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TELEPHARMACY SERVICES FOR IMPROVING MEDICAL CARE QUALITY ON BOARD SHIPS

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SOMMARIO

ABSTRACT

Travelling at sea for any reason poses travelers at risk of accidents or diseases. Treatment of these problems requires the availability of drugs and medical devices to cope with these situations.

Another problematic factor in case of pathologies onboard is the fact that with the only exception of passenger on cruise ships, merchant ships do not carry doctor or adequately trained paramedic personnel.

With the discovery and dissemination of the radio, the isolation conditions at the sea were interrupted and **Radio Medical Centers** were established to ensure reasonable levels of medical care on board.

When accidents occur on board or if a crew member suffers grave a disease of some complexity, the master may request the intervention of a physician on a nearby ship with medical facilities on board, or may ask medical advice to a maritime telemedicine assistance service (T.M.A.S.).

In this respect it should be mentioned that the Italian T.M.A.S., Centro Internazionale Radio Medico (**C.I.R.M.**), is the organization with the largest experience in the field worldwide.

The disparity between **national and international regulations** relatively to medicines that ships must have on board, can make healthcare complicated, especially in ships involved in long distance routes and far long times

Recent Information and Communication Technologies (ICT) technology advancements have led to health care improvement and increased the scope of technology in the medical fields.

What was impossible in the past due to technological limitations is now possible, improving health outcomes of vulnerable populations, such as seafarers.

The discipline that governs the application of modern medical technologies is called e-health or commonly referred to as “electronic health”.

This thesis describes in detail all the services that include electronic health with the advantages and limitations associated with them by analyzing in depth what these technologies are most widely used for applications are also presented according their use.

The rest of the document consist of some publications in specific e-health services published during my PhD program in telemedicine and telepharmacy by myself and all the team in the department I worked with.

In order to further improve the quality of assistance provided to seafarers (but, by extension, to all remote patients) **a questionnaire on "Customer Satisfaction" was developed**, submitted to both seafarers and their TMAS assistants. This allowed us to assess in first person the degree of appreciation of the services offered and experienced, overall.

Development of a system for handling the ship’s pharmacy requires knowledge of compliance, understanding of the life at sea and an analytical approach to managing the medical chest. The aim of the system is to manage the ship’s medical chest reducing as much as possible the human interaction avoiding misunderstanding and issues. The system developed has proved to be an effective tool which serves to guarantee the compliance of the ship pharmacy with

regulations of the flag state in terms of medicinal products and medications. Sharing the system with the Telemedical Maritime Assistance Service may result in avoiding mistakes in drug administration. Last but not least the availability of that software could help reduce/avoid problems with maritime health authorities in case any of the required medicinal products are missing.

CHAPTER 1 - INTRODUCTION

Medical care on board ships is one of the major challenges of modern medicine.

On board ships, access to medical services can be much slower; many ships do not have healthcare personnel onboard, and most of them sail offshore for days or months before reaching a port. The same environment of the ship cannot help maintain a good health status of the crew and passengers, and exposes the sailors to a greater risk of injury and illness compared to ground workers.

Over the last several decades there have been great advancements in medical care management and access onshore. However, this has not led to any significant improvement in the medical care available to our seafarers on the high seas.

In this regard, telemedicine is the best strategy for providing health care to ships without a physician on board. For this, to be really effective it is essential to:

1. *Provide access to quality medical assistance available 24x7*
2. *Ensuring the authorized person on board is aware of the systems available to seek medical assistance. This can be achieved through training and simple, efficient systems.*
3. *Synchronized system that allows for the doctor onshore to prescribe medicines that are available onboard the ship. [1,2]*

The remote medical (*or radio-medical*) assistance consists of a request by the master of the ship, which is the guarantor of good health of the crew, to a special center which provides medical

support to ships. Today there are several organizations around the world that provide assistance to mariners, and they have tried to improve the quality of the service provided over the years.

However, the best example of the evolution of medical radio assistance, starting from a national scenario to becoming a worldwide service, is represented by the Italian International Radio Medical Centre (CIRM), which started its activity in 1935 The purpose of assisting ships of all nationalities without a physician on board.

Subsequently C.I.R.M. has extended its activities to aircraft and isolated areas such as some small Italian islands. From 1935 to 1996 the C.I.R.M. Assisted 42935 patients, mostly seamen; this has made the Center the most active organization in the world in terms of telemedicine applied to the health of sailors [2].

In order to ensure an effective long-distance medical care, it is important to:

1. *Send, from the ship, clear information regarding the medical symptoms observed to allow for correct medical diagnosis;*
2. *Administer the prescriptions that the doctor has prescribed on the basis of the diagnosis and the availability of medicines present on board the vessel.*

1.1. Telemedicine, and potential applications of it

Telemedicine is defined as the use of the most up-to-date medical and computer technologies with the aim of providing healthcare to remote patients, which for various reasons cannot be physically visited by the physician. This distance communication may have problems stemming mainly from difficulties in dialogue by those who are not medical specialist, with the risk of misleading the doctor's judgment.

For this reason, telemedicine has been the subject of great research and development in recent years, with the intention to solve these problems, educating personnel embarked on the ships, and providing it directly with the tools to perform remote diagnostic tests (*such as EKG, Spirometry, blood glucose, etc*.), the results of which will be sent to the physician, who will have more resources to ensure effective diagnosis and therapy.

Medical care can be obtained through different instruments, such as telephone, fax, e-mail or telex; the telex requests should bring writings like "*MEDRAD*", so get priority in communications. So the first message to ask for medical assistance should include:

- Maritime information, such as:
    - *Anagraphic data;*
    - *Qualification or role on board;*
    - *Boarding day;*
    - *Date of Joining.*
- Ship information:
    - *International Call Sign;*

    - *Type of Ship;*
    - *Navigation Company*
    - *Coordinates of the ship, with date and time;*
    - *Port of origin;*
    - *Port of destination;*
    - *Any alternative ports on the route.*
- Clinical information about illness or accident (*for example symptomatology, or location and entity of the accident*);
- Information about the on-board pharmacy and its equipment;
- Any useful multimedia attachments, such as images or movies.

Subsequently, if necessary, the master may contact the service center again providing information on any eventual evolution of the disease or injury, and on the effectiveness of the therapy.

Information on upgrading seafarers' conditions is essential for both a proper continuation of care and for monitoring the effectiveness and appropriateness of care provided.

1.2. Medical chest: history and evolution

From the 18th to the 19th century, the physicians who embarked were carrying a cassette containing therapeutic prescriptions to be used on board in case of necessity [1]. Since the nineteenth century, many nations began to regulate hygiene matters aboard ships, and required the presence of a "*medicine box*" containing all the medicines used by sailors, with instructions for their use [3]. That is why, even today, all the medicines and all the medical supplies on board is called "*medicine chest on board*."

One of the main problems arising from the early use of these chests was the diversity of content between different flag vessels. In this sense, the best solution to this problem is in international agreements, to be reviewed periodically to establish the structure of a pharmacy well stocked border, especially in relation to those who are actually the main health problems in which sailors are involved.

For this reason, in 1967, the World Health Organization (WHO), under the recommendation of the International Labor Office, published the first edition of the “International Medical Guide for Ships”, containing a final appendix suggesting a minimum standard facility of medicines that had to be present in all the ships of the world [4].

However, even today the problem of standard medical equipment on ships requires an international resolution. WHO is undoubtedly the most appropriate supranational organization to embark on incisive efforts to unify on-board pharmacies, but it is also crucial that all health-care organizations, including trade unions, work with WHO in

the act of equipment standardization. Standardization that must be carried out indispensably in relation to those that are the main health problems of the seafarers, mainly based on epidemiological surveys on board ships. Inspiring on the International Medical Guide for Ships and the Medical First Aid Guide for use in Accidents Involving Dangerous Goods [5], both by WHO, many nations have regulated their own medical cassettes, different for each country, for to be mandatory board.

1.3. The Ship Pharmacy

The on-board pharmacy or “medical chest”, is the kit that, on board ships, allows the implementation of health care, providing therapeutic interventions of first aid. It is therefore a vital asset, which must contain everything that might be needed to ensure proper and complete health care for sailors.

Nowadays it is no longer a container enclosing medicines and medical devices, but rather a real pharmacy on board that has a wide range of health products. The manager of drug management is the master, or a designated officer, who also holds the responsibility of keeping the on-board pharmacy always stocked and efficient.

However, as this can be well supplied, and as the crew can be trained, neither this nor the medicine cabinet can be substituted directly to the doctor, who is therefore the true point of reference in case of illness or injury. That's why telemedicine is the cornerstone of medical care given to seafarers and, by extension, to all remote patients.

1.4. The World Health Organization's recommendations

The World Health Organization classified the ships, in the **International Medical Guide for Ships** (1967), relatively to the composition of the on-board pharmacy in three distinct categories, establishing for each of these the specialties considered essential on board, in a unique table, called **Table 10**.

This table is divided into **3 columns**, named **A**, **B** and **C**, and representing the abovementioned categories.

Column A of Table 10 indicates the minimum facility of medicines for ships which generally perform ocean voyages, usually lasting six months, with no doctor on board, and is in turn divided into two columns: 1) to ships carrying up to 40 people, and 2) for ships carrying more than 40 people. For journeys of up to 12 months, ships shall have double quantities available, with the exception of those indicated by the sign "X", the quantities of which are not calculated on the basis of the duration of the journey unless otherwise indicated.

Column B of Table 10 indicates the minimum amount of medicines for ships engaged in journeys not exceeding fourteen days, without onboard physician. The entries tagged with (*) refer to medicinal products that are not necessary for ships whose journeys do not normally last more than 12 hours from the port. The equipment to be held does not take into account the duration of the trip.

Column C of Table 10 indicates the minimum provision of medicines for ships used for coastal voyages without a doctor on board; It is recommended as a supply for fishing vessels whose journeys do not extend for more than 24 hours from the port of departure. Voices tagged with (**) may be reduced by half in ships carrying less than six people. As for the other columns, medical facilities shall be established regardless of the duration of the trip, unless otherwise indicated.

The doses must be clearly labeled, and all containers containing "*poison-based*" substances must be supplied in separate bottles and stored in specific cabinets.

The keys to these cabinets are kept by the master, which can in turn create duplicates to be assigned to an officer or to a person to whom he delegates the responsibility for health care on board.

1.5. European indications on the supply of medicines and medical instruments of which ships should be supplied

The European Community in Directive 92/29/EEC of the council of 31 March 1992, concerning minimum safety and health requirements for the promotion of better medical care on board ships, issued a number of recommendations, contained in several annexes.

In particular, **Annex II**, which deals with medicines on board, divides medicines into nine large families for the treatment of various pathologies, and within these families various classes of drugs.

The Directive recommends having certain drugs available depending on the vessel's characteristics.

Ships are classified as follows:

A. Ships engaged in maritime navigation or fishing in the sea, without any distance limit from the coast.
B. Ships engaged in sea navigation or fishing at sea in waters within 150 nautical miles from the nearest port adequately equipped for medical purposes.
C. Ship that practices harbor navigation, boats and vessels operating near the coast, or having only the wheelhouse as a compartment on board.

The above mentioned Annex II includes:

i. Drugs;
ii. Medical equipment;
iii. Antidotes.

The Directive is the reference point for all members of the Community who have access to the sea, and must adjust their national laws in order to improve the sanitary conditions on board ships that carry the flag states of the European Community (now European Union). [6-20]

1.6. Introduction to e-health

Nowadays the term e-Health or electronic-Health is commonly used in everyday life. The first use of the term is dated in 1999 in the 7th International Congress on Telemedicine and Telecare in London [21] in which a speaker mentioned a topic about the use of the Information and Communication Technologies (ICT) in the health sector of the Australian country. Mitchell promoted the concept that the advent of e-health in health sectors could be compared to e-commerce's birth in traditional commerce fields [22].

ICT refers to technologies that provide access to information through telecommunications. It is similar to Information Technology (IT), but focuses primarily on communication technologies. This includes the Internet, wireless networks, cell phones, and other communication mediums. In the past few decades, information and communication technologies have provided society with a vast array of new communication capabilities. For example, people can communicate in real-time with others in different countries using technologies such as instant messaging, voice over IP (VoIP), and video-conferencing.

In this respect, e-Health could be considered a total revolution in health care fields. From 2006 e-Health term is widely used by many academic istitutions, governments and companies all over the world. The meaning of the concept may vary and it depends mostly on previous educational background.

For this reason there is no a standard definition for e-health. The definition which best fits the concept is the use of information and communication technologies at a distance for sending and receiving

health information. The main idea related to e-Health is to improve the public health processes.

With the advent of new and better ICT technologies such as pc-network capabilities, high speed internet, digitalized products and services, there are improvements in health services. Through these technologies the impact of the health care process is becoming higher and higher (Figure 1).

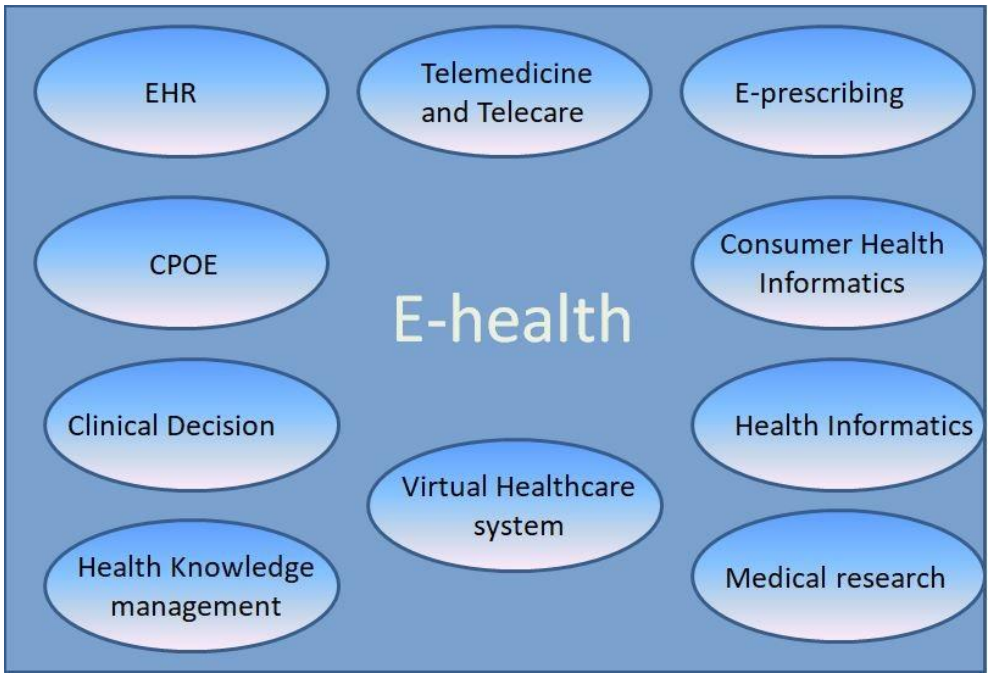


Figure 1: *Services included in e-Health concept*.

The primary aim of e-Health is the optimization and consequently the reduction of the cost-effectiveness of health care from patient and physician point of view. Moreover, e-Health tries to solve common issues related to accesses to care, quality and efficiency of the health care services and nevertheless deliver health care at a distance.

Provision of health care at a distance is one of the most important points because it allows to make diagnoses, medical visits without staying in front of the medical doctor.

Infact, telemedicine seems to focus on the same target since it is limitated to relation between patient and physician. It provides the informatic techniques concept of delivering medicine at a distance. In other words, telemedicine provides benefits especially to the patients using informatic techniques to establish communications between patients and physician.

Telemedicine identifies a market niche, while e-health, a sort of ”e-thing”, seems more open and promising and it is based on the traditional equipment sales model, while e-health is apparently oriented to service delivery. In other words e-Health represents a wide range of topics and concepts compare to telemedicine. In this respect, m-Health service could be considered as part of e-Health.

M-health is the discipline in which the patients can use mobile devices to use health care services. [23]

Nowadays one of the most significant problem encountered when e-health is mentioned is the legal problem that come with the concept itself. Infact, most of the countries don’t have specific law regulation and others have regulation that collide with diverse countries’ regulation. The following are the major legal issues related to e-health[24]:

- Regulatory obligations: both hardware and software involved in ehealth service must follow stricty rules. Hardware addressed for medical purposes is considered as medical device. The same situation

happens for software that based on the purpose which it was developed for could considered medical device, too.

- Licensing and Reimbursement: most of the e-health service providers belonging to a specific country must comply with the regalements of the origin country or they should have a local authorization in order to perform service in other countries.

- Data protection: different countries have different regulations to store and deliver patient sensitive data. Likely, a new regulation called GDPR for European Union has been developed to muffle the problem.

- Liability: in case of malfunctioning patients shall prove only the defect to support their claim for damages and the burden of proof shall be on manufactures to prove that the damages were not caused by the alleged defect.

- Information to patients: Since telemedicine and eHealth services often rely on data generated by devices used by patients themselves, in order to make such data reliable and useful for treatments the quality of them is crucial.

The term e-Health can encompass a range of services from:

- Electronic Health Records

- Computerized provider order entry (CPOE)

- e-Prescribing: the patients may print prescription of drugs and it allows transmission of the prescriptions directly from doctors to pharmacists

- Clinical decision

- Telemedicine
- Consumer health Informatics
- Health knowledge management
- m-Health systems
- Medical Research using high computing capabilities pc
- Health informatics

1.7. Electronic Health Records

EHR or Electronic Health Records refers to a digital collection of data related to a single patient or a population. These data can record any information including medical history, allergies, immunization status, laboratory test results, diagnostic examinations and billing data[25].

