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## Telemedicine for Managing Patients on Oral Anticoagulant Therapy

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### 1. Introduction

Telemedicine system is defined as the use of tele-communications to support health care with the purpose to facilitate the interaction between patient and health care provider and to achieve improved treatment results and lower treatment costs. This approach, currently spreading, is becoming a useful mean to ensure home health care, remote patient monitoring and disease management. Furthermore, telemedicine can support educational and training programs for patients and health care providers. Technological innovation in medical care and introduction of telecommunication technologies in medical practice have led to the development of telemedicine programs in many medical specialities. The principal aims of a telemedicine system applied to clinical practice are to improve health care and social assistance. The concept of telemedicine in Oral Anticoagulant Therapy (OAT) management grows from the necessity to improve interactions between patients and health care providers and, at the same time, to enhance management system. The increase of communication requests among different subjects can be facilitated through the elaboration of data networks between the Anticoagulation Clinic (AC), general practitioner or other peripheral districts and patients. Telemedicine systems for OAT have been developed during the last few years with the aim to decentralize in the health territorial care units the activity of ACs, improving the quality of life of the patients living far from the AC site and maintaining the same clinical quality levels. A telemedicine system for anticoagulated patients should be structured through net supported programs (intra and internet) to collect and elaborate clinical data, connected among hospital divisions, health care peripheral districts and patients. A digital format to collect clinical data, an electronic medical record, communication tools to connect patients and peripheral health care and a global quality control system are mandatory requirements to set up a telemedicine system. All communications, including clinical data, laboratory controls, alerts, prescriptions and recommendations have to be available in real time through a bi-directional connection. The telematic organization could develop different types of solutions for different types of patients in OAT population. For example:

- independent patient, who lives far away from the Clinic but can reach a peripheral district (Hospice, General Practitioner and so on);
- home patient not independent;

- totally independent patient.

From a general point of view, new web telematic organizations can provide several advantages in comparison with standard treatments, with the principal aim to improve patient management, as , for, example:

- direct communication between districts and AC;
- good or improved clinical quality (time spent in the therapeutic range and major complications);
- improvement in patient's satisfaction and in their quality of life;
- continuing medical record update;
- time gained by staff;
- possibility to manage different antithrombotic drugs (heparins and new oral anticoagulant agents).

## 2. Antivitamin K antagonists

In this chapter we will refer to OAT considering only Anti-vitamin K antagonists (AVK). The new oral anticoagulant drugs, very recently approved, are prescribed only in few countries all over the world and insufficient information on types of management are available at present. AVK are very effective drugs in many clinical conditions such as deep venous thrombosis, pulmonary embolism, atrial fibrillation, prostheses heart valve, myocardial infarction and cardioembolic ischemic stroke. AVK as oral anticoagulation therapy (OAT) are life-saving therapies that can effectively prevent cardioembolic strokes related to atrial fibrillation and heart valve replacements, treat venous thromboembolism, with a relative low risk of major bleeding complications. Because of their characteristics, still at present, AVK are under/and sub-optimal used and consequently their maximum efficacy is not still reached in the real world patient population. As well known, the major incidence of thromboembolic or haemorrhagic events occurs when the prothrombin time (PT), expressed as the international normalized ratio (INR), is out of the therapeutic range. Therefore effectiveness and safety of OAT increase when a good control of anticoagulation level is guaranteed. For this reason, a correct use of AVK requires a careful clinical and laboratory monitoring, as well as specific competences for managing the possible complications and/or emergencies (Ansell et al., 2008). The risk of thrombosis increases with age and the progressive ageing of the population causes a constant increase of patients who need OAT as consequence. For this reason, during the last 15 years, patients on AVK are constantly increasing and results coming from unofficial data show about 1.000.000 patients in Italy, with a prevalence that is 1.6% of the total population (Fig. 1). Vitamin K antagonists determine their anticoagulant effect by interfering with the metabolism of vitamin K. In Italy two different types of coumarins are available, warfarin (Coumadin) and acenocoumarol (Sintrom) which differ because of their half-life, that is longer for warfarin (36-42 vs 12-16 hours), the most prescribed drug in Italy at present. Warfarin has high bioavailability and is rapidly absorbed from the gastrointestinal tract; the maximal blood concentration is reached 90 minutes after oral administration. Coumarins in the blood are bound to plasma proteins (principally albumin) and accumulated in the liver, where they act through the inhibition of vitamin K epoxide reductase enzyme (Fig. 2).

The high inter and intra-individual biological variability is one the main problem in AVK management, principally due to genetic conditions, drug absorption, drug interferences, diet and co-morbidities (Feero, Guttmacher, 2011). On this basis many anticoagulation

clinics (AC) have been set up in Italy, operating in the framework of the Italian Federation of Anticoagulation Clinics (FCSA) (Fig. 3).

