanical ventilation performances.

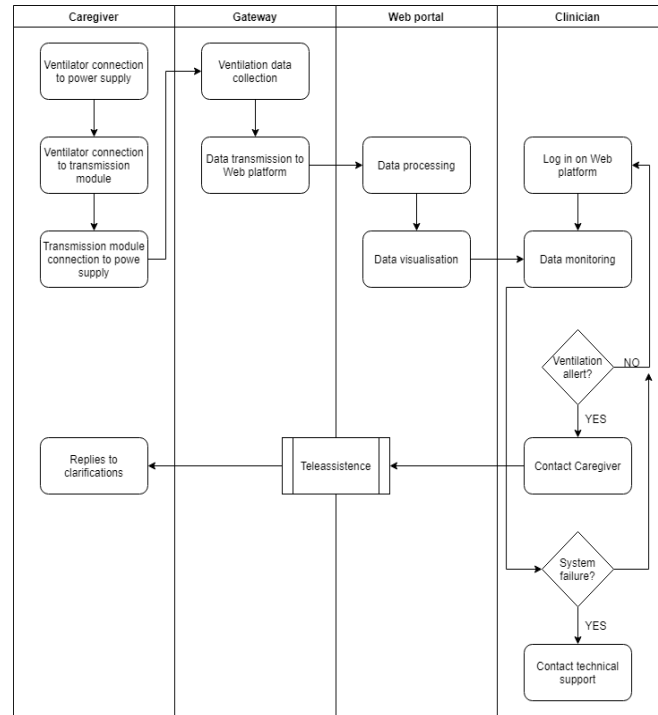


Fig. 3 – Telemonitoring the swimlane diagram.

The pulmonary ventilator and the platform communicate through the data transmission module, which is 24/7 connected directly to the ventilator and provides the transmission of ventilation registered data daily. The connection between the ventilator and the module does not affect the use of the first, and patients can continue its use even when the module is transmitting data. The transmission is made through GPRS or HSDPA connection, and the operation is carried out using the available telecommunication capabilities of the zone. Upload time depends on the amount of data to transmit. It can take from fifteen minutes to an hour. In case of failure or interruption in data transmission, the device retries to send them as soon as the problem is solved.

According to UE Regulation 17/745 on Medical Devices (MDs), this solution is a Class IIa medical device and complies with the specific requirements of the General Data Protection Regulation (UE) 2016/679 (GDPR). Along with the web-based platform, all the workflow complies with GDPR regulations. The data flow is evaluated by Santobono Data Protection Office, which also manages clinical informed consent to treatment and informed consent to data processing, signed by the patient and/or a legal representative. The platform server stores the data using encryption, and the

transmissions are encrypted using HTTPS/TLS protocols.

Along with the telemonitoring service, teleassistance is enabled by using WhatsApp Messenger®, available on almost every mobile device (Fig. 4). This application consents to telecare sessions through messages and calls.

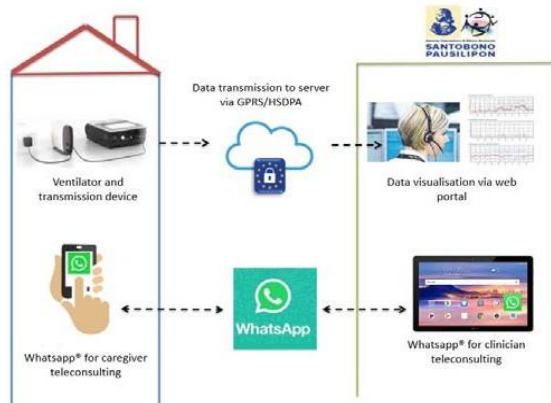


Fig. 4 – Guardian Angel 2.0 telemonitoring and teleassistance workflow.

These activities are necessary both for the patient, or his caregiver, to solve unexpected events that can be managed without a clinical practitioner and for the doctor to check the patient's status and the course of clinical treatment. All the clinical activities are encrypted with end-to-end protocol and are recorded on an activity log. Personal assistance is also provided on demand.

### 3. RESULTS

Up to 2021, [1], “Guardian Angel” has been telemonitoring a total of 22 of 33 patients assisted by the clinical service, characteristics are reported in Table 1.

In 2022, the number of patients assisted in telemedicine modality increased to 30, including 8 of the 11 patients followed before in traditional modality, due to technological improvements.

Telemonitoring is done by checking the web platform at least once a day for every patient, and it is checked more than once if the activation of set alarms is involved or on caregiver request. Activation for 2 patients was initially not possible cause of a lack of network coverage. Still, it was immediately made feasible to modify the position of the data transmitter only during the time of transmission (which is set at 12 AM). This modification does not impede the standard function of the pulmonary ventilator.

### 4. DISCUSSION AND QUALITY INDICATORS

The “Guardian Angel” telemedicine service has improved remarkably, enrolling new patients over time and solving problems on both hardware and software levels.