They represent the transformation of papers-based data and Electronic Medical Record (EMR) into digital format for highly improving the patient's life quality. Even if the EHR is commonly used in the worldwide, there is no standard approach and model to create it[26].

EHR systems are accurately designed to store data in order to capture the patient health state over the time and avoid, likely, data replication. The latter aspect is relevant because it drastically reduces the risk of outdated information that could be faced up with a paper-based system.

Furthermore, a digital format of data avoids dangerous misunderstanding, which may be originated by handwritten documents between patients, medical and paramedical personnel.

The benefits of using the EHR paradigm can be summarized as the following [27]:

- Improve quality of care
- Increase patient participation
- Practice efficiencies and cost saving

Several research papers show life quality improvements. More specifically, EHR can may improve the ability to diagnose diseases and reduce medical errors as well as to provide medical information of special populations of travellers such as seafarers. In particular, EHR may improve the ability to perform diseases diagnosing and reduce medical errors.

A survey conducted showed the following results expressed as percentage[28]:

1. 94% of providers reported that their EHR made records readily available at point of care

2. 88% reported that their EHR produced clinical benefits for the practice.

3. 75% of providers reported that their EHR allowed them to deliver better patient care.

Furthermore, if an EHR is properly implemented, and follows precise standards, it allows to “interpreting” the data inside it. In other words, it means which a good EHR can manipulate the information content in order to have some results for different patients. For

instance, it could recognize and then notify to the physicians, whether or not a new treatment can be in conflict with an old one.

Here, there is the possibility to add some new potential features provided by new mathematical approaches such as Artificial Neural Network, logistic regression and Bayesian Network in which the algorithm implemented has the possibility to improve adaptively its performance through the stimuli provided by the surrounding environments in which it is applied for.

In the case of an emergency, the information gathered through EHR is able to help the physician to choose the best treatment for the patient and reduce drastically the emergency management time[29].

EHRs can quickly help providers, systematically identify, and correct operational problems. In a paper-based setting, identifying such problems is much more difficult, and correcting them can take years.

Therefore, EHR is not or, at least, should not be only a data and transmission container but it can provide additional “smart” features, able to help both sides: physicians and patients. The number of hospitals and other caregivers association, adopting EHRs, is increasing worldwide.

Undoubtedly, despite all the benefits, there are many challenges to face up with EHR:

- Interoperability Hurdles: The hurdle of interoperability represents a key point. Actually, some researchers have expressed concern over the negative results in applying EHR in some fields. The problem is attributed to a poor EHR model design in which the developers do not take care about the standard features in order to have interoperability between different systems.

- Design Architecture: It is a relevant topic as EHR detractors criticize the design for its inflexibility and say it can interfere with the patient/provider interaction.

- Security: When the data are digitalized and they are spread across the internet, the most relevant challenge is to provide safety and security. Some new techniques have been developed to achieve a good security level.[30]

1.8. Consumer Health Information

Consumer health informatics (CHI) is a service included in e-health services that helps to reduce the gap between patients and health resources. It promotes self-care, healthy behaviors and peer information exchange.[31]

CHI reduces the gap through the analysis of the consumers' need, and it implements methods to integrate and increase the readability of medical information related to consumers' preferences.[32]

Due to the fact that, nowadays, the amount of medical information that is possible to retrieve online are growing fast, there is the necessity of helping patients and consumers to locate and evaluate the medical resources and understand them in order to obtain the awareness of the gotten information.

With this support all the consumers are trained to locate reliable medical information. Finding useful and reliable medical information is not easy above all if the seeker consumer is not a health care

practitioner. In this specific situation a huge problem could be dealt with. The advent of the Internet and the use of CHI's systems have promoted the possibility to have an easy access to any sort of medical information.

Having any kind of electronic device (such as computers, smartphone, tablet) with a suitable internet connection means having a huge library of knowledge.

Internet and specific technologies allow anyone, in a very democratic way, to write or publish whatever he/she wants; basically, it should not be such a big issue, but concerns arise when mistakes are inserted in information about the health context, in this way it can represent a dangerous threat for public health.

Usually, most of the users are not educated in medical field, so they are led to trust information they read on the web. A clear example is the damage taken by the no-vax movement, which, especially on the Internet, has caused a wide misinformation about vaccines among the population leading to a reduction of vaccination rate and a consequent flare of diseases normally under control.

Unreliability of health information on the web must not be underestimated. Some studies have been conducted in England, USA, Brazil, Canada and Australia about patients' Internet research habits, to know if they are aware of trustworthiness of health information and what they purpose.

Over the EU (European Union) some systems have been developed to try to certify medical information on internet. One of this system is HON which can evaluate the trustworthiness of health web sites to

discourage the use of those that causes misinformation and to help patients to choose always the right site.

Unluckily those system are not representing neither national or international standards because they have not solid pillars. From consumers or patients perspective the unique solution to bypass the issue is retrieving medical information through certified websites or in any case medical resources managed by trusted medical institutions.

Another crucial point is regarded the consumers' desires of having more responsibility for the health and from the practitioners point of view appreciate the potential of the patient and their families correspond with the emergence of interactive information technology solutions available to clients.

Consumer Health Information systems contain services such as:

- information resources
- communications
- remote monitoring
- videoconferencing
- telepresence

There are more than one definition for a CHI system. CHI as any electronic tool, technology, or system: (a) primarily designed to interact with health information consumers (anyone who seeks or uses healthcare information for non-professional work); (b) that interacts directly with the consumer who provides personalized health information to the to the CHI system and receives personalizes

health information from the tool or system and (c) in which the data, information, recommendations or other benefits provided to the consumer may be used with a healthcare professional, but is not dependent on a healthcare professional.[31,33]

1.9. THE PROPOSED QUESTIONNAIRE

With the term Customer Satisfaction, we generally mean the inquiry aimed at getting to know the degree of customer satisfaction and its expectations aimed at increasing the product's appreciation.

In health care, it is the investigation aimed at knowing the degree of user satisfaction with respect to the services offered by health service providers or bodies (companies), aimed at the continuous improvement of the services offered. The customer satisfaction must therefore be thought of as a "work in progress", in which methodology and intervention tools are adapted according to the results obtained and the interventions that are intended to be carried out. Normally, in this sector, customer satisfaction is achieved by service companies, with the main objective of evaluating not only the services provided but the overall offer of services made available to users. In the case of pharmacies on board commercial ships, listening

to customers' opinions and needs is less frequent, but when it is carried out it is certainly to improve the service offered.

The aim of the questionnaire is to take a broader look at the whole pharmacy management system on board the proposed ships, verifying the image of the on-board pharmacy and the "remote pharmacist" category more generally at the maritime user, to get out more and more from the self-referencing that often characterizes the professional categories in our country. The Social Customer Satisfaction of pharmacies on board commercial ships, without a doctor or pharmacist on board, is in fact a piece of the mosaic that the undersigned, in collaboration with the CIRM Centro Internazionale Radio Medico service company named “CIRM Servizi”, I decided to compose for to fully and truthfully highlight the value for shipping companies represented by the offer of a telephony service.

Customer Satisfaction is a complementary aspect of the proposed service. In addition to highlighting the "numbers" of on-board pharmacies benefiting from the service, it outlines the role that, such an innovative service represents, as a support to maritime activities, through an investigation to those who personally take advantage of the service. Customer Satisfaction of pharmacies on board ships, verifies and deepens the vision of users, as users of the service are satisfied with the quality and professionalism of the health workers providing the service.

<<How much does the "vision" of pharmacists coincide or deviate from the "sentiment" of the users? What are the needs satisfied and

still to be satisfied? What role do pharmacies on board ships and should play in ensuring adequate health care on board a ship?”>>

To these and other questions we tried to provide an answer through a survey to a sample of seafarers who use the proposed telepharmacy services.

CHAPTER 2 - ONTOLOGY BASED SYSTEM TO SUPPORT MEDICAL CARE ON BOARD SEAGOING VESSELS

Telemedicine, consisting in the application of information and communication technology (ICT) to the solution of medical problems and in the exchange of medical information, is changing our approach in the delivery of several health services.

Telemedicine includes a growing variety of applications and services the use of which will increase in the near future. Teleconsultation (e.g. the medical visit made via ICT) can be divided into different levels based on the players involved and the complexity of the information exchanged.

A basic (first level) teleconsultation is the electronic/telephonic communication between a client (patient) and a physician.

A second level teleconsultation involves a physician or another health professional and a specialist delivering health care services and information over small and large distances. In the second level teleconsultation, data, information, images and/or voice are exchanged.

A higher level of teleconsultation (third level) involves a medical team of a hospital addressing specific questions to the team of a specialized centre. In primary care, generally, teleconsultation takes place between a patient/caregiver and health care professionals (HCP) for diagnostic or therapeutic advice or for educational purposes.

Medical assistance of good quality is a right of all citizens, but it is not always easily deliverable in remote areas, such as seagoing vessels as well as small islands, rural regions, or in developing countries.

Remote teleconsultation therefore represents the only realistic way to deliver health care to patients not able to obtain direct medical assistance such as seafarers on board ships without medical facilities. Seagoing vessels represent a prototype of isolated place, and could remain at sea for days or weeks before reaching a port.

The largest majority of merchant ships do not carry doctors or expert paramedic personnel and an officer with medical duties (the captain or the first mate) is the person in charge of the patient in case of accidents or diseases. For more than 80 years, several radio medical services has been operational, starting by using radio signals and Morse code[34], evolving through telephones to full blown telemedicine solutions.

Today specialized ashore centres called Telemedical Maritime Assistance Service (TMAS) offer medical assistance to ships with no doctor on board.[35]

Telemedical consultations, however, have some innate limitations.

One consists in the fact that the great majority of people asking for medical advice by means of ICT resources do not have proper medical training.

The communication of symptoms or specific clinical situations can therefore be difficult or misleading in case of absence of objective information such as biomedical data and/or video support.

This work presents a system conceived to improve the first level teleconsultation by allowing the correct flow of the relevant information on the status of a patient, avoiding problems related to verbal communication or jammed transmission.

This system guides the ship captain in the medical examination, increasing the preciseness of the information transmitted with the consequent possibility to obtain more accurate and quicker diagnosis. Potential users of the system besides seafarers could be also other isolated populations such as personnel on-board of commercial aircrafts or oil-rig workers or people living in rural areas.

Hence, a potential high number of users can benefit from the system that will allow, starting from a given sign, the identification of the cohort of other signs and symptoms present.

2.1. THE USER'S INTERFACE

The hierarchical organization of concepts and the superclasses make easier and less time-consuming for the user to navigate the information. Selecting the main sign, the system asks to consider a series of additional signs and detailed information.

These are organized in big groups (superclasses). If the patient doesn't manifest the sign to which the group is referring or doesn't want to consider that superclass, he can simply answer "No" (or don't click) to the relevant superclass.

By clicking on a superclass, the series of detailed info about that clinical status appears. They can be answered in the following three main ways (Figure 2):

- **Boolean selection (Yes/No)**
- **Multiple selection**
- **Typing (generally a string or a number)**

A personal history of the patient is required to be filled:

- **Age**
- **Name**
- **Birthdate**
- **Sex**
- **Nationality**
- **Rank**

Complete medical history and drug history of the patient should be included in the following order:

Previous most significant diseases

- **Chronically administered drugs**
- **Drugs administered for the actual condition**

Once answered all the detailed information referring to all the superclasses as described above, the user can submit them, sending the data package to the maritime telemedical centre (TMAS) (Figure 2).

The system has been adapted in particular for naval communication. Then, a series of information about the ship is required to be inserted, such as:

- **Ship Name**
- **Ship Type**
- **Ship Owner**
- **RadioCode**
- **Master**
- **Ship Nationality**
- **Port of departure**
- **Port of arrival**
- **Speed**
- **Position**
- **Telephone / Fax / E-mail**

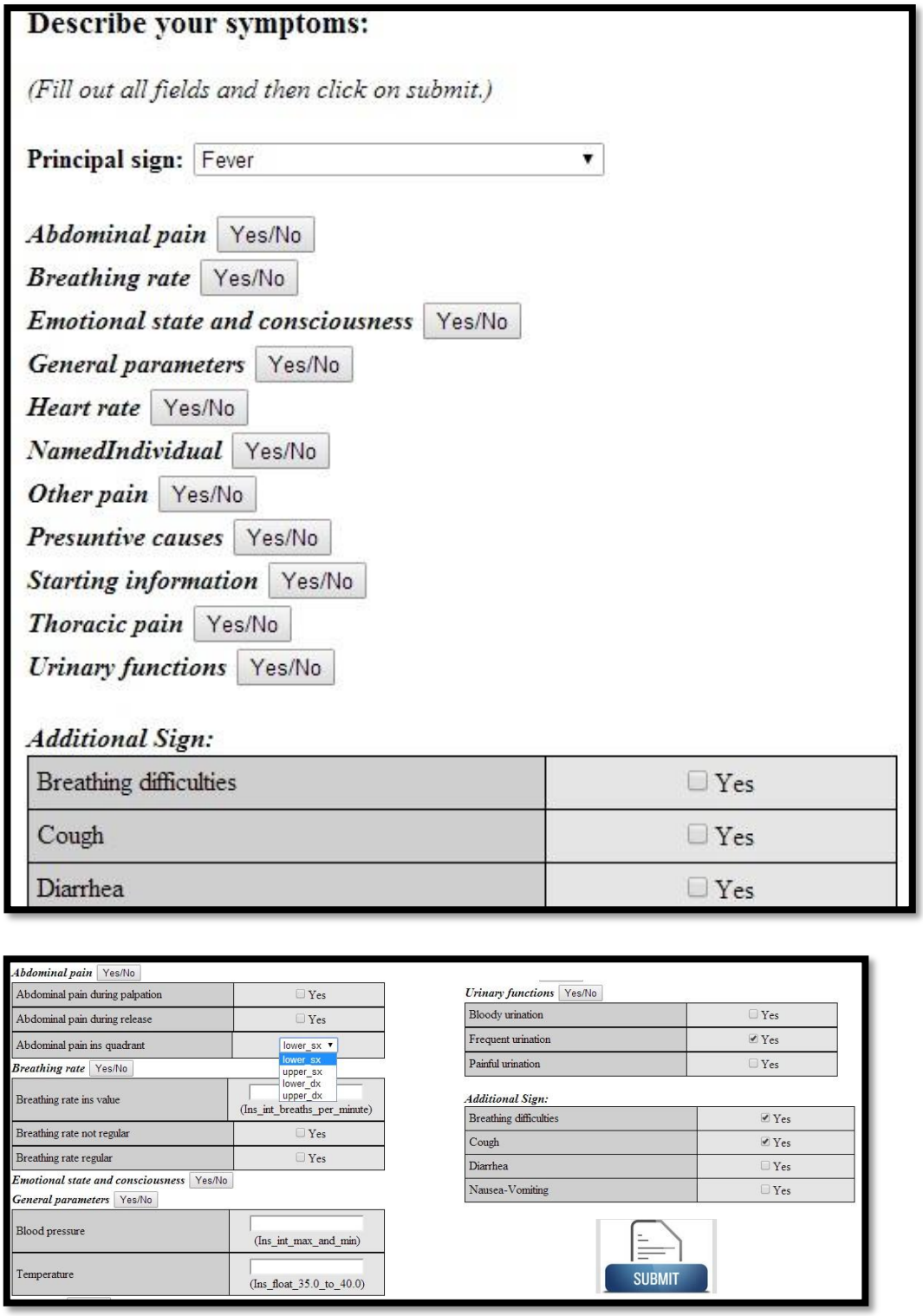


***Figure 2**: Left part shows a detailed information referring to each superclass with the relevant answer options to select or fill in. The right part of the Figure shows the procedure ends with the submission of the compiled form.*

2.2. SYSTEM TESTINGS

Tests of the system are ongoing in collaboration with Centro Internazionale Radio Medico (CIRM), the Italian Telemedical Maritime Assistance Service (TMAS), [36] using seagoing vessels as a prototype of isolated places.

CIRM medical assistance is given to ships of any nationality sailing worldwide.

The service is provided 24 hour a day and 365/366 days per year by doctors on duty.

The centre receives the request of assistance and gives instructions for the case.

For assessing the quality of the system, 150 teleconsultations between seagoing participating voluntarily to the experiments (users) and CIRM medical team (experts), were evaluated.

Evaluation of the system involved both the user's and the expert's side and both user's satisfaction and technical aspects.

The parameters listed below were considered compared to standard communication systems:

- **Accuracy of the request (No. of non-ambiguous signs communicated per request)**
- **Accuracy of the diagnosis made by the centre (N. of correct verified diagnosis/total cases)**

- **Speed of a complete round: time to make the request/time to provide the answer**
- **Speed of the diagnosis**
- **Usability (easiness of use, even by an inexpert user)**
- **Wiliness to use**
- **Completeness of the information**
- **Overall reliability of the system**

A score from "**High**" to "**Medium**" to "**Low**" was assigned by the testers (users and experts) for each of the above parameters.

CHAPTER 3 – HANDLING THE MEDICAL CHEST

Pharmacotherapy represents a pillar of modern medicine. This is true also in case of diseases or accidents occurring on board ships. Ships should carry compulsorily given amounts of medicines and medications facilities which may vary depending on the flag of the vessels.[34]

The medicine and medical equipment stores compose the so called “Ship Medicine Chest”. The “Ship Medicine Chest” is not really a chest anymore, but the name is still there, although it would have been more appropriate today to talk about ship pharmacy[34,37].

