Survey on the Management of Oral Anticoagulation Therapy (OAT) in Italy

Objective
- The management of the 0.6-1 million Italian patients [1-2] chronically treated with oral anticoagulation therapy (OAT) poses organisational challenges that are traditionally approached with decentralised procedures, relying on hospital-based clinics. However, the availability of near-patient testing devices for the monitoring of OAT effectiveness (INR measurement) allows for alternative management models (patient self-monitoring – PSM).
- PSM has been proven effective and safe [3-8], and could be attractive, especially in the perspective of the patient, whose life cycle is severely affected by the treatment and time implied in the process of OAT management.
- In order to assess the potential economic impact of PSM in Italy, there is a need for real-world economic and organisational data. This study was planned to investigate treatment patterns and the average costs borne by OAT patients in Italy.

Methods

Questionnaire
- The study was conducted in the period July-November 2008 by means of a questionnaire developed ad hoc and administered to patients face-to-face by volunteers of the main Italian OAT patients association (AIPA – Associazione Italiana Pazienti Anticoagulati). The inclusion criterion was current OAT. The questionnaire was anonymous; participation to the survey was voluntary and not remunerated.
- The questionnaire was composed of a general section (age, gender, employment, association to AIPA) and 19 further questions, divided into two broad domains: a. OAT regimen: underlying diagnosis, anticoagulant drug, target INR, duration; b. Organization and logistics: place and technique of blood sample collection, modality of results delivery, time-place concomitance of specimen collection and visit, monitoring frequency, ranges of distances covered and times dedicated for monitoring and visit, working time loss ranges for patient and companion, and other costs related to OAT monitoring.

Analyses
- Returned questionnaires were collected, checked for inclusion criterion (current OAT) and tabulated on a worksheet. Inconsistent (e.g. monitoring and visit in the same facility but different distances) and contradictory data (e.g. retired patient claiming time off work) was discarded.
- For each item explored, descriptive statistics were calculated and presented in form of distribution among available options for categorical variables and as mean +/- SD for continuous variables.

Costs
- Based on the data collected, costs borne by patients were evaluated.
- Cost incurred for the transportation was estimated based on the assumption that patients used a private vehicle and applying the cost/hm indicated by the Italian Car Association for an average economy car (€ 0.43/km) [10].
- Earning losses were estimated by multiplying the reported monthly time off work by the employment-specific average net hourly wage reported by the National Statistics Institute (ISTAT) for 2005 [11].
- Monthly extra-out-of-pocket expenses were directly extracted from the answers on the questionnaire.

Results

In July 2008, the questionnaires were sent out to the AIPA sections located throughout Italy. By the end of November 2008, 4,725 questionnaires were returned from 37 sections.

Average cost per patient was calculated based on the average of reported subgroup-specific costs for the corresponding prevalence percentage. For this purpose, all costs for the not concomitant groups have been based on the conservative hypothesis of one adjustment visit every 4 INR tests.
- Mean monthly time dedicated to OAT management was calculated separately for patient subgroups. It was reported separately from time-off work, as a great proportion of patients was retired or unemployed.
- Costs accruing due to time-off work requested by the companion were not imputable to the patient, whose perspective is adopted in the analyses, and therefore were reported separately.

In Italy, there is a need for real-world economic and organisational data. This study was planned to investigate treatment patterns and the average costs borne by OAT patients in Italy.

Manuscript:
S. Iannazzo 1, O. Zaniolo 1, P. Botrugno 2
1 AdRes HELFO, Turin, Italy
2 Roche Diagnostics, Monza, Italy

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Discussion
- The most often reported home clinic distance range is 1-5 km. Average time dedicated for each monitoring episode is just over 2 hours.
- Time off work requested by actively employed patients for their blood sample to be taken ranges from 30 min to 3 hours per episode. The adjustment visit, when done separately from the blood test results last longer than 5 hours in 40% of cases.

Conclusions
- This study contributes in clarifying the picture on current management of the Italian OAT population.
- The results obtained should prove helpful in programming and evaluating alternative management options, such as those based on patient self-monitoring, which will almost inevitably gain more popularity in the next years, as anticoagulation clinics are approaching their maximum work capacity, and the trend towards a progressive increase in OAT patients does not appear to have reached its plateau.

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References