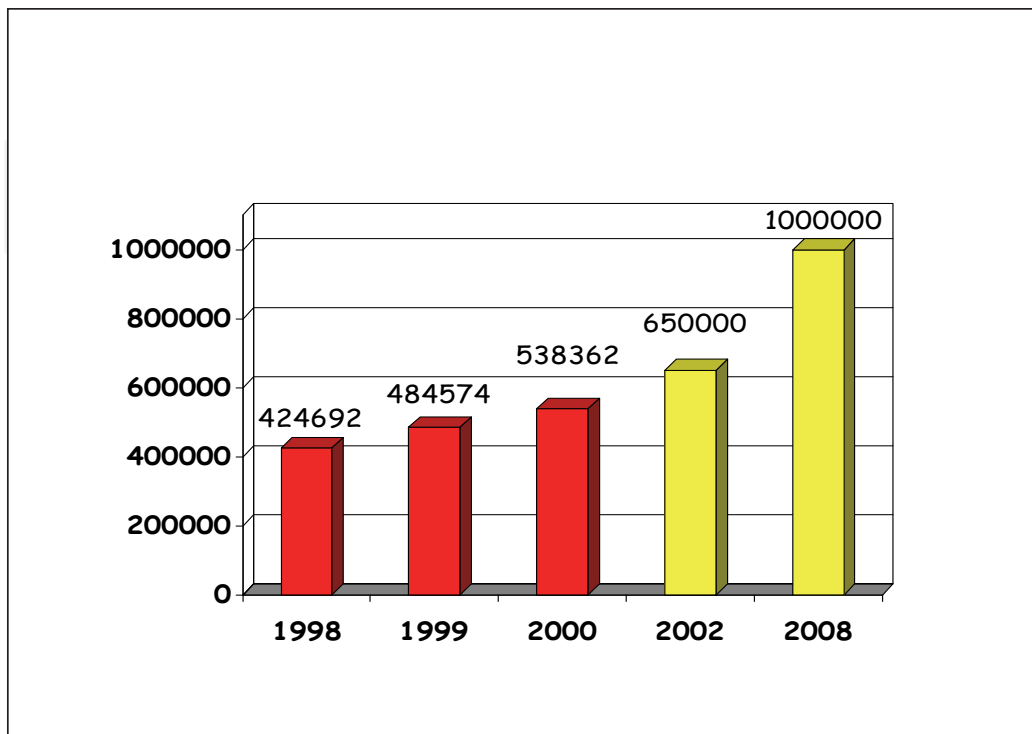


Fig. 1. Increase of patients on AVK in Italy

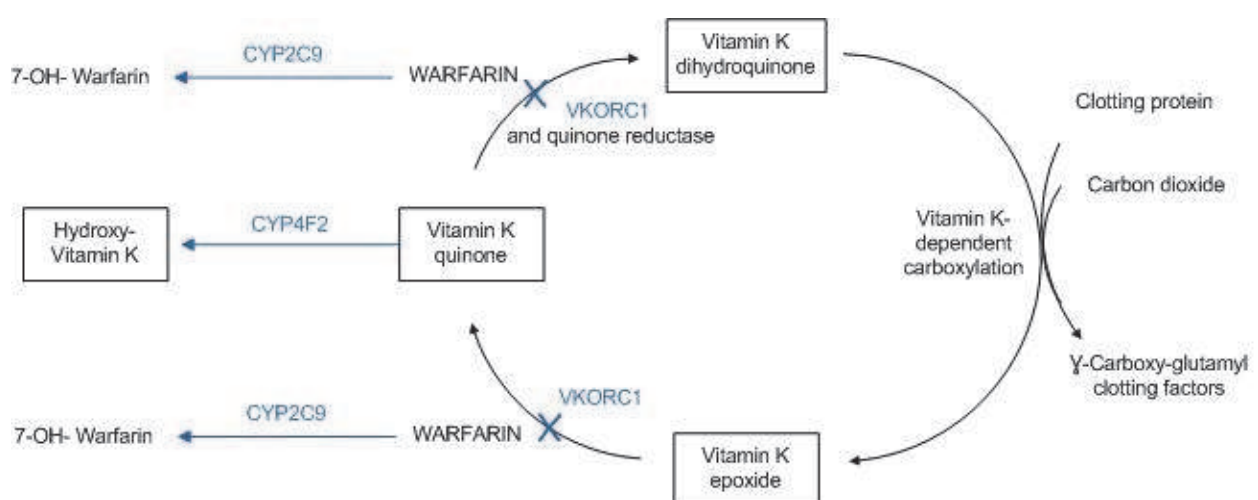


Fig. 2. Warfarin and vitamin K cycles

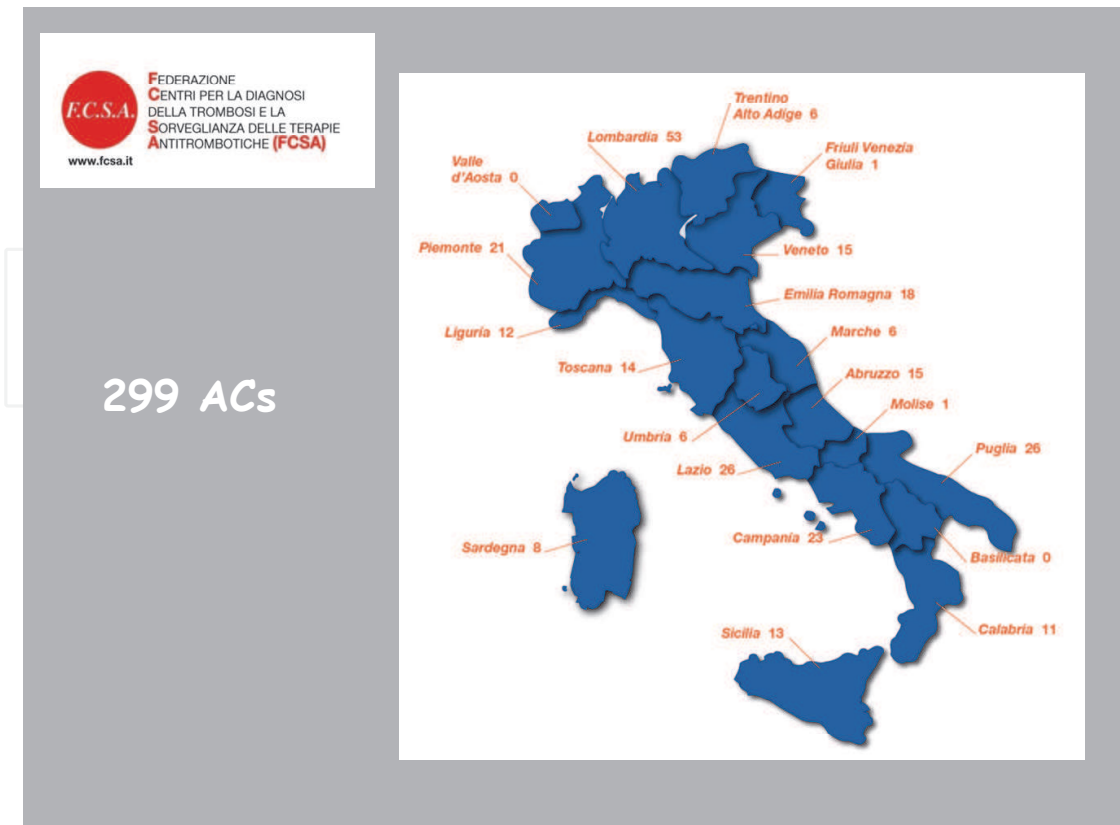


Fig. 3. Italian Federation of Anticoagulation Clinics (FCSA): ACs distribution

Compliance of patients that require long-term therapy is a crucial problem and represents an important factor of variability of both quality of treatment and patient management. In fact, as shown in literature, patients on chronic therapy omit about 40% of their daily medications and 10-26% of the patients on chronic OAT are not compliant (Barcellona et al., 2002). As a consequence, poor compliance is associated to bad quality treatment. Educational courses for patients (indications for treatment, risk and benefit, problem in drug administration, dietary behaviour, interactions with other drugs and intercurrent disease) and for health territorial care units can improve patient's compliance (Barcellona et al., 2002). Telemedicine systems can empower educational programs with the aim to improve drug adherences, increase interactions between OAT patients and health care organizations. Taking into consideration economical and clinical advantages provided by AC, compared to other types of management (see paragraph 3.3), the decentralization into peripheral health units using telemedicine systems, represents an effective evolution of the management strategies.

3. Model of management

3.1 Type of management

As for all pharmacological treatments even for AVK, three crucial points should be considered to define not only the correct drug indications but also risks and advantages. In synthesis before starting anticoagulation we should answer to the following questions:

- is OAT indicated on that clinical condition ? (= treatment effectiveness);
- is there an increase of benefit compared to OAT risk? (= treatment safety);

- which is the appropriate management model ?(= type of patient management).