Activities at sea, represent one of the jobs that does not make it similar to other types of activities on the ground. Seafarers are a category of workers for whom the ship, is not only the workplace but often a true living environment for long periods, during which with increasing probability increases injury risk, with reference to events often disabling or fatal.[37,38]

This concern cannot be considered completely new, because almost all national laws - even before the European Union - foresaw, in a more or less stringent medical safety standards and minimum supply of drugs. [39]

The existence of many different nationalists and some supranational ones (WHO,EU) does not help ship officers with duties of control of the ship’s pharmacy to perform easily their work.

Medicinal products considered restricted for some countries are not the same in others and this could create confusions and penalties as ship officers with duties of controlling the pharmacy have no enough

knowledge of pharmacology for preparing for instance a box of restricted products before landing in Russia or when a ships stops in Nigeria.

The supply of medicinal products exhausted in some countries may result in the availability of boxes the understanding of their contents may be not obvious. On an international level we today have the following lists:

- An “old” recommendation from WHO/ILO/IMO in the second edition of the International Medical Guide for Ships– with quantities of each medicine to be carried on indicated. Up to this day this list has been in use, inspite of a new on in the 3rd edition of IMGS, because of its recommendations of quantities, although some medicines in use nowadays are lacking. [40]

- In the last edition of the IMGS – the IMGS3 – there is another updated list [41], this time without recommended quantities. The lack of quantification has caused a lot of trouble both to shipowners, seafarers, suppliers and inspectors – what should be on board? Nobody knows it. When we should require a new supply of a given compound?

- The so-called “Quantification Addendum: International Medical Guide for Ships 3rd edition” from WHO was published in September 2010. The surprise is that WHO had declared rather explicitly that there was no need of quantification to the Ship Medicine Chest contents.

In these conditions it appears obvious that auto-supervision of the ship’s pharmacy is not enough and also to delegate this task to local pharmacies or organizations selling medicinal products is not the best

solution. Related to above law regulations and considering the high risk of injuries, the project ”Pharmacy Ships” was developed.

It is a management and monitoring system to evaluate the drugs on board the ship. It reduces the handmade management of the inventory and it allows a fast evaluation of the available drugs to reduce time in case of crew’s injuries /diseases which happen frequently.

3.1. THE “PHARMACY’S SHIP” SOFTWARE

PharmacyShip’s is a tool to manage in a smart way the inventory pharmacy’s inside a vessel. It allows to decrease the difficulties of managing the quantity and the types of drugs and medical advices inside the ship. Furthermore, there is an improvement for the institutional organization for control point of view, too.

Infact, with this software, a standardization is created to reduce time in control and mainly, avoid misunderstanding. Right now no standardization at all can be seen in this field of medicine and every shipowner manages on your own the drugs and medical advices.

For that reason, PharmacyShip’s wants to handle, in a smart and optimal way the medicine’s store.

It is developed through Windows Access 2007 software and it consists mainly of two parties: medical advices and medicines. Both of them have a storing part, Access database, with the whole information of the items and a mask to edit the database with some mandatory rules given by the nation’s law where the tool is used.

The reason of the division in these two main parts it was taken after a deep study due to the amount of information.

Moreover the drugs database needs to store more information compared to the medical advices one.

The first page that appears is a report where there are, if presents, the medicines that will expire within 30 days from the current date.The report notifies in advance the user according to Expiry date database field (Figure 3).

***Figure 3**: An example of the software's automatic expiring feature*

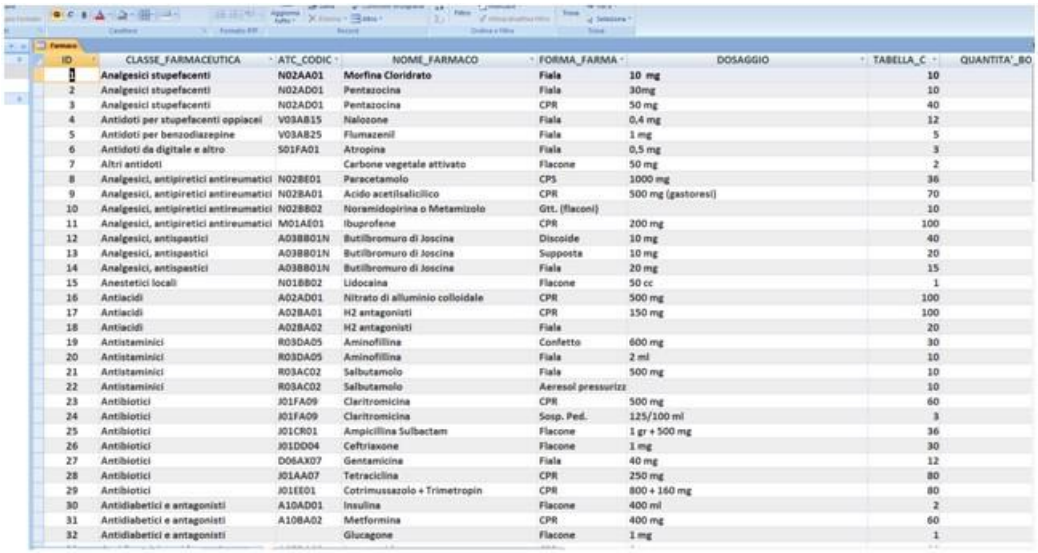
3.1.1. MEDICINE SECTION

A snapshot of the drug's database it is shown in Figure 4.

Each row represents one medicine with its related information. For each of them there are the following information:

- Pharmaceutical class;
- ATC code;

Figure 4: List of drugs inside the software



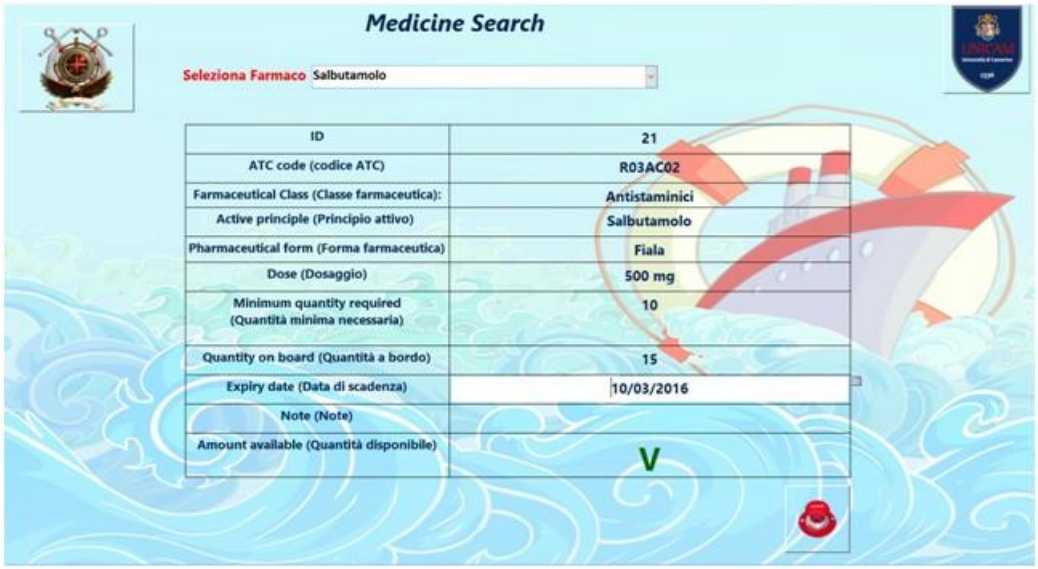
ID	CLASSE_FARMACEUTICA	ATC_CODIC	NOME_FARMACO	FORMA_FARMA	DOSAGGIO	TABELLA_C	QUANTITA'_BO
1	Analgesici stupefacenti	N02AA01	Morfina Cloridrato	Fiala	10 mg	10	
2	Analgesici stupefacenti	N02AD01	Pentazocina	Fiala	30mg	10	
3	Analgesici stupefacenti	N02AD01	Pentazocina	CPR	50 mg	40	
4	Antidoti per stupefacenti oppiacei	V03AB15	Nalozone	Fiala	0,4 mg	12	
5	Antidoti per benzodiazepine	V03AB25	Flumazenil	Fiala	1 mg	5	
6	Antidoti da digitale e altro	S01FA01	Atropina	Fiala	0,5 mg	3	
7	Altri antidoti		Carbone vegetale attivato	Flacone	50 mg	2	
8	Analgesici, antipiretici antireumatici	N02BE01	Paracetamolo	CPS	1000 mg	36	
9	Analgesici, antipiretici antireumatici	N02BA01	Acido acetilsalicilico	CPR	500 mg (gastoresi)	70	
10	Analgesici, antipiretici antireumatici	N02BB02	Noramidopirina o Metamizolo	Gtt. (flaconi)		10	
11	Analgesici, antipiretici antireumatici	M01AE01	Ibuprofene	CPR	200 mg	100	
12	Analgesici, antispastici	A03BB01N	Butilbromuro di Joscina	Discoide	10 mg	40	
13	Analgesici, antispastici	A03BB01N	Butilbromuro di Joscina	Supposta	10 mg	20	
14	Analgesici, antispastici	A03BB01N	Butilbromuro di Joscina	Fiala	20 mg	15	
15	Anestetici locali	N01BB02	Lidocaina	Flacone	50 cc	1	
16	Antiacidi	A02AD01	Nitrato di alluminio colloidale	CPR	500 mg	100	
17	Antiacidi	A02BA01	H2 antagonisti	CPR	150 mg	100	
18	Antiacidi	A02BA02	H2 antagonisti	Fiala		20	
19	Antistaminici	R03DA05	Aminofillina	Confetto	600 mg	30	
20	Antistaminici	R03DA05	Aminofillina	Fiala	2 ml	10	
21	Antistaminici	R03AC02	Salbutamolo	Fiala	500 mg	10	
22	Antistaminici	R03AC02	Salbutamolo	Aerosol pressurizz		10	
23	Antibiotici	J01FA09	Claritromicina	CPR	500 mg	60	
24	Antibiotici	J01FA09	Claritromicina	Susp. Ped.	125/100 ml	3	
25	Antibiotici	J01CR01	Ampicillina Sulbactam	Flacone	1 gr + 500 mg	36	
26	Antibiotici	J01DD04	Ceftriaxone	Flacone	1 mg	30	
27	Antibiotici	D06AX07	Gentamicina	Fiala	40 mg	12	
28	Antibiotici	J01AA07	Tetraciclina	CPR	250 mg	80	
29	Antibiotici	J01EE01	Cotrimussazolo + Trimetropin	CPR	800 + 160 mg	80	
30	Antidiabetici e antagonisti	A10AD01	Insulina	Flacone	400 ml	2	
31	Antidiabetici e antagonisti	A10BA02	Metformina	CPR	400 mg	60	
32	Antidiabetici e antagonisti		Glucagone	Flacone	1 mg	1	

- Active ingredient's name;
- Pharmaceutical form;
- Dose;
- Minimum quantity required;
- Quantity on board;
- Medicine's expiration date;
- Note;
- Amount available;

The mask created upon this database is the following in Figure 5.

Here, the user can select a specific medicine and instantly he gets all the information of the drug chose. He can control, the quantity on board, if there are some important clipboards, etc.

The software allows to the user to modify some fields such as Quantity on board. For instance, if inside the ship there is a health emergency and a specific drug is used, an update of the Figure 5: Software's frontal page



field "quantity on board" must be stored inside the database. In the case that, the new amount of quantity on board about the used medicine is less than the amount of minimum quantity required for the law point of view, the software pops up an alert to notify to the user that the depot needs to refill, as soon as possible, with the specified medicine (Figure 4).

If the amount of quantity on board is less than 50% of the minimum quantity required, the software pops up another alert. However, in this case, the alert is blocked and the user cannot use the software anymore before he refills the depot (Figure 5).

There is a field that inform in direct way if the quantity on board is greater or equal than minimum quantity required through a red "X" or a green "V". In Figure 5 the quantity on board is greater than the

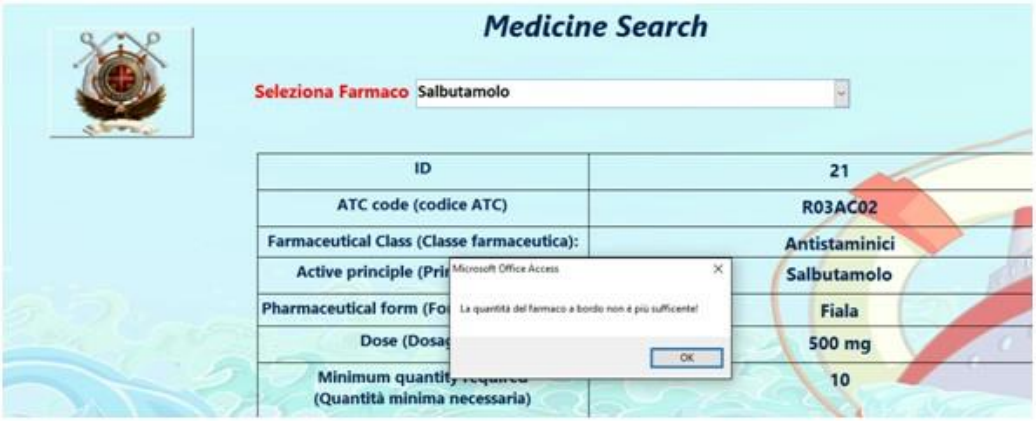
minimum quantity required and thus a green ”V” appears on the screen.

These two validation rules allow the user to abstract in a good way the management of the medicine’s store. In fact, the user must update only the medicines through the corresponding mask.

After that, the software processes the data and eventually, whether necessary, it alerts the user. Moreover the software checks every time, the expiration date of the all medicines present inside the database.

Finally, it stores the updates and the warnings inside the database automatically.

***Figure 4**: Software’s frontal page with quantity notification alert*



3.2.2 MEDICAL ADVICE SECTION

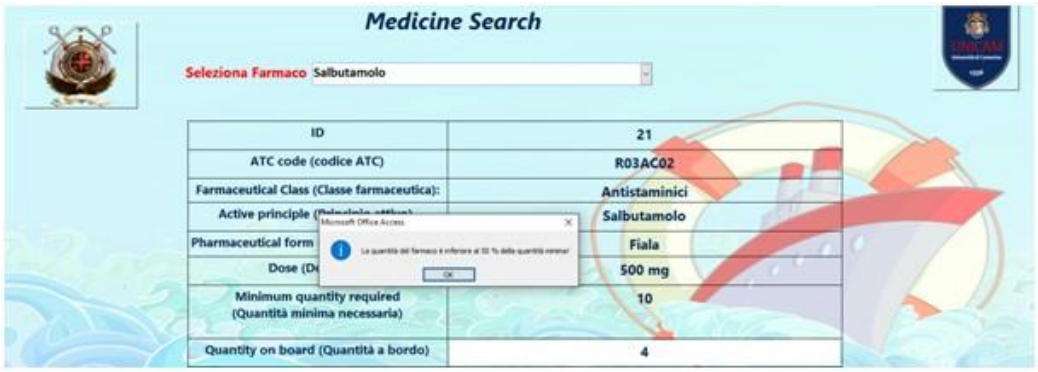
The medical advices section is quite similar to the medicine section. It owns another database with the information about the medical advices (Figure 6 and another mask to manage and modify the related information.

For each medical advice there are the following information:

- ID
- Group;
- Medical Advice name;
- Minimum quantity required;
- Quantity on board;
- Note;
- Amount available;

The medical advice mask has the same functionalities of the medicine sections mask. There are the two warnings related to the quantity on board when it is less of the minimum quantity required, like for the previous section of this article (Figure 6).

***Figure 5**: Software's frontal page with quantity notification alert. The block is enabled due to the fact the minimum quantity on board is not enough*



The sea voyage both tourist and merchant requires the assurance of the availability of drugs and medical equipment to deal with any possible situation of injury.

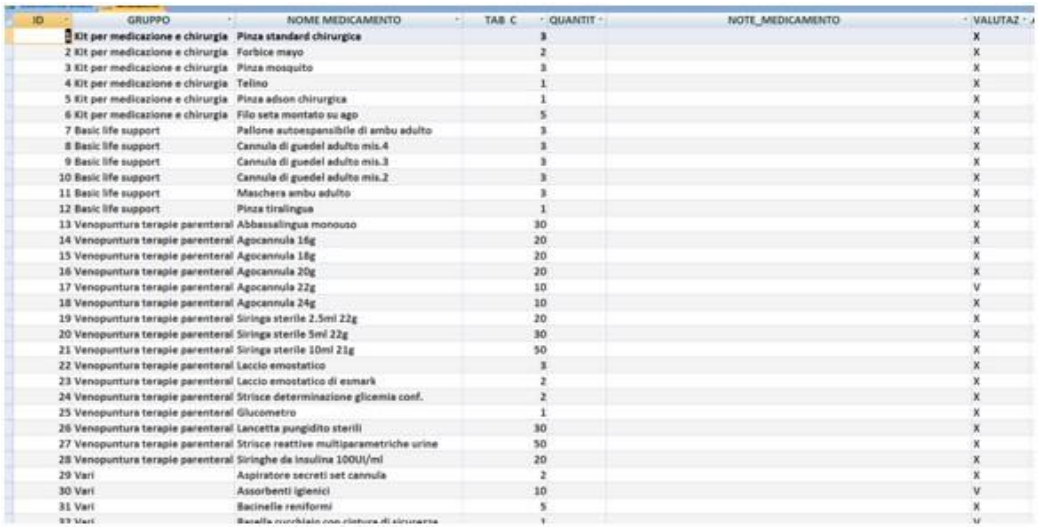
This fact implies that, in addition to the ephemeral ability to predict the unpredictable, it needs of a software instruments able to allow in a timely manner an adequate design of intervention in many cases of accidents that frequently occur as a significant problem. Considering the fact that injuries are the leading cause of disease, within this framework of security founded the project PharmacyShips.