A rigorous evaluation of activities to give clinical evidence is needed. Therefore, it is necessary to define simple, concise, complete, inexpensive, and applicable quality indicators. Thus, developing the indicators should be an integral part of the telemedicine service design. The quality indicators can be related to the structure, process, and outcomes [16, 17]. Those related to the structure account for the features of the hospital, the organizational skill of the management staff, availability of equipment and human resources, and so on. The indicators characterizing the process are widely recognized clinical standards and can be extracted from the clinical agenda. The clinical

outcomes usually are arranged according to the type of clinical service. As they represent the state of health of the patient, they must include measurement on the efficacy of the clinical pathway, data on access by clinical practitioners at the patient's home, morbidity, and, where possible, perception and satisfaction of the patients at discharge, and quality of life during the treatment.

Table 1  
Patients' characteristics (2021)

Indicator	Value	
Age [yy], mean (SD)	9 ( $\pm 5$ )	
Sex, N° (%)	Male	Female
	21 (63.6)	12 (36.4)
Diagnosis, N° (%)	Neurological	22 (66.6)
	Cardiological	4 (13.3)
	Genetic	5 (13.8)
	Pneumological	2 (6.3)
Days between admission and firstre-hospitalization [dd]	P1	31
	P2	457
	P3	184
	Mean	224
Patient assistance, N° (%)	Telemedicine	Traditional
	22 (66.6)	11 (33.4)

During the design phase of the indicators, these steps were followed:

- definition of what is going to be measured and the possibility of measuring it;
- creation of a consensus between the stakeholders on the value of the chosen indicators;
- make the corresponding arrangements with the usual indicators from the health unit and authorities in charge of the country information systems (EHR);
- establishment of a workflow to have periodical measurements;
- implementation of a pilot;
- organization of a revision process.

The indicators chosen for “Guardian Angel” are presented in Table 2. Real measurements are a work in progress that started in early 2022 and will be completed, along with the gathered results, in the next months. Partial obtained data already describe a positive impact of the service.

### 5. CONCLUSION

Telemedicine is rapidly becoming a key factor in medicine and healthcare, especially after Covid 19 emergency, where televisit and teleassistance were indispensable in the assistance of patients. The telemedicine project “Guardian Angel”, updated in 2019 at the pediatric hospital Santobono-Pausilipon of Naples, significantly improved since its first appearance in 2014. During these years, problems like network coverage are still present but can be solved with easy practical solutions. Quality by design approach adopting innovative workflow is useful to implement new technologies. This allowed taking full advantage of new functionalities available on the web-based platform “Airview” by Resmed® too. Indices for structure – process – clinical outcomes have been idealized to measure the quality of the service. They are under evaluation, considering even the fact that the service is relatively new to the Italian Health System.

Table 2  
Suggested quality indicators for Guardian Angel project

<b>STRUCTURE</b> AORN Santobono-Pausilipon, Service center	<b>PROCESS</b> Telemonitoring and Teleassistance of home- assisted patients with chronic respiratory diseases	<b>OUTCOME</b> Measure of telemedicine service effects on the AORN and the caregivers
<p><b>Complexity</b></p> <ul style="list-style-type: none"> <li>• Type and number of professional figures involved in the provision of the service (Medical Specialist, Nurse, etc.).</li> <li>• N°. of operators involved in providing the service / No. of users.</li> <li>• Devices and ICT resources.</li> </ul>	<p><b>Process size</b></p> <ul style="list-style-type: none"> <li>• N°. of users followed in the last 9 months / No. of users followed in the previous 9 months.</li> <li>• Target coverage (%): Percentage of users followed out of the total number of users affected by the pathology covered by the service in the area of interest.</li> <li>• Average size: average number of contacts/month average number of contacts/months per user</li> </ul> <p><b>Process stability</b></p> <ul style="list-style-type: none"> <li>• Duration: N°. of months of activity from the activation of the service</li> </ul> <p><b>Operational efficiency</b></p> <ul style="list-style-type: none"> <li>• N° of hours of use of the service / N°. of professionals involved.</li> </ul>	<p><b>Efficacy</b></p> <ul style="list-style-type: none"> <li>• N° of re-hospitalizations for acute cases among users followed in Telemedicine in the last 9 months</li> <li>• Average days of hospitalization in the last 9 months per user followed in Telemedicine</li> <li>• Average time of home visits with telemedicine in the last 9 months (television duration)</li> <li>• N° acute situations (non-compliance, abnormalities) detected with the telemonitoring service in the last 9 months</li> <li>• Absolute Drop-Out: N° of users who leave the Telemedicine path by choice / 6 months</li> <li>• Relative Drop-Out: N° of users who leave the Telemedicine path by choice / 6 months.</li> </ul>

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