The growth of OAT population recorded in the past twenty years is undoubtedly related to many factors, including the organization of Anticoagulation Clinics (AC) and the standardisation of laboratory methods, which has allowed to perform clinical trials in order to demonstrate OAT efficacy and safety (Bussey et al., 1989). These studies have supplied a better knowledge of therapeutic indications, optimal anticoagulation levels (therapeutic ranges), risk of haemorrhagic and thrombotic complications, pharmacological interference and the importance of a specialistic management (Charney et al., 1988). However, in daily clinical practice OAT is still underused because often considered by the medical class itself as a therapy that can be hardly managed, laborious and potentially dangerous for the patient, and a certain number of patients self-prescribe without specific training with serious risks for their health. We can consider 4 different management models: 1) routine medical care (RMC), 2) AC, 3) patient self testing and 4) patient self management. The four models for OAT control are variously developed in different countries. The model prevailing in the United States is the Usual Care (UC), in which patients refer directly to their own general practitioner or specialist; the INR is determined in external laboratories or in general practitioner's consulting room through portable monitors. In countries such as England, Holland, Italy and Spain, Anticoagulation Clinics (AC) are developed. ACs can interact with the general practitioners on various levels, according to their competence. In particular, ACs have been set up in Italy in order to:

- determine the appropriate clinical indications for anticoagulant treatment;
- determine the laboratory tests necessary for pharmacological monitoring;
- prescribe the anticoagulation regimen based on the results of the laboratory tests;
- define intervals for regular anticoagulation controls;
- evaluate any potential pharmacological interference;
- take care of patients undergoing surgical interventions or invasive procedures;
- manage the patients during intercurrent diseases;
- hold training courses and educational programs for patients and healthcare providers.