PharmacyShips is a easy to use tool and it allows to manage in a mostly automated inventory of drugs and medicaments on board vessels reducing the possible human intervention (by the crew on board) which can lead, very often, to errors and oversights. This means that, periodic monitoring of equipment is simplified and speeded up by the staff.

The user also has the ability to search within the database, a specific drug through its active ingredient and / or his immediate ATC code identifier to find out all the information above. In these conditions it appears obvious that auto-supervision of the ship's pharmacy is not enough and also to delegate this task to local pharmacies or organizations selling medicinal products is not the best solution.

The software also has the ability to create an Excel file with the entire contents of the database for a transfer or printing on paper for subsidized bodies responsible for monitoring inventory by optimizing the timing and quality of service.

People living ashore may have medical services available within a short time. This is not the case of seagoing ships, the majority of which do not Figure 6: List of medical advice



ID	GRUPPO	NOME MEDICAMENTO	TAB C	QUANTIT	NOTE_MEDICAMENTO	VALUTAZ
1	Kit per medicazione e chirurgia	Pinza standard chirurgica		3		X
2	Kit per medicazione e chirurgia	Forbice mayo		2		X
3	Kit per medicazione e chirurgia	Pinza mosquito		3		X
4	Kit per medicazione e chirurgia	Telino		1		X
5	Kit per medicazione e chirurgia	Pinza adson chirurgica		1		X
6	Kit per medicazione e chirurgia	Filo seta montato su ago		5		X
7	Basic life support	Pallone autoespansibile di ambu adulto		3		X
8	Basic life support	Cannula di guedel adulto mis.4		3		X
9	Basic life support	Cannula di guedel adulto mis.3		3		X
10	Basic life support	Cannula di guedel adulto mis.2		3		X
11	Basic life support	Maschera ambu adulto		3		X
12	Basic life support	Pinza tiralingua		1		X
13	Venopuntura terapie parenteral	Abbassalingua monouso		30		X
14	Venopuntura terapie parenteral	Agocannula 16g		20		X
15	Venopuntura terapie parenteral	Agocannula 18g		20		X
16	Venopuntura terapie parenteral	Agocannula 20g		20		X
17	Venopuntura terapie parenteral	Agocannula 22g		10		V
18	Venopuntura terapie parenteral	Agocannula 24g		10		X
19	Venopuntura terapie parenteral	Siringa sterile 2.5ml 22g		20		X
20	Venopuntura terapie parenteral	Siringa sterile 5ml 22g		30		X
21	Venopuntura terapie parenteral	Siringa sterile 10ml 21g		50		X
22	Venopuntura terapie parenteral	Laccio emostatico		3		X
23	Venopuntura terapie parenteral	Laccio emostatico di esmark		2		X
24	Venopuntura terapie parenteral	Strisce determinazione glicemia conf.		2		X
25	Venopuntura terapie parenteral	Glucometro		1		X
26	Venopuntura terapie parenteral	Lancetta pungidito sterili		30		X
27	Venopuntura terapie parenteral	Strisce reattive multiparametriche urine		50		X
28	Venopuntura terapie parenteral	Siringhe da insulina 100UI/ml		20		X
29	Vari	Aspiratore secreti set cannula		2		X
30	Vari	Assorbenti igienici		10		V
31	Vari	Bacinelle reniformi		5		X

have a doctor or adequately trained paramedic personnel and may be in the sea for days or weeks before they can reach a port. In this situation, the best possibilities for treating diseases or injuries on board are:

- provide medical advice via telecommunications systems;
- guarantee proper training of personnel with the responsibility of health care on board;
- have an adequate supply of drugs and essential medical equipment (the so called ship's medical chest).

In addition, in 1988, the World Health Organization has published a guide, for those states that did not have any legislation, with a mandatory list of included pharmaceuticals products for each vessel.[42] According to art. 58 of the Regulations of maritime health (RD 29/09/1895 n. 636)[43], all the ships assigned to

extended voyages or of great cabotage should carry a box equipped with medicines and disinfectants prescribed by ministerial instructions. The captain must see the health equipment before departure and if everything is fine, maritime health surveillance delivers the conformity certificate.[44]

It is not expected the presence of a pharmacist on board ships.[45]

***Figure 6**: Frontal sofware's page of medical advice*

This "exclusion" was given by the World Association of Pharmacists (Federation InternationalePharmaceutique - FIP) during the last World Congress held in Sydney in September 2003.[46]

It approved a statement on the policy to be pursued by category issue of supply of drugs to the ships and their proper use. Industry Italian National legislation with the DM 05/25/1988 n.279 and subsequent revisions, until the decision of 1 October 2015, where

paragraph 5 provides for detention of drugs consist of molecules similar to those in equal quantities and overlapped with identical[47]therapeutic indications - indicates the medicines, dressing objects and tools of which must be provided by the merchant ships traffic and fishing, as well as boats and recreational vessels.[48]

That decree lists in three tables, the size and quality of the equipment boxes medicines, depending on the type of navigation where the vessel is enabled. In this light, the project Pharmacy Ship's was born.

The goal of the software, as well as the automation of some actions which are still carried out manually, is to standardize procedures and protocols used inventory.

From this it turns out to be innovative and fully adhering to those who are new requirements on prevention, protection and health of seafarers under the Decree 1st October 2015.

In this perspective, the innovative software in the field of Pharmacy Ship's medicine chest, is an extremely effective tool that allows to guarantee precise prescription of medicines available on board, identify them by number and consequent reduction of possible mistakes in administering pharmaceutical compounds to seafarers.

Often prescriptions are not adequate due to the lack of a given compound as it is expired or finished. Monthly collection data on the availability of ship's pharmacy with prescriptions of replenishment of the missing medicines will avoid these problems.

The software does not need internet connection because, nowadays, most of the ships don't own stable internet line. For the

future, when all the ships will be predisposed to a stable internet connection, a web software module can be integrated to enable real-time, and independently communication with land.

Pharmacy Ship’s is a unique and extraordinary in its kind, innovative and huge application potential.

CHAPTER 4 – TELEPHARMACY: MANAGEMENT OF THE ONBOARD PHARMACY

A novel solution to management of medicine chest at sea not having a doctor or qualified pharmacist onboard.

Maritime healthcare has evolved in the way we seek and receive medical assistance onboard vessels. However, in most cases management of the Sickbay continues to follow redundant methods that could be automated to bring in greater efficiency, transparency and most important take up less time of the officer in charge.

The 360o approach to the Sickbay management includes:

1. Mandatory Flag State compliance

The flag state compliance is the most important. The system is configured with the Flag State requirements for the sickbay and automated checks and alerts are configured to ensure compliance is always maintained. The system also allows administrators and crew managers to compare the flag states to better understand and manage their fleet with various Flag States.

2. Automated Alerts

The system is developed to provide timely alerts to the Master / Officer in-charge and the tele-pharmacist on inventory status and

medicine expiry. These alerts prompt the user to the next actions to be taken to comply with international standards.

3. Automated check-list reminders to ensure compliant medical chest

A defined check-list has been constructed that guides the Master / Officer in-charge to go over the important aspects of Medical Chest and ensure compliance. At all steps the Tele-pharmacist is available to guide and assist the Master / Officer in-charge.

4. Automated Order form validated and certified by the tele-pharmacist

With the medical chest being e-certified quarterly the minimum quantity and the expiry of medicines is routinely checked. The automated alerts, not only alert regarding the expiry of medicines, but also if the quantity is low the system will auto create an order form that will be validated by the Tele-pharmacist.

5. Smart Restocking & Disposal protocols

On shore one can go and buy medicines from a pharmacy easily. However, on the high seas or on port to purchase a medicine the process involves a lot of paper work and can be extremely expensive. Therefore, having an automated system that can allow you to restock smartly looking at consumption trends and availability of medicines makes this a great value-added deliverable of the service.

6. E-Certification and Analytics

The Tele-pharmacist conducts an e-audit every quarter to issue the e-certificate of compliance to the vessel. This certificate of compliance is evidence of the effort being put to ensure compliance with flag state requirements.

Analytics derived from the data give insight on the consumption and wastage both which can lead to cost savings and also identifying any unhealthy trends onboard the vessel.

4.1. The Ship's Pharmacy Compliance Certificate

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Società a Socio Unico
Via dell'Architettura 41, 00144 Roma, Italy
info@cirmservizi.it; www.cirm-servizi.it

CHECKLIST FOR THE SHIP'S PHARMACY INSPECTION

Ship's Name	Ship type	Flag
Call sign	**IMO No.**	**M.M.S.I. No.**
Armatore **Managing Company**		

Medicine chest regulation reference	Medicine chest scale class	If compliance to IMDG/MFAG Scales required
Number of people on board	Officer responsible of ship's medical chest handling (name and rank)	Instructions for Handling Ship's Medicine Chest Available (if any)

Date of inspection of ship medicine chest	Inspector (name and rank)	Pharmacist supervising
	DR. GIULIO NITTARI PHARM D	DR. GIULIO NITTARI PHARM D

00144 Roma – Via della Architettura, 41 – Tel +39-0669327894

e-mail: occupational.medicine@cirmservizi.it

C.F. 12947211004 /P.I. 12947211004

1.0	Policies and Procedures	Yes	No
1.1	Has the Ship's pharmacy documented policies and procedures/SOPs? The following are		
	a) Storage of medicines		
	b) Sourcing of medicines		
	c) Expiry date checking		
	d) Storage and record-keeping for controlled drugs		
1.2	Supervision of supply of periodic pharmacy board (3/4 months)		
1.3	proper disposal of expired drugs, particularly narcotics drugs		
1.4	the management staff of the medicine chest undergoes training		

2.0	Duty Register	Yes	No
2.1	Has the Ship's Pharmacy a duty register/log for the current year?		
2.2	Is the duty register being correctly maintained?		

3.0	Prescription Register/ Dispensing Report/Inventory (Medical Chest Log	Yes	No
3.1	Is a dispensing report filled in ?		
3.2	Is the dispensing report filled in with a frequency of (day, week, month……)		
3.3	Are the dispensing reports/prescriptions for the previous two years available for review on the premises?		
3.4	Is there any Medical Chest Log Book ?		
3.5	Is the Medical Chest Log Book properly filled in and maintained ?		
3.6	Are dates of update of the Medical Chest Log Book and of the person in charge of it indicated?		
Check if a prescription register exists, if there is the indication of the person in charge of maintenance of it. **COMMENTS:**			
Check if a Medical Chest Log Book is properly maintained, if there is the indication of the person in charge of maintenance of it. **COMMENTS:**			

4.0	Controlled Drug Register	Yes	No
4.1	Has the Ship's Pharmacy a CD register?		
4.2	Is the CD register completed in accordance with regulations?		
4.3	Is there evidence of routine review and stock balance checks?		
Check if a prescription register exists, if there is the indication of the person in charge of maintenance of it. **COMMENTS:**			

5.0	Controlled Drug Safe	Yes	No
5.1	Has the Ship's Pharmacy a CD safe?		
5.2	Is there a written 'keyholding' policy for the CD safe?		
5.3	Is the safe secured in accordance with regulations?		
5.4	Does the safe have sufficient capacity?		

6.0	Storage of Medicinal Products requiring refrigeration	Yes	No
6.1	Has the Ship's Pharmacy a dedicated fridge?		
6.2	Is the fridge temperature monitored and recorded on a WEEKLY basis?		
6.3	Is the temperature in the dispensary and any additional storage areas monitored and recorded on a WEEKLY basis?		
Check cleanliness of fridge, condition of stock. **COMMENTS:**			

7.0	Storage of standard Medicinal Products	Yes	No
7.1	Are medicinal products properly stored in medicine chests and cabinets?		
7.2	Is there a correspondence between the place where medicinal products are and where they should be based on the Medical Chest Log Book ?		
7.3	Are expiry dates of medicinal products indicated clearly ? Where ? INVENTORY.		
Check storage areas and condition of stock. **COMMENTS**			

4.2. Checklist for the Ship's Pharmacy Inspection

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prot.nCD.

SHIP'S PHARMACY COMPLIANCE CERTIFICATE

(ATTESTAZIONE DI CONFORMITÀ DELLE DOTAZIONI DI MEDICINALI, OGGETTI DI MEDICATURA E UTENSILI VARI DI BORDO)

SHIP'S NAME (NOME DELLA NAVE)	SHIP'S TYPE (TIPO DI NAVE)	FLAG (BANDIERA)
CALL SIGN (NOMINATIVO RADIO INTERNAZIONALE)	IMO No. (NUMERO I.M.O.)	M.M.S.I. No. (NUMERO M.M.S.I.)
MANAGING COMPANY (ARMATORE)		

MEDICINE CHEST REGULATION REFERENCE (NORMATIVA DI RIFERIMENTO ALLA DOTAZIONE PRESCRITTA)	MEDICINE CHEST SCALE CLASS (TABELLA DI APPARTENENZA)	IF COMPLIANCE TO IMDG/MFAG SCALES REQUIRED (SE SOGGETTA A PRESCRIZIONI IMDG/MFA)
Italian Ministry of Health decree 1 October 2015, **DECRETRO 1 OTTOBRE 2015** (Modificazioni della tabella allegata al decreto 25 Maggio 1988, n 279, che indica i medicinali, gli oggetti di medicatura e gli utensili di cui devono essere provviste le navi nazionali destinate al traffico mercantile ,alla pesca e al diporto nautico.)	**C**	

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e.mail: occupational.medicine@cirmservizi.it
e.mail: gnittari@cirmservizi.it

P.I. IT12947211004

NUMBER OF PEOPLE ON BOARD (NUMERO PERSONE IMBARCATE)	OFFICER RESPONSIBLE OF SHIP'S MEDICAL CHEST HANDING (name and rank) UFFICIALE RESPONSABILE DELLA TENUTA (nome e qualifica)	INSTRUCTION FOR HANDING SHIP'S MEDICINE CHEST AVAILABLE (if any) (EVENTUALE GUIDA ALLA TENUTA DELLA FARMACIA DI BORDO DISPONIBILE)

DATE OF INSPECTION OF SHIP MEDICINE CHEST (DATA ISPEZIONE FARMACIA DI BORDO)	INSPECTOR (name and rank) RESPONSABILE DELL'ISPEZIONE (nome e qualifica)	PHARMACIST SUPERVISING (FARMACISTA SUPERVISORE)
	Dr. GIULIO NITTARI Pharm D	**Dr. GIULIO NITTARI** Pharm D

DETAILED INSPECTION RESULTS

1.0	Policies and Procedures	Yes	No
1.1	Has the Ship's pharmacy documented policies and procedures? The following are recommended:		
	a) Storage of medicines (conservazione dei farmaci)		
	b) Sourcing of medicines (fornitura dei farmaci)		
	c) Expiry date checking (controllo della data di scadenza)		
	d) Storage and record-keeping for controlled drugs (conservazione e compilazione del registro di farmaci stupefacenti)		
1.2	• Supervision of supply of periodic pharmacy board (3/4 months) (supervisione delle forniture della farmacia di bordo periodico (3/4 mesi)		
1.3	• proper disposal of expired drugs, particularly narcotics drugs (corretto smaltimento di farmaci scaduti, in particolare stupefacenti)		
1.4	• the management staff of the medicine chest undergoes training (il personale preposto alla gestione della farmacia di bordo è sottoposto a formazione)		
	On board there are instructions on how to store medicines with particular reference to controlled drugs. There is also a manual on "First Aid" (A bordo ci sono le istruzioni su come conservare i farmaci con particolare riferimento ai farmaci controllati. C'è anche un manuale su "First Aid"?)		

2.0	Duty Register	Yes	No
2.1	Has the Ship's Pharmacy a duty register/log for the current year? (La farmacia di bordo ha un adeguato registro per l'anno in corso?)		
2.2	Is the duty register being correctly maintained? (Il registro è redatto e compilato in maniera corretta?)		

3.0	Prescription Register/ Dispensing Report/Inventory (Medical Chest Log Book)	Yes	No
3.1	Is a dispensing report filled in? (Esiste un rapporto di erogazione compilato?)		
3.2	Is the dispensing report filled in with a frequency of (day, week, month……)? (Il rapporto di erogazione è riempito con una frequenza di giorno, settimana, mese ……)		
3.3	Are the dispensing reports/prescriptions for the previous two years available for review on the premises? (Sono le relazioni / erogazione prescrizioni per i due anni precedenti disponibili per la revisione nei locali?)		
3.4	Is there any Medical Chest Log Book? (Esiste un diario di bordo per la cassetta medicinali?)		
3.5	Is the Medical Chest Log Book properly filled in and maintained? (Il diario di bordo è debitamente compilato e conservato?)		
3.6	Are dates of update of the Medical Chest Log Book and of the person in charge of it indicated? (Sono indicate le date di aggiornamento e il nome della persona addetta al registro?)		