Several studies have shown that anticoagulation management is crucial to ensure quality of treatment and, among different types of management, Anticoagulation Clinic (AC) results in better clinical control compared with routine medical care (RMC) (Bussey et al. 1996; Chiquette et al. 1998).

### **3.2 Patient self testing and patient self management**

New technologies applied to INR testing determined the development of portable coagulometers. Portable monitors are small, handy instruments, easy to transport and allow PT/INR testing with a drop of whole blood. The widespread use of portable monitors in clinical practice allowed the development of point of care testing, shifting the analytical phase from the laboratory to patient with considerable advantage in terms of convenience and comfort for the patient. Those systems are very useful to manage patients at home or at peripheral health care units (nursing homes, groups of general practitioners, health communities), simplifying and improving OAT management. OAT self monitoring through portable coagulometers has the potential advantage to be easy to use for the patient or caregivers and potentially improve patient's quality of life (Tripodi et al. 1993). There are several ways for using portable coagulometers that we can summarize as self-testing (PST) and self-management (PSM). With PST the patient autonomously monitors his/her own



PT/INR using portable coagulometer, living OAT decision to AC. Self-testing therefore offers the patient the opportunity of increasing test frequency (Watzke et al., 2000). With PSM the patient not only monitors his/her own PT/INR but also self-prescribes drug dosage. As shown in literature self-testing and self-management leads to a significant 50% reduction in thromboembolism and 13% reduction in major haemorrhage, compared to RMC (Fitzmaurice et al., 2005; Sawicki et al., 1999). A recent Cochrane review analyzed 18 randomized trials, including 4723 patients, to compare PSM vs RMC and confirmed an advantage for self-management in thrombotic and haemorrhagic complications (RR for thrombosis=0.47; RR for bleeding=0.56) (Garcia-Alamino et al., 2010). We have to highlight that just a few number of patients, highly selected, has been enrolled in these studies and a real clinical advantage of self-management compared with ACs hasn't been demonstrated (Garcia-Alamino et al., 2010; Cromheecke et al., 2000). Several experiences of OAT management in peripheral health units, involving general practitioners and nursing homes, coordinated by ACs through telemedicine system, have been started in the last years. Aim of these projects, as example of virtual "coagulation clinic", is to facilitate the anticoagulant treatment, improving management quality, reducing risk of complications due to inadequate monitoring, with a continuous update of clinical data recording.

3.3 Cost analysis of different management strategies

In the last few years, we observed an increased interest in define and control health care costs. First Anglo-Saxon countries, in particular the United States, assessed the costs of different anticoagulation management, comparing the specialist system (AC) with non specialist system (general medical care, including all physicians who manage patients on OAT-RMC) (Elston-Lafata et al., 2000). Although several studies have been published on bleeding and thrombotic complications on OAT, only few of them have been focused on the evaluation of differences between the two management models (RMC/AC) (Bussey et al. 1996). It should be noted that most of the available data derived from studies on controlled population managed by Anticoagulation Clinics, making it difficult to determine the true incidence of complications in other management models. In the ISCOAT study, the most large, prospective Italian investigation study, including a cohort from 34 ACs, the incidence of major bleeding complications was 1.25 for 100 patient-years, whereas the incidence of thromboembolic events was 3.5 for 100 patient-years (Palareti et al., 1997). Literature analysis showed that patients on RMC had a 2-fold increase (2.5 vs 1.25% patient-years) and 3-fold increase (10.5 vs 3.5% patient-years) of bleeding and thromboembolic risks, respectively, compared to patients followed by AC (Palareti et al., 1996; Palareti et al., 1997) (Tab. 1).

COMPLICATION	RMC (PERCENT P-Y)	AC (PERCENT P-Y)	OR (CI= 95%)
Major bleeding	2.5	1.25	0.49 (0.31-0.76)
Thrombosis	10.5	3.5	0.22 (0.13-0.37)

Table 1. Risk of major bleeding and thrombotic complication in RMC versus AC

The final result of the analysis, regarding cost of complications (elaborated on the basis of the economic values calculated for diagnosis related groups -DRG- of the Lombardy Region in Italy) and the cost of management in ACs, showed an advantage for ACs (366,1 € vs 688,5

€). In conclusion AC reduces risk of complications and allow to save 322 € per patient per year. The superiority of this anticoagulation management model is due to several reasons, the most important of which probably are the accurate laboratory control of PT/INR, a structured network for the management of emergencies and major and minor complications and a general system that guarantees education, communication and patient’s follow-up continuously. For all these reasons ACs currently represent the reference standard for OAT management and all new management systems, such as patient self testing (PST) and patient self management (PSM), must be compared to ACs to define their global quality (Tab. 2, Tab. 3, Tab. 4). In summary:

- RMC is less expensive, but less effective and safe;
- AC represents a very good model in term of quality of management, but it’s more expansive compared with RMC;
- PSM is effective and safe, but it can be applied only in nearly 25 % of the patient population , highly selected and trained;
- PST represents the best model (increase in Time spent in Range-TTR, but no differences in clinical events compared with AC), but it is the most expensive. It represents an opportunity to increase frequency of testing.