- **Medicinal products are cataloged and stored according to the progressive list mentioned in the Italian Ministry of Health decree 1 October 2015, No. 279.**

(I medicinali sono catalogati e archiviati secondo l'elenco progressivo di cui al Decreto del Ministero della Sanità 1 Ottobre 2015)

- **A review of available medicines is done every three months.**

(Una revisione dei farmaci disponibili è fatto ogni tre mesi.)

- **Health training of the staff on board according to the standards listed below: First Aid Course (all crew members); Advanced Course of Medical Care (Master, Chief Officer, 2nd Officer, 3rd Officer).**

(Il monitoraggio della salute del personale di bordo secondo gli standard elencati di seguito: Corso di primo soccorso (tutti i membri dell'equipaggio); Corso Avanzato di cure mediche (Comandante, Amministratore Delegato, 2 ° Ufficiale, 3 ° Ufficiale).

- **The Medical Chest Log Book is kept by the Captain and by the 2rd Officer in the ship's hospital.**

COMMENT: **CAPTAIN.**
(IL REGISTRO STUPEFACENTI ESISTE ED è CONSERVATO E COMPILATO DAL CAPITANO)

4.0	Controlled Drug Register	Yes	No
4.1	Has the Ship's Pharmacy a CD register? (La farmacia di bordo ha un CD di registrazione?)		
4.2	Is the CD register completed in accordance with regulations? (Il CD è completato in conformità con le normative?)		
4.3	Is there evidence of routine review and stock balance checks? C'è evidenza di revisione di routine e controlli di magazzino ?		

5.0	Controlled Drug Safe	Yes	No
5.1	Has the Ship's Pharmacy a safe CD? (Il CD della farmacia di bordo è messo in sicurezza?)		
5.2	Is there a written 'keyholding' policy for the CD safe? Esiste una politica 'di ritenuta della chiave' scritto per il CD di sicurezza?		
5.3	Is the safe secured in accordance with regulations? (È la cassaforte fissata in conformità alla normativa?)		
5.4	Does the safe have sufficient capacity? (La cassaforte ha una capacità sufficiente?)		

6.0	Storage of Medicinal Products requiring refrigeration	Yes	No
6.1	Has the Ship's Pharmacy a dedicated fridge? (La farmacia di bordo fa un frigorifero dedicato?)		
6.2	Is the fridge temperature monitored and recorded on a weekly basis? (È la temperatura del frigorifero monitorato e registrato su base settimanale?)		
6.3	Is the temperature in the dispensary and any additional storage areas monitored and recorded on a weekly basis? (È la temperatura nel dispensario e le eventuali aree di stoccaggio aggiuntivi monitorato e registrato su base settimanale?)		

7.0	Storage of standard Medicinal Products	Yes	No
7.1	Are medicinal products properly stored in medicine chests and cabinets? (Sono i prodotti medicinali correttamente conservati in cassetti e armadi?)		
7.2	Is there a correspondence between the place where medicinal products are and where they should be based on the Medical Chest Log Book? (Esiste una corrispondenza tra il luogo in cui i medicinali sono e dove dovrebbero essere in base al diario di bordo?)		
7.3	Are expiry dates of medicinal products indicated clearly? (Le date di scadenza dei medicinali sono indicate chiaramente negli appositi cassetti?) **Check storage areas and condition of stock.** **COMMENTS:**		

8.0	Other comments/observations
8.1	• **The list of medicinal products and other medication items was reviewed. Missing items were prescribed and loaded on board.** • **WERE MADE BETWEEN THE FOLLOWING REPLACEMENT DRUGS THERAPEUTILLY EQUIVALENTS** (L'elenco dei prodotti medicinali e altri articoli di medicazione è stato rivisto. Elementi mancanti sono stati prescritti e caricati a bordo. Sono state effettuate le seguenti sostituzioni tra prodotti terapeuticamente equivalenti come previsto da norma (comma 5 D.lgs 1 Ottobre 2015)

Based on the above results we hereby certify the compliance of the ship's pharmacy according to the Italian Regulations established by Italian Ministry of Health Decree 1 October 2015, No. 279. Medicines and medical devices contents required by Italian Regulations correspond to those indicated by the Council Directive 92/29/EEC of 31 March 1992 harmonized in the frame of European Union legislation and to the International Medical Guide for Ship (IMGS) published by the World Health Organization (WHO) and Medical First Aid Guide (MFAG) published by International Maritime Organization (WHO).

(Sulla base dei risultati di cui sopra si certifica la conformità della farmacia della nave in oggetto al Regolamento italiano stabilito dal Ministero della Salute Decreto 1 Ottobre 2015. Farmaci e Dispositivi Medici richiesti dalla normativa italiana corrispondono a quelli indicati dal Consiglio la direttiva 92/29 / CEE del Consiglio, del 31 marzo 1992 armonizzato nel quadro della legislazione dell'Unione europea e alla Guida medica Internazionale per nave (immagini) pubblicato dall'Organizzazione mondiale della sanità (OMS) e Guida medica primo soccorso (MFAG) pubblicato dalla International Maritime Organization (OMS).)

Validity of the document: **six months from the date of presentation**

(Validità del documento: sei mesi a partire dalla data di redazione)

Date/data:

4.3. The Order Form

CIRM SERVIZI s.r.l. - ORDER FORM

Address : Via dell' Architettura 41 00144 Rome, Italy	**Thelephone number:** +39 06 69327894 **Fax:** +39 06 69327897	**E-mail:** info@cirmservizi.it **Web:** http://www.cirm-servizi.it
SHIP'S NAME: **SHIP'S TYPE:** **FLAG:**	**CALL SIGN:** **IMO No :** **M.M.S.I. No:** **MANAGING COMPANY:**	**N. Buono d'ordine:** **Issuing date:** **PharmD Supervising**

N°	ATC Code	Active principle	Pharmaceutical form	Note	Required quantity*
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					

*The indicated quantity, are expressed in dose units.

CHAPTER 5- GENERAL DATA PROTECTION REGULATIONS (GDPR)

Nowadays, most of our information and data are stored in cloud computing and so they can be accessed via Internet everywhere. Formally, cloud computing represents the delivery of computing in the remote location through the ICT approaches[49].

This is very useful and mandatory in 2017 with the globalization because, most of the time, is needed to retrieve such data wherever you are. Indeed, having the information spread could be dangerous above all if that information represents sensitive information.

In this respect The General Data Protection Regulation (GDPR) is an important document for protecting the personal data of individuals in European Union.

It was adopted by REGULATION (EU) 2016/679 of the European Parliament in April 2016. It aims to the protection of natural persons with regard to the processing of personal data, free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation; Official Journal of the European Union L 119/1) and shall apply across the European Union (EU) from 25 May 2018 [50].

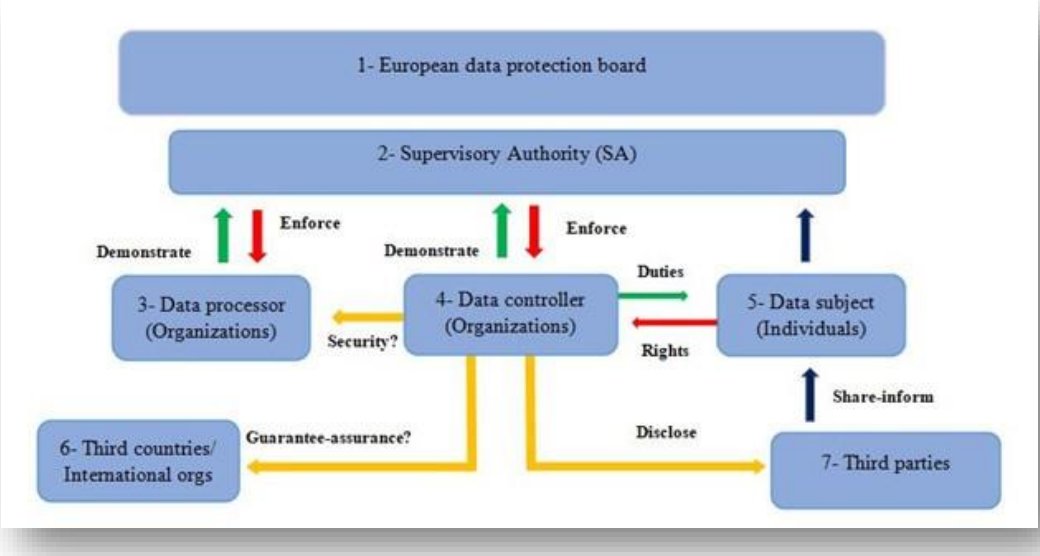
GDPR replaces the Data Protection Directive adopted in 1995. (2. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to

the processing of personal data and on the free movement of such data. Official Journal L 281 , 23/11/1995 P. 0031 - 0050).

This new regulation has a lot of goals including: harmonize data privacy laws across Europe, protect and empower all EU citizens data privacy and reshape the way organizations across the region approach data privacy.

The principal actors involved in this regulatory are Supervisory Authority (SA), data processors, data controller, data subject, third countries and international organizations and third parties. In Figure 7, a data flow between actors involved in such new regulament and their tasks has been shown.

***Figure 7**: The data flow graph of GDPR with the main actors and the relationships between them.*



SA actor is a public and independent authority, which is elected by each Member State and it checks whether the regulation is

effectively executed in the State. It can cooperate with other SAs of the other countries.

Data Processor actor is a natural or person, public authority or agency which processes personal data on behalf of the controller. It is able to process data when the controller requests it.[51]

Data Controller actor is the organization / entity, regardless of being public, private non-profit etc. That determines the manner and purpose of collecting personal data. From the GDPR, it represents the actor involved with the most responsibility. In other words, a data controller defines what it wants and what the final purpose of them is.

Data Subject actor represents a natural person and the GDPR protects his rights and freedom. Actually, through the GDPR, the data subject is the owner of his personal data, and he is free to move the data elsewhere or delete them. Third countries and International Organizations actors represent the countries outside the EU and if there is a necessity to send data subject to them, a condition is mandatory to guarantee the protection of the personal data that would to be sent. In this category, there are some third parties actors as lawyers, solicitors or members who are able to execute a data subject's rights.

Moreover, they can process the data on behalf of the data subject. Recently, there are many developments in bioinformatic for using personal health data for different application like

processing and research. These lead to more attention for protection of personal health data in digital environment.

The GDPR covers many aspects of the rights of personal data beside the research and public health purposes. In this paper, we discussed the aspects related to computer sciences points of view such as data security, data-portability and data erase (the right to be forgotten).

5.1. Data security

The term of data security in health reflects the managing personal data including protection against unauthorized or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organizational measures[52].

It is one of the most significant subjects in bioinformatic. According to article 31, the Controller should establish requirements for the protection of personal data. These requirements must be complied before and during data processing.

During the designing stage of requirements, they should consider the cost of implementing them because the cost of meeting these requirements must be equivalent to the expected risks.[53]

Article 35 introduces a mandatory data protection officer for the public sector and in the private sector, for large enterprises or where the core activities of the controller or processor consist of

processing operations which require regular and systematic monitoring.

In articles 36 and 37, it sets the position and his core tasks of this officer.

The controller must implement strategies and mechanisms to ensure that they process personal data according to the specific purposes. Personal data should not be retained after completing the defined process.

Unlimited number of processors nor unlimited processes cannot have access to personal data. In addition, each part of personal data must be made available only to the process that requires that part, as well as to the processor who needs this part of the data to complete the specific process.

This amendment is very important because it ensures that any third party requests personal data for a specific process cannot receive all the personal data of a data subject. For example, if a medical institution requests a person's personal data for medical treatment purposes, the controller can send just the medical part section of that data and he does not have any permission to send parts of political or philosophical opinions.

To achieve this relevant objective an implementation of different kinds of authorizations inside the system is needed. This key point could be expanded to all information included in the electronic record of the user (Article 23).

According to this regulation, the controller and the processor must implement strategies and use appropriate techniques to ensure the personal data protection of the data subjects. These strategies and techniques should be appropriate to the potential risks, the nature of the data, the purposes of the process, and the implemented process on that data. In addition, they have to guarantee an appropriate level of encryption, confidentiality and reliability.

The processor and the controller should ensure data access and the availability in the case of any data breach or malfunction. Finally, the processor should check, test and evaluate any strategies and techniques that he used to protect personal data.

He should guarantee that those techniques and strategies are appropriate to protect the personal data. This regulation also gives a great attention to the risks resulting from personal data processing, specifically the unauthorized modification or destruction. As well as data loss, revealing or illegal access during the data storage or transferring.

As it determined, it is the responsibility of the controller and the processor to take appropriate steps to avoid the above- mentioned risks. Among these techniques and strategies, it is possible to count data encryption, authorization, confidentiality, non-repudiation, integrity, identification and authentication and storage provider verification.

Those techniques together should be able to prevent all the common issues about data in cloud computing [54].

One of the new additions to this act is setting out codes of conduct in one of its chapters. By which it is possible to determine that the processor and controller have complied with data protection requirements (Article 32).

Since ‘personal data breach’ defined as ‘a breach of security’ may lead to physical, material or non-material damage to natural persons [52], the processor must notify the controller of any breach of any personal data ones he is aware. The controller must report the occurrence of the breach to the authorities within three days.

The communication must contain a thorough description of the breach, as well as the number of the affected records and persons. He must also describe the consequences and damages of this data. The controller must mention the steps that he has taken or should have taken to minimize the consequences of a data breach. The breach must be documented, its causes and all the facts associated with it and the steps taken by the controller.

After notifying the breach to the authorities, the controller must notify the Data Subject about the owner of breached data. The controller can bypass notifying the Data Subject only in the case that he had applied appropriate techniques to protect his personal data before the occurrence of the data breach, or if he took steps that had reduced the damages of the breach.

However, if the breach has taken too many of the data subjects, and it is difficult to notify each individual, the controller can communicate them publicly (Article 33).

5.2. Data deleting (Right to be forgotten)

Nowadays, bioinformatic world recognizes secure data deletion because its data is more sensitive, for example, health personal data may need to delete securely once it is no longer needed. In some conditions, personal data are not accurate so it is important to take reasonable measures to delete them.

A data subject shall have the right to delete his personal data, in the case of the termination of the purposes for which he has given his consent. Or when his personal data has been processed illegally or in the case that such data is no longer useful for the purpose for which it was collected, or in the absence of a legal base for processing that data, or if the laws of the EU obligates the controller to delete that data.

The controller must delete a personal data requested to deleting by its Data Subject immediately. Except in the case that he has provided convincing legal justifications for not deleting that data.

This Article increases the effectiveness of the data protection law as it does not leave unnecessary data or because the processor has processed it. That gives more privacy to the Data Subject, the risks

of theft data, infringement or unauthorized access, and avoiding illegal or unauthorized use.[55]

After the completion of the processing on behalf of the controller, the processor should, at the choice of the controller, return or delete the personal data, unless there is a requirement to store the personal data under Union or Member State law to which the processor is subject.

5.3. Portability

One of important additions to this directive is the right of data portability. Based on article 18, the data subject shall have the right to transmit the personal data and any other information by the data subject. It will let a user the right to request a copy of his personal data from an institution, agency or a system in a format usable by them and electronically transmissible to another processing system[56].

This means that the controller who has received personal data of a Data Subject must store data in a structure or a format that is compatible with the common systems and readable automatically.

Therefore, it does not constitute an obstacle to a Data Subject in case he decided to transfer his data to another institution or another system. For example, if a user decides to transfer a medical file from a clinic to another one or from an association agency to another one, the controller must have stored that file in a manner consistent with the other clinic, agency systems.

Consequently, the new clinic can include that file automatically in its system without obstacles. This amendment encourages the creation of standardized data storage. It also increases the ease of data flow. In the condition where, regardless of the user's right of data portability, data is stored in a manner consistent with common systems, it leads to the speed and ease of receive these data from other parties and includes it in a new system.

In consequence of the Right of Portability, It would enhance the quality of services offered by companies and the competition between them[57].

Data controllers should implements different data portability opportunities, for example they should offer direct download for the data subject or should allow them to directly transmit data to another data controller[58].

5.4. DISCUSSION ON GDPR REGULATIONS

GDPR is a new EU data protection that prepares a harmonization of data protection regulations throughout the EU for extending the EU data protection law.

After this analysis, we can certainly say GDPR affects a large portion of EU which have a customers which are citizens of the EU, US and companies around the world who have data on their systems comprised of EU citizens.

What separates this regulation from other regulations is that companies will be forced to be compliant because of the sanction (fines 20 million euro or 4% of revenue whichever is larger)[59].

The most advantage of this is that a single set of rules will apply to all EU member states, which means the data controller, processor, or the data subject are based in the EU.

Each member state should establish an independent SA to hear and investigate complaints, sanction administrative offences, etc. SAs in each member state will cooperate with other SAs, providing mutual assistance and organizing joint operations.

Where a business has multiple establishments in the EU, it will have a single SA. Thanks to the regulament, a sort of top-level standardization takes place. GDPR could be considered as an interface that all the people or entities involved in data protection care should compliance with.

This approach let the entities to be very independent but comply with the GDPR pillars. Data security contains factors that could be used to identify an individual, such as their genetic, mental, economic, cultural or social identity.

They should take measures to reduce the amount of personally information they store, and ensure that they do not store any information for longer than necessary. About data deleting, in order to ensure that they do not take the data longer than necessary, controller should determine time limits for erase or for a periodic review[60].

GDPR makes a new right to data portability which is a little close but differs from the right of access in many ways. This new right

empowers the data subjects and provides more control over the personal data.

It also makes easier switchings between different service providers. Each private or public bodies needs to have a data protection officer so the controller and the processor shall design this. In previous drafts of the Regulation, Data protection officer was a requirement for companies with more than 250 employees.

In the final publication of the Legislation (which was ratified in 2016) this limitation was changed and it includes companies of all sizes If any system contains “high risk” privacy-related information, a privacy-impact assessment is also required.

According AMPLEXOR’S GDPR WORKSHOP [60], there are four essential keys which can help companies prepare for GDPR, before it is implemented and enforced on 25 May 2018. These four keys including: Accountability, Physical archives,Acceptance testing, Local implementation. Accountability means organizations need to describe and analyze every system that deals with privacy-related information (likely most systems in big corporations).

This is one of goals of the new GDPR. The relation of physical archive and GDPR is privacy, because still some companies have paper archives which include personal privacy data and makes that information available for use so it could fall under the GDPR rules. Nowadays, there are a lot of companies that use production data in their acceptance systems to simulate the circumstances in production.

In these cases, they should obey the rules of GDPR perfectly. Every EU country’s local legislation needs to detail specific GDPR

implementation guidelines so due this fact Local implementation is also important. Since in less than a year, EU's data protection rules will have their biggest changes, in this research we try to show what you need to know about how and when your data you hold, will be processed.

The GDPR is Europe's new framework for data protection laws – it replaces the previous 1995 data protection directive, which current UK law is based upon. Any company which stores or processes data of EU citizens are required to meet all of the regulations set forth within GDPR.

So, all companies and organizations need to perform an initial assessment to determine whether they are in-scope to being compliant with GDPR. All types of industries from financial, insurance, healthcare, service providers and companies who provide services to other companies who are in-scope for GDPR are impacted. Even companies who have no operations in the EU and scan their customer databases to ensure none of their customers is located in EU countries could still be in-scope for GDPR [58].

Article 24 to 31 introduce principal actors and their responsibility. The controller shall take appropriate measures to provide any information referred to Articles 13 and 14 and any communication under Articles 15 to 22 and 34 relating to processing the data subject in a concise, transparent, intelligible and easily accessible form, using clear and plain language, in particular for any information addressed specifically to a child.

The data subject shall have the right to receive the personal data of him or her, which he or she has provided to a controller and they have the right to transmit those data to another controller without

hindrance from the controller to which the situation is compatible with Article 20. Even if data is stored and backed up, it may not be separable from the software application. In the new Software as a Service (SaaS) or cloud computing environment where data is stored remotely by the service provider, it may not be separable from the service[59]. Every organization must document its processes or systems that manage privacy-related information. Additionally, privacy-related information classified as “high risk” (such as children’s personal information) must be proactively reported to the data protection authorities.[60]

Due to the fact that the amount of digital information we create and store has vastly increased and the old protocol is no longer is suitable for purpose so GDPR is the solution.

It will change the method of organizations for handling their information of customer in the best way. There will be large changes for both public and businesses and bodies that handle personal information. GDPR will be a kind of revolution for data privacy laws across Europe as well as give greater protection and rights to individuals.

Since GDPR is a very new concept, there is no direct confirmation of the improvements, yet. Likely, the process of managing sensitive information will be improved from all point of view.

CHAPTER 6 –THE QUESTIONNAIRE

6.1. Methods

The Customer Satisfaction of pharmacies on board commercial ships, without a doctor, pharmacist or paramedics on board, was built by constructing a computerized structured questionnaire that was sent by e-mail to seafarers on commercial ships flying the Italian flag and to land crews responsible for logistics. The reference universe is represented by the Italian maritime population. The anonymity of the user has been guaranteed, maintaining the role dimension held (commander, officer, ground personnel) keeping as much as possible the correspondence between the interviewed sample and the demographic structure of the maritime population.

The questionnaire is shown below, in full, as proposed to users.

6.2. The Proposed Questionnaire

Dear User,
As part of our "Pharmacy Ship's" service for the quality and management of pharmacies on board commercial ships without medical assistance on board, in accordance with the UNI EN ISO 9001: 2015 standard, we would like to submit a questionnaire that is very important in order to obtain information on the degree of satisfaction and at the same time to allow us to identify the aspects that require specific actions to improve the service offered.
We would therefore be grateful if you would like to fill in all parts of the questionnaire, which also includes the possibility of sending us suggestions, advice or comments that can help us improve, in order to be more and more able to respond to users' needs.

Thank you for your cooperation and suggestions of improvement you might want to suggest.

N.B. The data collected in this questionnaire will be kept and managed in accordance with the provisions of Legislative Decree no. 196/2003 (privacy code) and for the purposes strictly connected to the service they refer to.
This data will be managed by C.I.R.M Servizi s.r.l, guaranteeing the anonymity of the shipping companies that have completed this questionnaire.
For more information, please contact:
Dr. Giulio Nittari
E-mail: giulio.nittari@unicam.it
* The questionnaire can also be completed anonymously.

Express an opinion on the ease and speed of access to information regarding the services provided by CIRM Servizi, with regard to the following communication channels: *

	1 Not satisfied	2	3	4	5	6 Completely satisfied
Telephone (Availability of the responsible pharmacist by telephone)	☐	☐	☐	☐	☐	☐
E-mail (E-mail replies to the responsible pharmacist)	☐	☐	☐	☐	☐	☐
"Pharmacy Ship's" remote management software	☐	☐	☐	☐	☐	☐

Insert any comments on the opinion expressed here

La tua risposta

. Express an opinion on the clarity, completeness and adequacy of the procedures for the revision and management of medical and remote inspection, concerning the services provided (procedure to follow, forms to be used, contact personnel, timing) documentation and certifications / obtained through: - pharmacist responsible for the service, through dedicated e-mail channel:

	1 Not satisfied	2	3	4	5	6 Completely satisfied
Release of order sheet related to inventory control	☐	☐	☐	☐	☐	☐
Release of compliance documentation	☐	☐	☐	☐	☐	☐
Certification of therapeutic equivalence (in case of drugs replacement)	☐	☐	☐	☐	☐	☐
Indications and notes regarding the management of any problems of loading, unloading of registers and disposal of expired drugs	☐	☐	☐	☐	☐	☐

Insert here any comments on the opinion expressed

La tua risposta

Give an opinion on the availability and collaboration of the staff with whom you have come into contact during the request for information and the provision of the service: *

	1 Not satisfied	2	3	4	5	6 Completely satisfied
Release of order sheet related to inventory control	☐	☐	☐	☐	☐	☐
Release of compliance documentation	☐	☐	☐	☐	☐	☐
Certification of therapeutic equivalence (in case of drugs replacement)	☐	☐	☐	☐	☐	☐
Indications and notes regarding the management of any problems of loading, unloading of registers and disposal of expired drugs	☐	☐	☐	☐	☐	☐

Insert any comments on the opinion expressed here

La tua risposta

Express an opinion on the competence and professionalism of the staff with whom you came into contact during the service: *

	1 Not satisfied	2	3	4	5	6 Completely satisfied
Release of order sheet related to inventory control	☐	☐	☐	☐	☐	☐
Release of compliance documentation	☐	☐	☐	☐	☐	☐
Certification of therapeutic equivalence (in case of drugs replacement)	☐	☐	☐	☐	☐	☐
RigaIndications and notes regarding the management of any problems of loading, unloading of registers and disposal of expired drugs 4	☐	☐	☐	☐	☐	☐

Insert here any comments on the opinion expressed

La tua risposta

Express an opinion on the comprehensibility of the requests for additions relating to the adaptation to the Tab C of the decree of 1st October 2015 (both in administrative and technical terms) for the following services: *

	1 Not satisfied	2	3	4	5	6 Completely satisfied
Indication of the active ingredients to be integrated	☐	☐	☐	☐	☐	☐
Detailed indication on the formulation and dosages required	☐	☐	☐	☐	☐	☐
Indication of any special receipt due to the fact that the drug belongs to particular therapeutic indications of the quantities in terms of dosage units required Indications of any notes regarding the conservation and use of the pharmacological specialties	☐	☐	☐	☐	☐	☐

Please enter any comments on the opinion expressed here

La tua risposta

Express an opinion on the timing of release / dispatch of the documentation and certifications provided by the service "Pharmacy Ship's": *

	1 Not satisfied	2	3	4	5	6 Completely satisfied
Issue of order sheet concerning inventory control	☐	☐	☐	☐	☐	☐
Release of conformity documentation Certification of therapeutic equivalence (in case of drugs replacement)	☐	☐	☐	☐	☐	☐
Indications and notes related to the management of any problems of loading, unloading registers and disposal of expired drugs	☐	☐	☐	☐	☐	☐

Please enter any comments on the expressed judgment here

La tua risposta

Express an opinion on the capacity of the "Pharmacy Ship's" service in its entirety to meet the requirements for proper management of the armacres aboard the ships:

	1 Not satisfied	2	3	4	5	6 Completely satisfied
Insert any comments on the express judgment here	☐	☐	☐	☐	☐	☐

Insert any comments on the express judgment here

La tua risposta

The use of the Pharmacy Ship's service has been able to ensure proper management, also in economic terms, of the expenses incurred by the company for the maintenance in terms of medications and medications of the medical chest? *

- YES
- NO

If Yes to the previous answer, would you be able to indicate approximately the percentage of savings estimated by the company between the management of the pharmacy without and subsequently with the use of the Pharmacy Ship's service? *

- 5%
- 10%
- 15%
- 20%
- 30%
- 40%
- 50%
- 60%
- 70%

Please enter any comments on the opinion expressed here

La tua risposta

Express an opinion on the response speed of the service providers in the face of any problems and / or requests of the supervisory bodies: *

	1	2	3	4	5	6	
Not satisfied	○	○	○	○	○	○	Completely satisfied

Enter any comments on the expressed judgment here

La tua risposta

Please express your Global level of satisfaction towards our service company, with regard to the quality of the services offered to the user *

	1	2	3	4	5	6	
Not satisfied	○	○	○	○	○	○	Completely satisfied

Is this level of satisfaction in line with your initial expectations? *

- ○ YES
- ○ no is greater
- ○ no is less

Thank you for your kind cooperation

Data

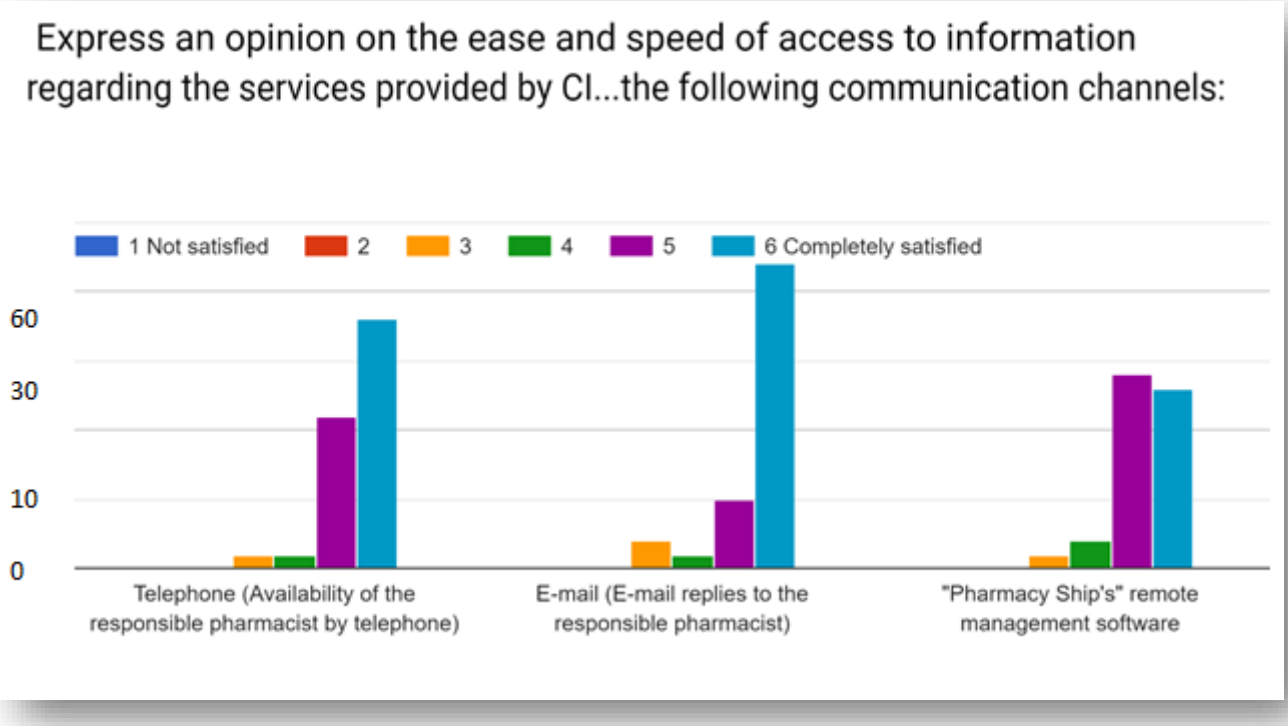
gg/mm/aaaa

INVIA

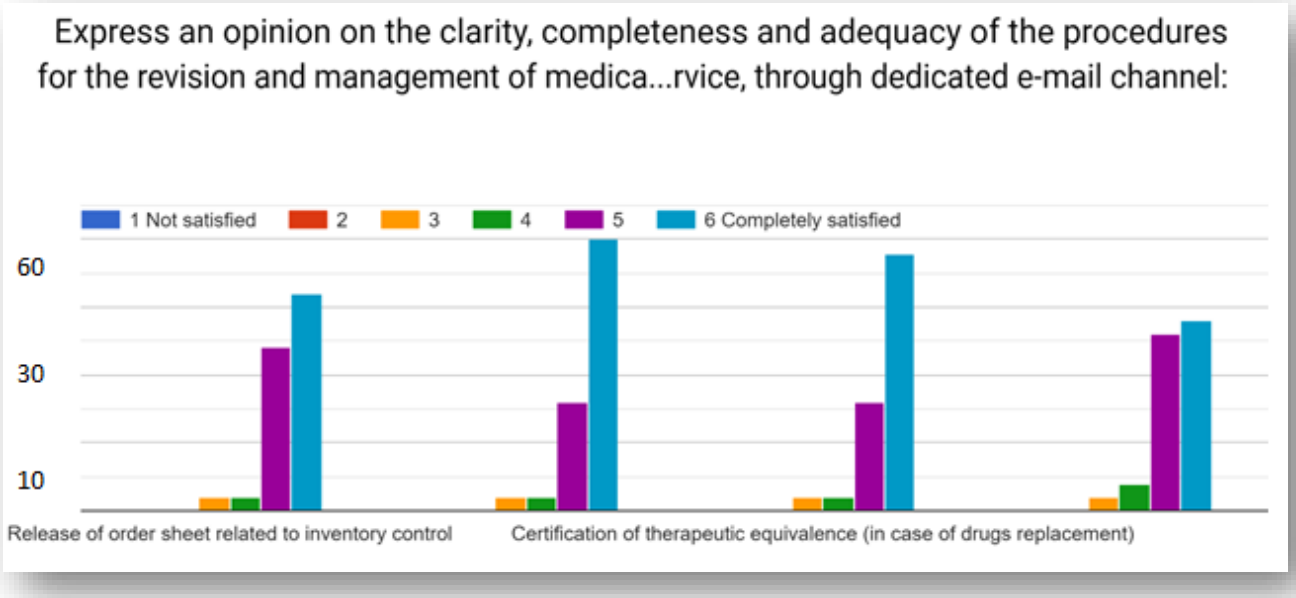
Non inviare mai le password tramite Moduli Google.

6.3. Results of the Questionnaire

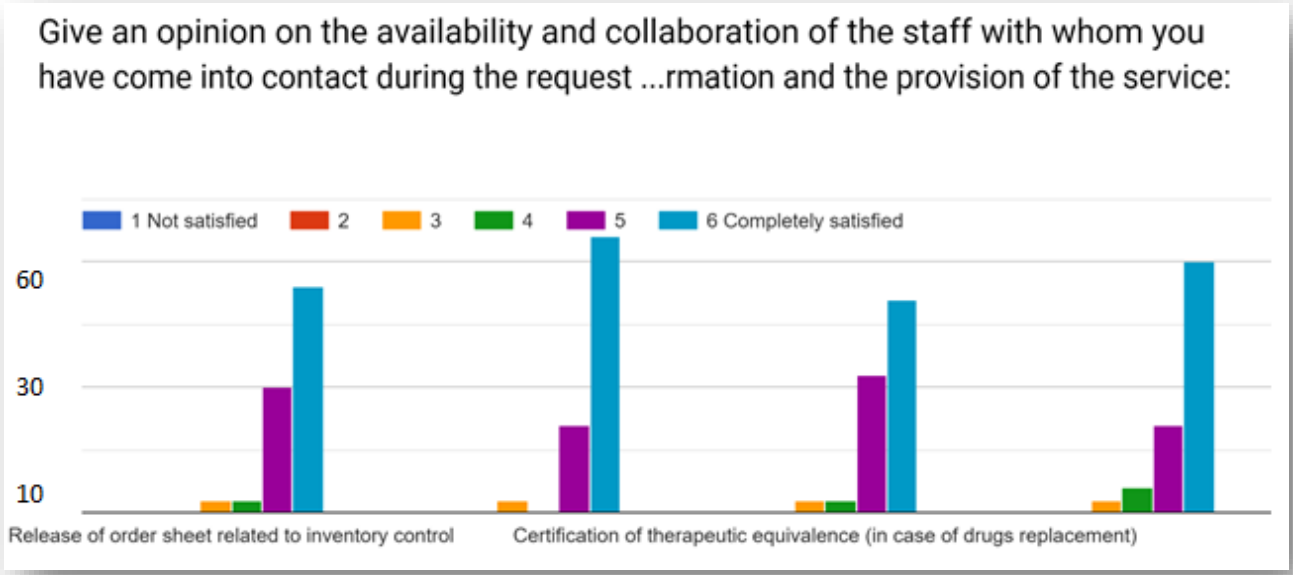
Customer Satisfaction verifies and deepens the vision of the telepharmacy service, through the perception of the users: how much are the users satisfied with the service and with the quality and professionalism offered by the service providers? How much does the "vision" of pharmacists coincide or deviate from the "sentiment" of the users? What are the needs satisfied and the needs still to be satisfied? What role do pharmacies on board of ships could and should play in seafarers' health care? To these and other questions we tried to provide an answer through a survey to a sample of 130 users, representative of the Italian maritime population in the roles of captains and officers, direct users of the service.