	OD (95% CI)	P
RMC/AC	0.53 (0.29-0.98)	0.03
RMC/PST	0.19 (0.09-0.39)	<0.01
RMC/PSM	0.57 (0.32-1.03)	0.04
AC/PST	0.36 (0.17-0.75)	0.002
AC/PSM	1.07 (0.58-1.98)	0.07
PST/PSM	2.2 (1.04-4.72)	0.02

Table 2. Time spent in range: comparison among different types of OAT management

Economical variables	RMC (€ PT/Y)	AC (€ PT/Y)	PST (€ PT/Y)	PSM (€ PT/Y)
Laboratory monitoring	65.7	65.7	250	250
AC management	---	147.3	147.3	---
Warfarin	30.4	30.4	30.4	30.4
Total	96.7	243.4	331.7	280.4

Table 3. Cost comparison among different management strategies



	RMC	AC	PSM	PST
CLINICAL QUALITY	+	++++	++++	++++
TTR	+	+++	+++	++++
ACCESSIBILITY	++++	++	+	++
COSTS	+	++	+++	++++

Table 4. Summary of the characteristics of the different management models

4. Telemedicine applied to Anticoagulation Clinic

4.1 Anticoagulation Clinic

Taking into account both economic and clinical advantages provided by an AC, and also the logistic problems, a reorganization plan could be necessary. The most frequent difficulties that an AC could face are the following:

- strong increase in the number of patients within the AC, mainly on long-term treatment, without a concomitant development of structures and increase of health care personnel;
- difficulty for many patients living far from the AC location in reaching the hospital clinic as well as the lack of any AC in the peripheral areas;
- discomfort of patients (and their relatives) due to overcrowding and lack of public transportation;

A telemedicine system offers the opportunity to empower the daily activity, decentralizing the management into peripheral health units, using informatic support and bi-directional web connection (Gardiner et al., 2006). In particular the aims of a telemedicine reorganization could be summarized as follow:

- reduce the number of patients referring daily to the AC, decentralizing in peripheral health units;
- maintain the same quality levels defined as the time spent in the therapeutic range and number of complications;
- reduce patient’s discomfort;
- increase the total number of patients with OAT indications, creating a network that reaches home and remote patients;
- send therapy prescription in real time, through the direct communication between the Anticoagulation Clinic and peripheral districts;

Telemedicine reorganizations give opportunities to peripheral health units to provide the following services:

- Anticoagulation testing performed with portable coagulation analysers, assessing the prothrombin time (PT) expressed as international normalized ratio (INR);
- Quality control of the portable coagulation analyzers;
- Clinical evaluation of patients (concomitant disease, changes in the drug regimen, administration of new drugs, potential surgical interventions, planning of specialist visits) through the administration of a medical history questionnaire;
- Real-time data transmission to the AC.

Bi-directional connection between AC and peripheral districts allow two different management levels: 1) treatment prescription and patient management centralized in AC; 2) treatment prescription and patient management performed in peripheral health units,

referring to AC in case of complications, over/under treatment, surgery, bridging. The AC has also organizing and epidemiological functions. The AC should ensure clinical validation of the data received, transmission of therapeutic measures and clinical advices, patient management in case of complications and in case of any other clinical condition interfering with treatment. Through a telemedicine system AC can provide healthcare to both home monitored patients and self-managing patients. Home monitored patients, defined as patients who cannot leave home due to serious physical illness, documented disease or advanced age, are managed by trained staff using mobile monitoring units connected with AC. These equipments can perform INR measurement and transmit the clinical data to the AC from the patient's home setting, in order to receive indications for appropriate therapy and urgent medical advice. Self-testing patients, defined as stable and trained patients, directly communicate with AC using a telemedicine device installed at home. These patients are able to perform PT INR on portable monitors and receive therapy prescription from the AC through the web.

#### 4.2 Portable monitor quality control

In peripheral health units, INR measurement from capillary blood specimens could be performed by portable monitors in a quality assurance global system (Marco et al., 2000). The PT/INR determination from venous blood specimens, performed in AC's laboratory, could be considered as the reference system. Taking as reference system PT/INR performed on central laboratory, the assessment of agreement should be always evaluated both for single patients and for the global accuracy. In general, quality control procedures are performed on all portable monitors to assess accuracy and efficacy and, because of no standardized recommendations are available, some predefined criteria have to be established. Based on current guidelines for laboratory QC the following items can be applied:

- PM suitability: a) precision calculated on normal plasma pool, repeated 10 times, acceptable if  $CV < 5\%$ ; b) accuracy, evaluated on 10 pathological specimens with  $INR < 4.0$ , acceptable if  $INR \text{ differences} < \pm 0.5$ .
- Intra-assay precision: each PHU elaborates monthly the Lewej-Jennings cards. Internal QC, provided by the company, is performed at the beginning of each session and every 20 samples. A CV between  $\pm 20\%$  is considered acceptable.
- Quarterly accuracy to assess the agreement between analytical instruments: every 3 months PT values from 3 venous blood samples of patients with capillary whole blood PT values in the low (2.0-3.0), intermediate (3.0-4.0) and high ( $> 4.0$ ) INR range are compared. Differences  $\leq 0.5$  INR are considered acceptable. In case of discrepancies between capillary and venous PT values of more than  $\pm 0.5$ , the portable monitor is replaced. The choice of this cut-off value derived from the fact that a higher value would require remarkable adjustments in the therapeutic regimen.
- External quality assessment (NEQAS): it considers both laboratory data and clinical treatment, to assess the accuracy of the global therapeutic management (Kitchen et al., 2006).

#### 4.3 Staff training

All the staff involved in the global patient management (physicians, laboratory technicians, nurses) has to be trained through specific educational programs and updating sessions as

for example, recommended by the Italian Federation of Anticoagulation Clinics (FCSA). The program should include educational courses on OAT, dedicated courses on the use of portable monitors and training on computer programs (Sawicki et al., 1999). Specific manuals for patients, physicians and nurses should be structured. Periodic evaluations should be planned, reviewing all procedures and discussing results and problems.

#### **4.4 Telemedicine global quality assessment**

A quality assessment plan should be available to control and monitor a telemedicine health care system. A system for automatically flagging and providing information on the results has to be structured specifically. In detail a telemedicine system for anticoagulated patients requires alerts on the following indicators:

- control of coagulation testing;
- time spent in therapeutic range for patient managed in AC versus peripheral health units;
- number of controls for patients/year/peripheral health unit;
- number of bleeding and thromboembolic complications (percent patient-years);
- increase in patient attendance at the medical services provided by the peripheral health units resulting in a better distribution of workloads;
- waiting times for access/blood drawing;
- waiting times for therapeutic prescription;

A patient's satisfaction questionnaire has to be structured.

### **5. A telemedicine Anticoagulation Clinic: An example of web organization**

In Italy from the beginning of 2001, some AC started telemedicine projects in different areas, interesting the following cities: Bologna, Cremona, Merano, Parma, Perugia. Even if these organizations differ in some aspects, like type of software used and level of management, the general principle and aims are common. As an example we describe the experience of the Cremona Hospital. Cremona AC started its activity 20 years ago and in 2011 is managing about 4494 patients. In 2002 a project intended to define criteria for decentralizing the management of OAT patients in suburban health districts, through a telemedicine system, bi-directional connected was elaborated. Principal aims were to create a web organization in order to improve the quality of life of the patients living far from the AC site, maintaining the same clinical quality level. All procedures adopted are on controlled certified quality program. The INR is determined on capillary blood through portable monitors and the AC receives INR results with anamnestic questionnaire. Electronic medical record includes information upload on general clinical conditions, diet intake and drug co-medication, INR and other laboratory data, general compliance and drug adherence, significant clinical events such as hospitalizations, surgery and invasive procedures. These data, collected in peripheral health care units (Nursing Homes, Groups of General Practitioners (GPs) and other hospitals of the area), are sent in real time to the AC, in order to share bi-directionally all clinical records. Moreover, AC is able to manage home patients (who can not leave their home due to serious physical problems, diseases in progress, old age) through mobile units and totally independent patients who directly communicate through the web connection system with the AC (Fig. 4).

11 peripheral health care units (2 Nursing Homes and 9 GP's peripheral health units) and 20 self-testing patients are currently connected for a total number of 1393 patients, i.e. 31% of

the total number of patients. 106 GPs and 22 nurses underwent training courses. As regard clinical quality indicators, no differences in time spent in the therapeutic range were observed between AC and GP’s units, while Nursing Homes showed, as expected because of sub-acute illnesses, the lower TTR (TTR AC=73%; TTR GP’s units=73.4%; TTR Nursing Homes=66%) (Tab. 5). No differences in major (haemorrhagic and/or thrombotic) complications were observed (Tab. 6).