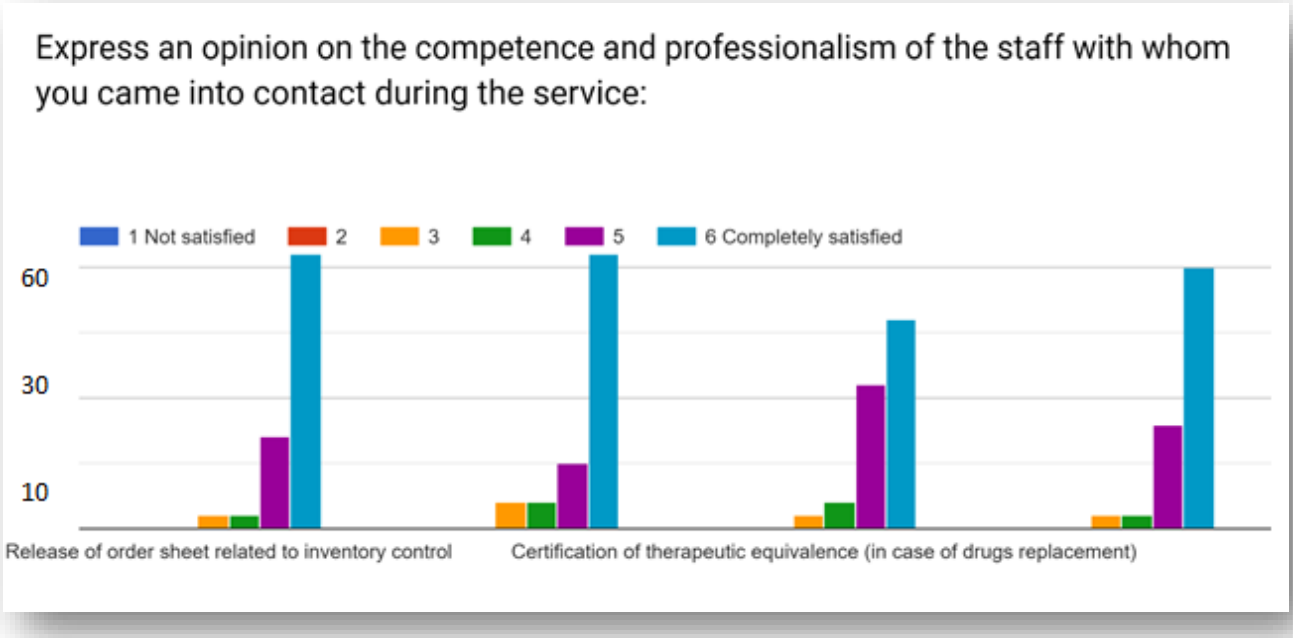


The first questions from the survey confirm the idea that the on-board pharmacy management service provides the maritime population with a quality service that is particularly appreciated. It resulted to be fundamental in terms of health care for the particular class of workers that is of seafarers.

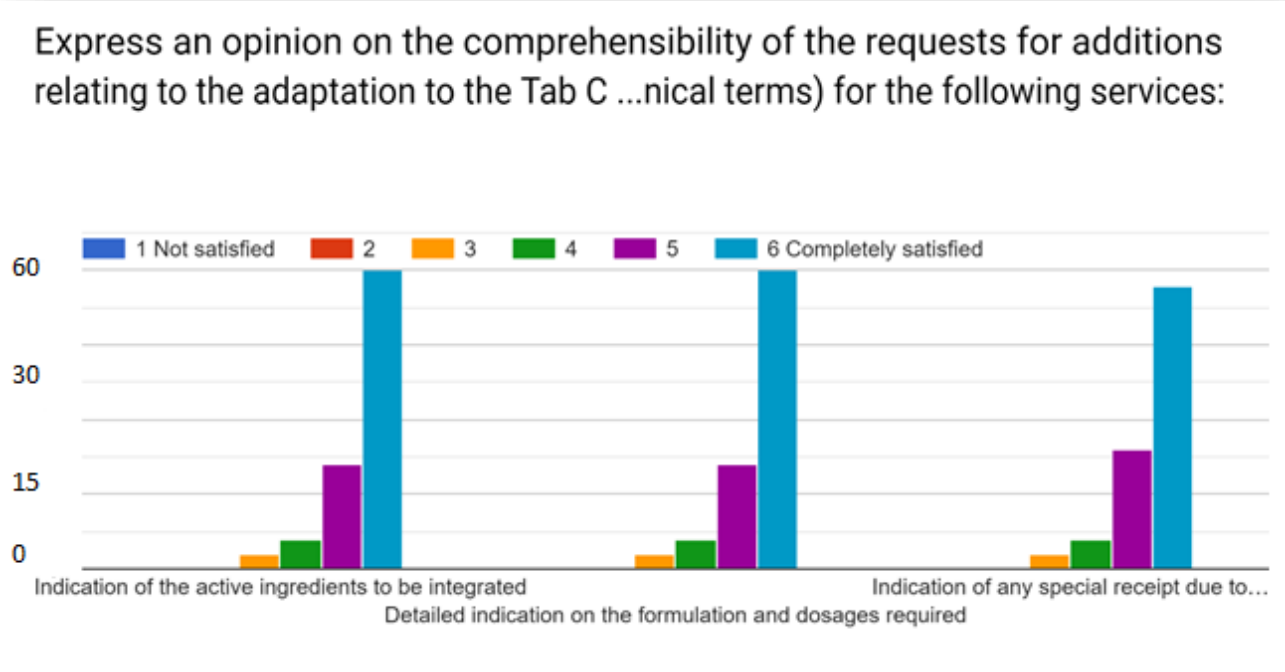


At the service of management and control of pharmacies on board the ships, users gave the greatest evaluation for all the parameters, expecially to control and release of conformity certification, evaluation and replacement of therapeutically equivalent pharmaceutical species.

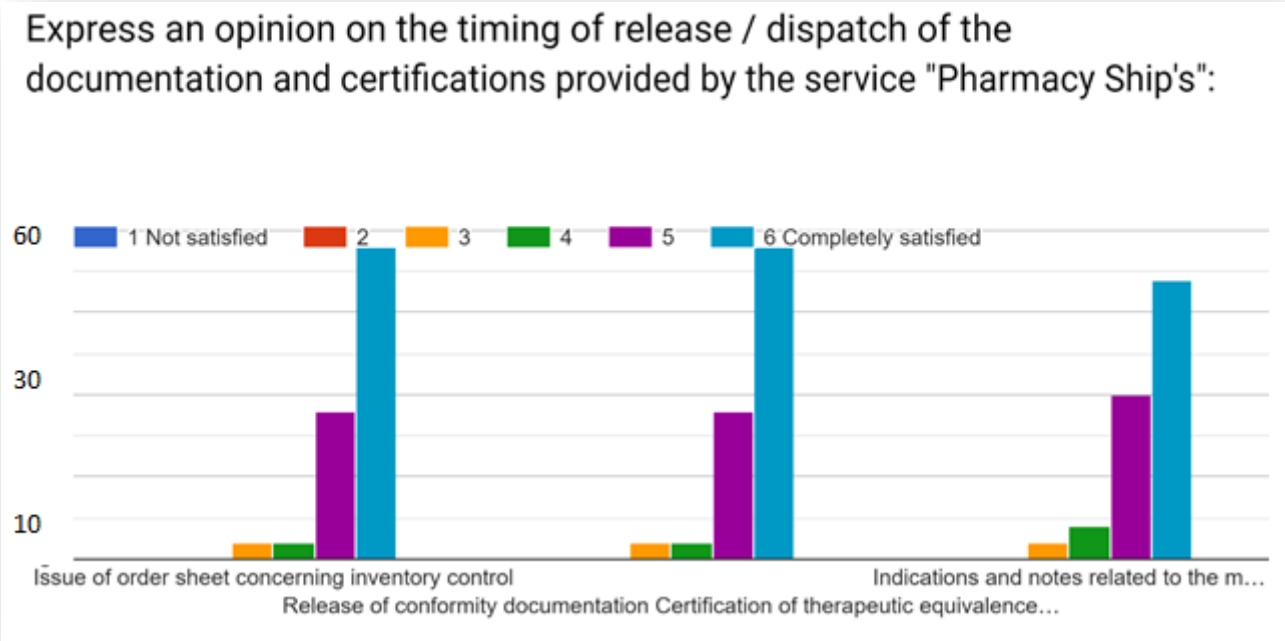




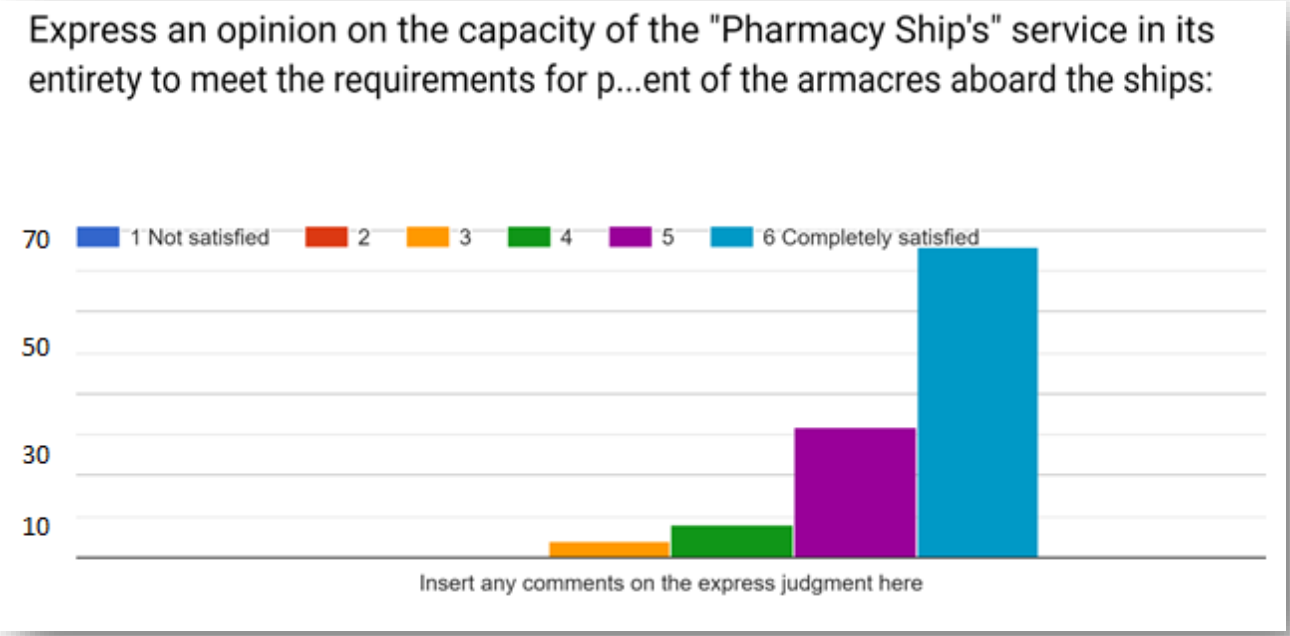
Also in terms of professionalism and reliability, problem-solving ability and also quality/cost ratio, the Pharmacy Ship's service collects abundantly positive evaluations.



The service collected abundantly positive evaluations also relatively to the assessment requested in the matter of clarity and precision concerning issues very far from maritime activity as indications relating to the active ingredients of drugs, to formulation, to conservation to administration, to complementarity with current legislation in terms of disposal of drugs, storage and registration.

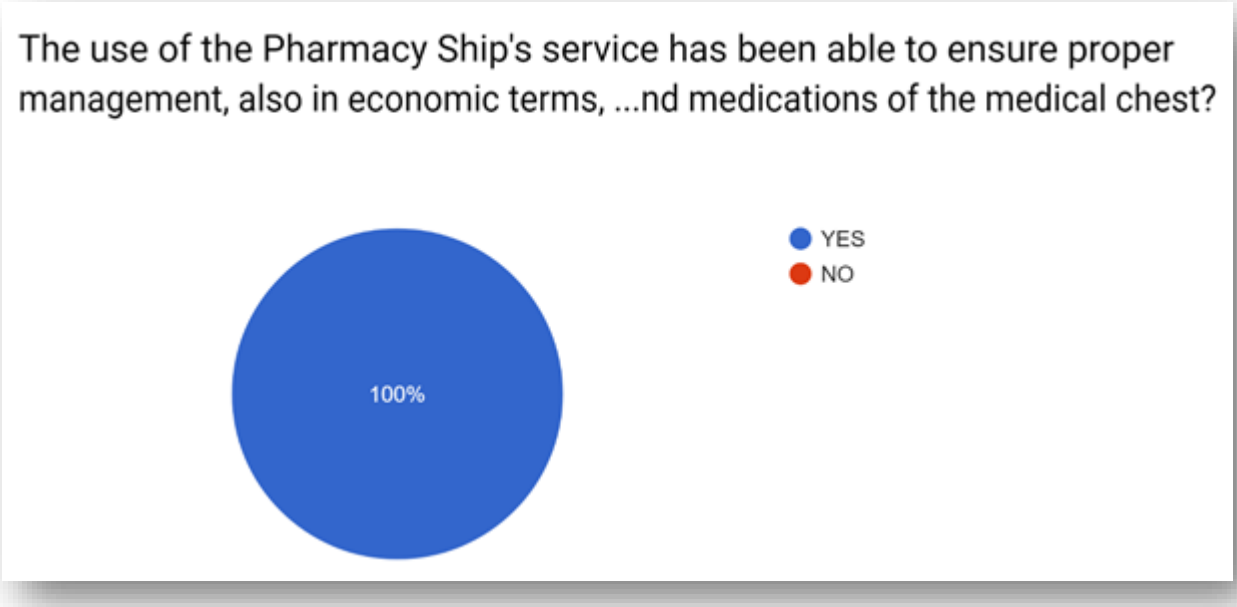


Extremely positive results also emerged from the evalutation requested on the certification release timing, with an assessment of 6 (completely satisfied) for about 95% of the interviewed sample. The same applies for "resolution of technical problems, specific indications and IT assistance when necessary".

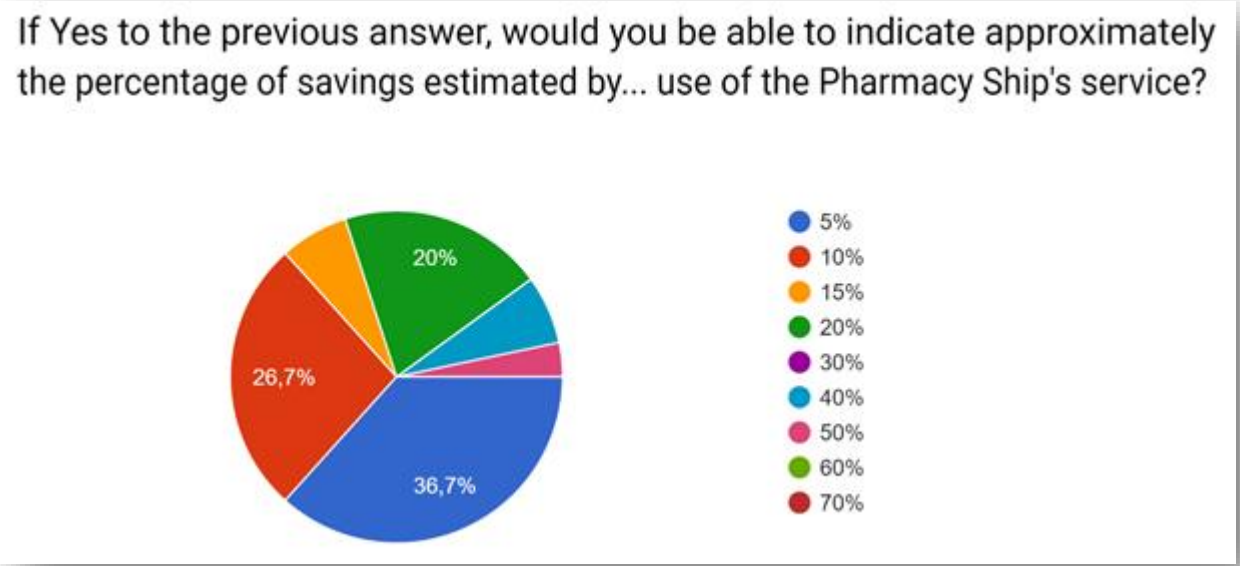


The degree of satisfaction about the service received for the management of pharmacies on board the ships without a doctor on board, is very high for all aspects investigated, with percentages ranging from completely satisfied (90% of the sample) and 10% satisfied.