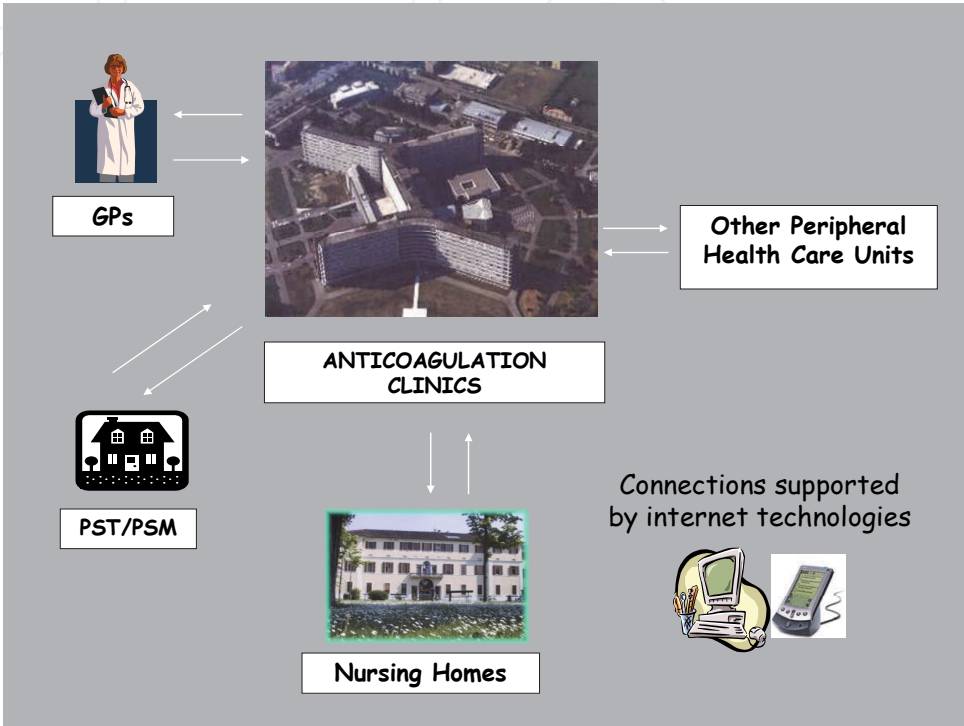


Fig. 4. A model of web organization

	% IN RANGE	% UNDER RANGE	% OVER RANGE	INR > 4.5 (%)
AC	73.7 %	21.5	4.8	0.2
GPs	73.4 %	21.3	5.3	0.2
Nursing Homes	66 %	24.2	9.8	0.6

Table 5. Time spent in range: comparison between AC and Peripheral Health Units

EVENTS	AC	Peripheral Units
MAJOR BLEEDING (percent p/y)	1.1 %	1.0 %
THROMBOSIS (percent p/y)	2.8 %	2.5 %
MINOR BLEEDING (percent p/y)	4.5 %	3.1 %

Table 6. Clinical Quality 2010

All patients express their satisfaction, showing a general improvement in their quality of life. The development of this telemedicine organization facilitates patient access and reduces waiting times for patients and their relatives as well as improves global quality of clinical assistance. The bi-directional informatic system used in this project is planned to set up the anticoagulated patient’s clinical record that is constantly updated and already structured to manage new anticoagulant drugs (Fig. 5).

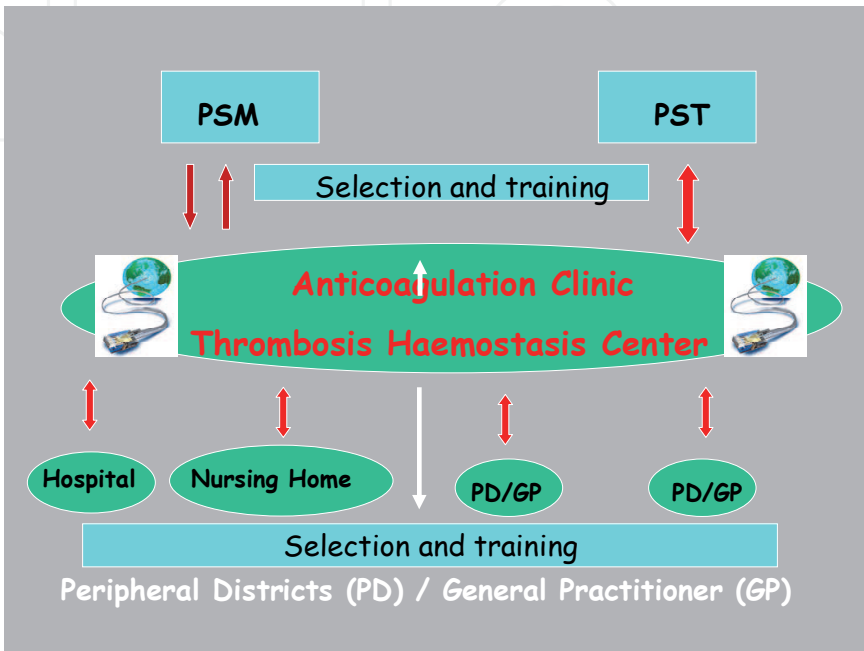


Fig. 5. Bidirectional connection between AC and peripheral districts

6. Limits in telemedicine development

Several barriers can limit the development of telemedicine in health care system. Major difficulties are represented by differences among different countries and regions, due to legal, cultural and organizational problems. Informatic evolution technologies should solve problems in connectivity among different health care structures. Furthermore, the lack of clear regulations for telemedicine development still represents a limit, increasing the rate of uncertainty. A telemedicine system have to guarantee a strict surveillance to avoid the potential lack of data and all unauthorized accesses. Health care telemedicine systems should be validated by experts, easy to use, flexible and adaptable in different clinical conditions. Training for all health care staff on new technologies have to be provided before starting up telemedicine management. Clinical protocols and all procedures have to be shared and formally approved, waiting for institutional regulations.

7. Conclusion

One of the major problem in anticoagulation management is represented not only by the increasing number of OAT patients as a result of ageing, but also by the extension of clinical indications and choice of the best management strategies to assure effectiveness and safety. Telemedicine systems are technologies that allow the development of new management



models in different medical fields (Klonoff, 2009). Telemedicine applied to anticoagulated patients offers several advantages, both for organization as well as for improving communications. Decentralize clinical activity through a telemedicine system give the opportunity to redistribute patient population into different health care areas, whose medical services could be otherwise underused, and to facilitate accessibility to health care services for an increased number of patients, empowering management strategies. At the same time the web creates the opportunity to export quality procedures and competences outside specialized centres, increasing communications, not only between physician and patient, but also between different medical specialties. Telemedicine organizations are opportunities to improve health care and patient's quality of life through a capillary distribution of medical assistance, supporting physicians in the application of good clinical practice in anticoagulation management and in providing the following actions :

- properly define indications
- avoid treatment in patients who have major contraindications
- stop therapy when advantages are less than risks
- identify drug and food interactions
- provide educational courses for patients and relatives
- determine a proper periodical control of anticoagulation level
- prescribe the right daily drug dose
- manage complications
- define protocols for patients undergoing invasive procedure or surgery
- periodically verify clinical and analytical performances

Telemedicine systems should help physicians to ensure the above mentioned items in order to give the best quality of management and avoid malpractice. The mainstay of this model relies on its extreme flexibility and that it can be adopted by either nursing care facilities, such as nursing homes, or healthcare facilities equipped with a medical staff, than by hospitals or groups of general practitioners. Moreover, it may help patients who cannot attend AC because of work-related reasons or remote location (patients on self-testing or self-management) or for those who cannot leave their homes because of chronic illness. As regard clinical quality, telemedicine system provide a very high quality comparable to the best standard and it can allow a reduction of health care costs through a more effective patient management compared to RMC. The service's accessibility represents probably the best advantage, giving to all patients the opportunity to be managed with a good clinical quality. Telemedicine represents an improvement in equity of health care and should be empowered by the government of different countries (Clark et al., 2010). The bidirectional computer connection allow peripheral health units to directly communicate with References structures, like AC or other specialists, creating electronic clinical chart constantly updated. Because of anticoagulant drugs are changing in the last few years and will rapidly change in the next future, through the introduction of new antithrombotic drugs, telemedicine could help the management. Informatic connections represent the starting point of a telemedicine system that will enable healthcare providers to monitor patients either on OAT or treated with new classes of anticoagulants (low molecular weight heparins, fondaparinux, idraparinux, dabigatran, rivaroxaban, apixaban or other new oral factor II or factor X inhibitors, etc). Probably, the new-generation antithrombotic drugs will need different types of management compared with AVKs, with a less frequent clinical and laboratory control. Nevertheless it will be necessary to follow up and record patient's data to guarantee the



strict quality control on adherence, compliance, time in the therapeutic range, incidence of intercurrent diseases, adverse events and complications. Telemedicine can also support, in the next future, pharmacovigilance procedures, useful to improve knowledge on all new drugs (adverse events, major and minor complications, potentially dangerous drug interactions). However, notwithstanding these advantages due to telemedicine organizations, periodical clinical evaluations will be mandatory in order to assess any disease progression or changes in individual bleeding/thromboembolic risks. For these reasons a direct interactive communication between general practitioners and medical specialists is necessary and a telemedicine model will prove to be very useful, facilitating contacts and reporting. Health Authorities should promote telemedicine development with the aim to favour web organization for anticoagulation among different structures and specialists like Anticoagulation Clinics, General Practitioners or others. A web telemedicine organization has to assure the adoption of certification procedures to guarantee the quality of management and pharmacovigilance reports for the different anticoagulant drugs. The advantage of a web organization can be summarized as following:

- accessibility for a higher number of patients to a high quality management system;
- integration among different specialists and health structures
- continuing medical record update;
- possibility to manage patients on different antithrombotic drugs.

The web gives the possibility to rapidly increase connections modulating the management in relation to different molecules, assuring clinical control for all patients.

It's advisable the empowerment of telemedicine strategies in routine clinical practice, through informatic programs suitable for each type of anticoagulant and patient, to favour a global management.

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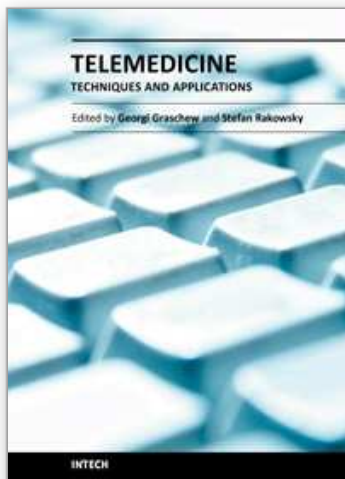
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