In the first place the courtesy, kindness and willingness to listen to the staff are recognized followed by clarity, professionalism, competence of the service providers, of the answers provided (94% of the interviewees).

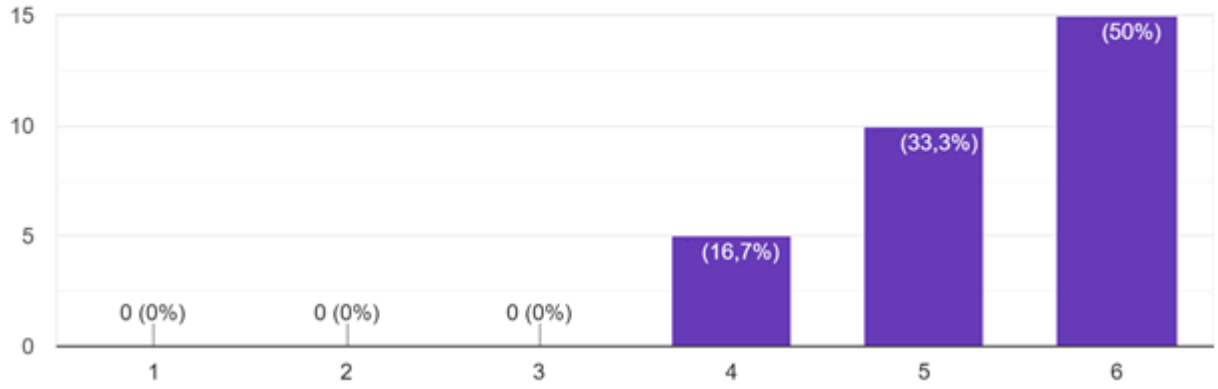


100% of the interviewed stated that the use of Pharmacy Ship's guaranteed correct and efficient management of the on board pharmacy, from every point of view.

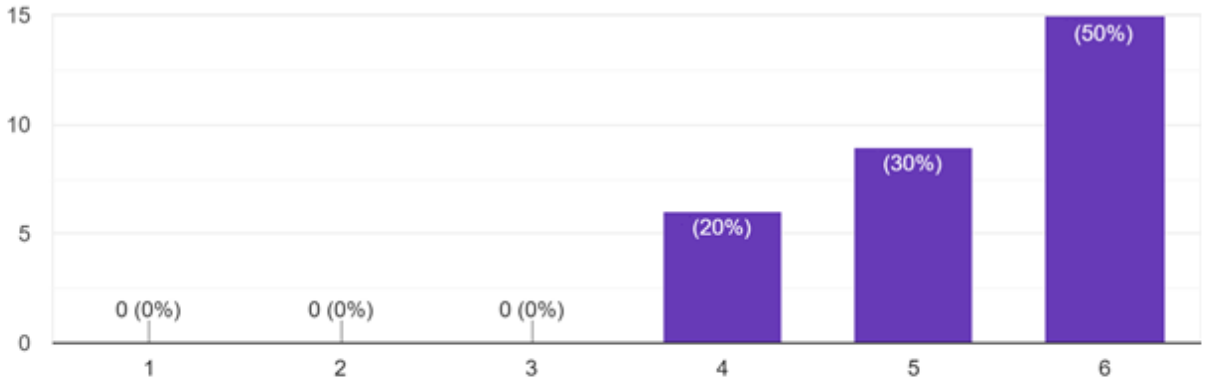


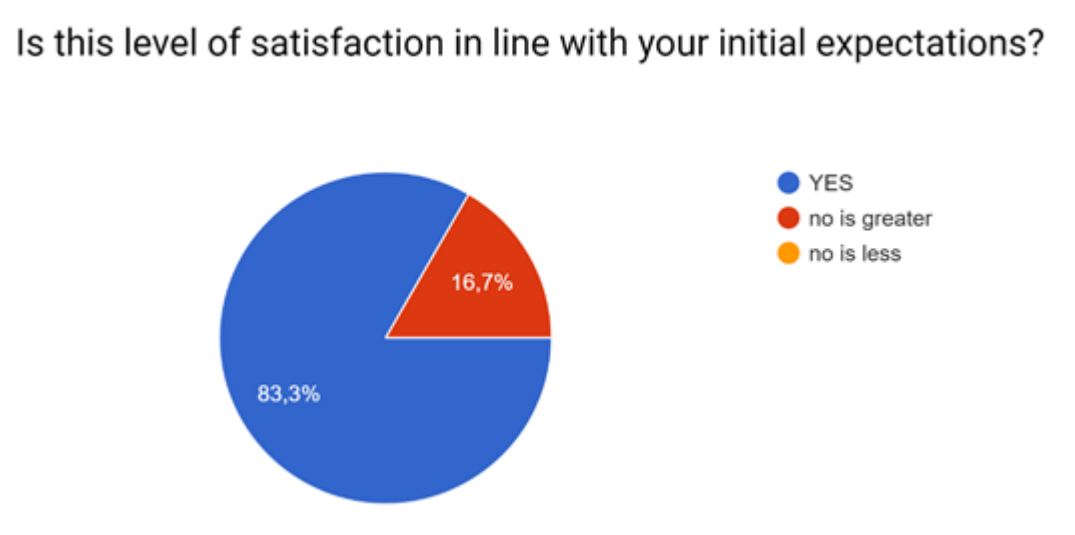
Interestingly, the use of this service has also guaranteed economic savings from shipping companies in terms of purchase and supplies for the on-board pharmacy. The estimated percentage of savings, based on the interviewed, goes from 5% on total spending in 36.7% of cases, passing to 10% for 26.7% of cases up to 20% in terms of total economic savings for 20% of respondents.

Express an opinion on the response speed of the service providers in the face of any problems and / or requests of the supervisory bodies:



Please express your Global level of satisfaction towards our service company, with regard to the quality of the services offered to the user





The survey confirmed the appreciation of the sampled maritime population. Pharmacy Ship's service demonstrated to be able to efficiently and effectively manage the on-board pharmacy, disseminating health information, prevention and protection of seafarers' health: 83.3% of the interviewed said they were satisfied, while 16.7% even very satisfied (the results were greater than their expectations).

The interviewees are almost all convinced (100%) that the pharmacy ship's service leads to an improvement in the efficiency of the pharmacy on board the ships. They believe, almost in equal measure, that this will lead to a greater attention and a substantial improvement in the quality of health care on board ships, guaranteeing high quality health care for this particular class of workers.

6.4. Evaluation of the economic impact that the "pharmacy ship" system determine on the management cost of a merchant ship

It has been confirmed and published by the Maritime Health Assosation that 1 ship of 5 is diverted every year due to a medical problem on board [61]. Historically, health care has always been difficult to be provided on-board. The disparity between healthcare provided onboard ships and healthcare ashiore has an impact on efficiency, productivity and, overall, costs. Reliable on-board health care, enabling rapid diagnosis and guided treatment is the way forward. In this framework the best chances of treating illnesses and injuries on board are represented by the following three opportunities:

1. provide medical advice through advanced telecommunication systems thanks to wifi points available anywhere on the ship. In this way, all types of monitoring devices can be connected and managed from a central point;
2. guarantee a continuous and adequate training of the personnel who on board have responsibility in terms of the health of the crew;
3. ensure appropriate stocks of drugs and other medical equipment on board.

The lack, or the malfunctioning and management of these three fundamental possibilities of intervention, usually represent the main determining factors of the operations of diversion of the ship.

According to the British company Martek Marine, each deviation costs an average of 180,000 dollars [61].

The English term MEDICAL EVACuation (Med Evac) in German MEDizinische EVAKuierung (med. Evak.) designates the service of severely injured or severely ill persons from one place to another to provide the necessary and urgent medical treatment. This can be done by land or by sea or by air (AirMedEvac).

Usually, in a work environment such as the cargo ship, where the ship sails in the open sea for weeks or months before being able to reach a port, the air route is the most used in case of health emergencies.

The possibility to have better healthcare onboard ship will allow to perform more efficient work operations at all times and will allow to ensure the maintenance of efficient and budget-friendly procedures.

Comparing the data on the two-year use of the Pharmacy Ship service (2017-2018) with the data related to the previous two-year period (2015-2016) in which the service had not yet been used (Figure 8), a significant reduction of the MEDEVAC is highlighted.

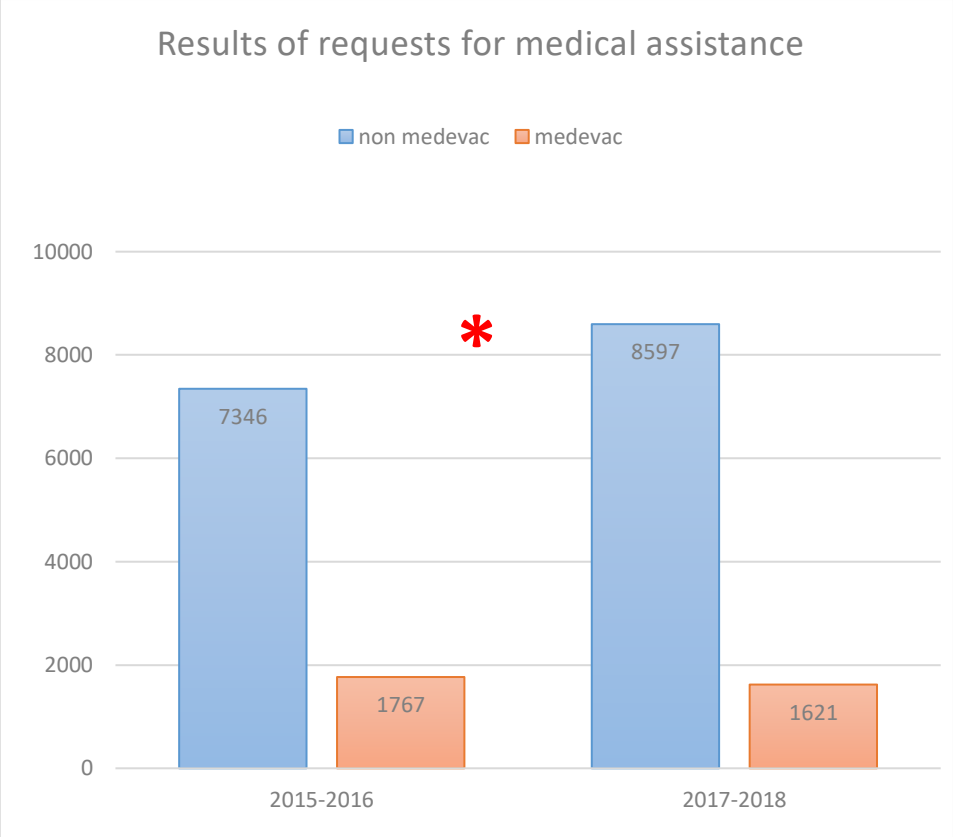


Figure 8: *comparison of the total cases assisted by the CIRM in the two-year period 2015-2016 and those of the two-year period 2017-2018 with relative MEDEVAC requests.* *: ** The change in the number of landings in the two-year period 2017-2018 is significant for p <0.05 (chi-square test).*

Specifically, in the two year period 2015-2016, the landings with diversions occurred respectively 839 and 928 times, for a total number of 1767 hijackings on the 7346 cases in the two-year period (19.39%). In the two-year period 2017-2018 the total number of landings was 1621 compared to the 8597 total cases managed by the operating physicians team (15.87%).

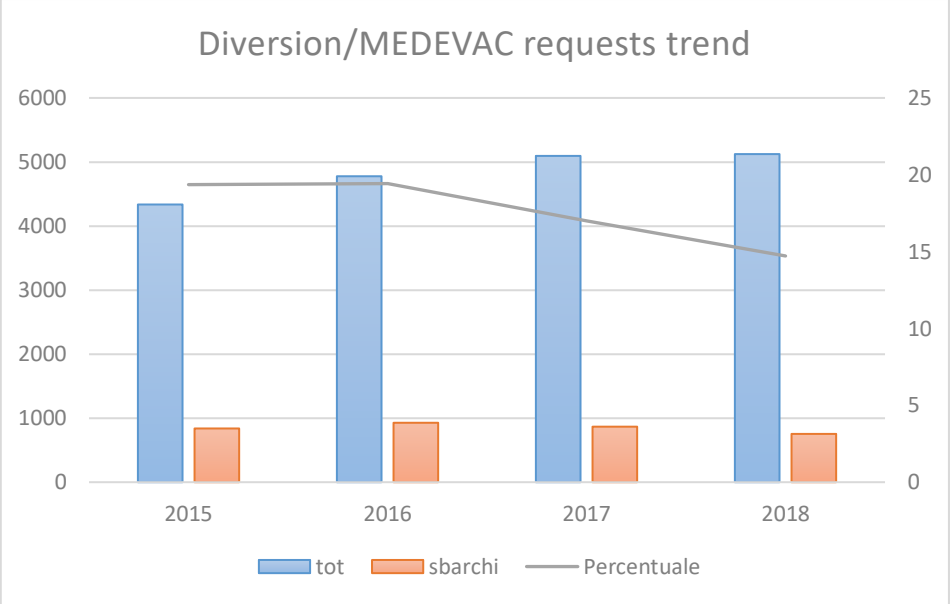


Figure 9: *representation of the trend over the four-year period of the decrease in the MEDEVAC request*

Figure 9 shows that the annual cases of diversion progressively reduced from 20% in 2015-2016 to 17% in 2017 and to 14% in 2018, with an overall reduction of about -25%.

The digital service offered by the Pharmacy Ship management system to have on board ships all the medicines and medical devices indicated by the regulations of the reference country, which represent the minimum stocks necessary to ensure a valid health care. Moreover, this guarantees the physician to manage the patient in the best possible way, through a more appropriate use of the drugs, also avoiding having to resort to an off-label use of these.

The unavailability of drugs and medicines in an emergency situation often force to request for a MEDEVAC, and therefore may force the diversion of the vessel;

These are another reasons why the Pharmacy Ship software contributes in reducing emergency evacuations: by allowing the stabilization of the patient, by ensuring the arrival at a port according to the scheduled timing, and so on.

The use of the Pharmacy Ship management system contributes to save about 25% of the expenses that the companies annually have to pay for the diversions requests due to on-board health related issues.

CHAPTER 7 – DISCUSSION AND CONCLUSIONS

E-health is a very new field and it contains a lot of services strewed around the whole traditional medicine. Every field of the traditional medicine is surrounded by the related e-health service. Practical application of ICT in medicine fields have enormous advantages from every point of view. Of course, there are drawbacks since the positive aspects are much more visible. The benefits from patients or consumers to physician's perspective are tremendously high.

The present work has described some of the applications of ICT to traditional medicine such as:

- logistic regression for creating a mathematical model to perform noninvasive diagnostic evaluations in breast cancer disease.
- ontology based approach for developing a software in order to guide the user-patient to provide the best description of the symptoms.
- ICT for developing a software able to manage the ship's medical chest. The software decreases as much as possible the human interaction notifying, automatically, whether or not a drug has been expired or is next to the expiration date (actually, 30 days before).
- Analysis of the current telerehabilitation services' state of art. For each application field a discussion about drawbacks and advantages have been done evaluating the practical use of the technologies.

From the deep analysis, we can ensure that in most of the fields, ICT technology is ready to be used over traditional medicine. In other

hand, there is a loss of human contact between patients and physicians and moreover, most of health care delivers are not ready to spend money on these technologies.

Infact, one of the biggest disadvantage of ICT is the money cost because developing a system for health care needs a deep analysis and should be reliable and secure for the users.

Reliability is fundamental because the software is used for people's health care. An error in the system can cause huge problems and even death of the patients.

In my honest opinion, e-Health is the present and it will be improved over the years improving the life quality. The health care institutions of each country should invest more money for the e-Health services improvements providing funds to health care deliver such as hospitals and clinics.

Small hospitals need enormous financial investments for developing and maintenance of e-Health services. The term e-Health is synonymous of: better life quality of all people around the world.

To provide support to the ship personnel responsible for handling/managing the ship's pharmacy we have developed the PARSI ("Pharmacy Ship") software. The purpose of this was to provide standard operative procedures for handling the ship's pharmacy and to automatize some actions which are still carried out manually.

PARSI is easy to use, and it allows the user to manage the inventory of drugs and medicaments on board in a mostly automated way possible, thus reducing the risk for potential errors and oversights. Thanks to this computerised system, periodic monitoring of ship's

pharmacy is simpler and less time-consuming. The user can search for a specific drug by typing in its active ingredient and/or its ATC code to find out all the information. In the future, an improved and more attentive handling of the ship's pharmacy will facilitate the management of diseases and accidents occurring on board. Occasionally it is impossible to fill prescriptions issued by the Telemedical Maritime Assistance Service due to the lack of a given drug on board. Monthly reports on the contents of the ship's pharmacy will help avoid these problems.

On the other hand, an easier way of classifying medicinal compounds available on board, identified by numbers could be accompanied to the reduction of possible mistakes in administering pharma-ceutical compounds to seafarers. To sum up, PARSI offers unique opportunities to simplify the management of the ship's pharmacy and consequently, to improve the quality of medical assistance on board ships.

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