TWO PHASES STUDY ON THE PERSPECTIVE OF HEALTH CARE PROFESSIONALS ON CURRENT MECHANISMS FOR AUTHORIZING THE PRESCRIPTION OF SPECIFICALLY CONTROLLED MEDICINES IN SPAIN.

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Introduction

►A control (inspection) system (CIS) for authorizing the prescription and dispensation of specifically defined groups of pharmaceutical products exits in Spain.
►Different from the regulation on controlled medicines enacted to avert misuse, the inspection system of prescriptions was introduced in the 70´s to restrict the access to either costly or potentially harmful products with partially known medical effects[1,2].
►Traditionally, medical prescriptions has been assessed manually. Currently, the implementation of electronic systems for the prescription and dispensation of medicines is modifying the whole process for accessing to treatments countrywide.
►The medical inspector plays a key role on the assessment of prescriptions of inspected medicines[3] .

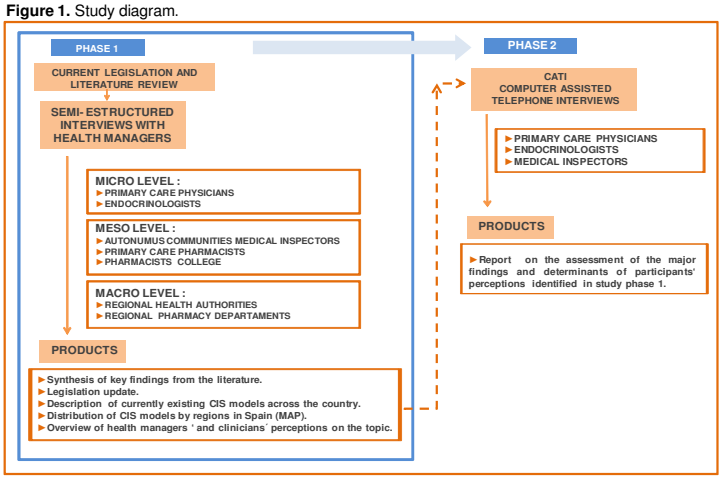
Objectives

This study aims to explore health care professionals' views on the impact of the implementation of an electronic system on the prescription and dispensation of specifically controlled medicines in Spain.

Methods

Observational, cross-sectional, exploratory, two phases study **(Figure 1)** based on qualitative research techniques, including literature review, review of the current legislation, semi-structured (phase 1) and structured interviews (phase 2) with health managers and clinicians actively involved in decisions related to the prescription of controlled (inspected) medicines in the public health sector in Spain. During phase 1, exploratory and descriptive objectives were sought. Phase 2 referred to the assessment of phase 1 key findings. This communication reports on **phase 1** results**.**

Figure 1. Study diagram.



For the **review of the literature (2005-2010)** flexible inclusion criteria were defined to embrace the highest possible number of publications due to the scarcity of scientific information on the topic available. Several electronic, medical and regulatory databases including PubMed/MedLine, ISI WoK, CSIC, Cochrane, Science Direct and Google Scholar as well as the websites of local newspapers and of Scientific Societies were searched.
For the **review of the legislation,** the websites of the health offices at the Ministry of Health and in the Autonomous Communities in Spain were searched
For the **semi-structured interviews,** participants were chosen based on their expertise on medical practice, ambulatory care and their professional location (urban vs. rural). Representatives of the macro-, meso- and micro-level of health managing decision were identified and invited to take part in the study.

Results. Review of the literature and of current legislation

Literature review. A total of 11 medical publications [n=8, national; n=3, international), 2 Scientific Societies' reports, and 8 press articles specifically devoted to the inspection system of medicines in Spain were analyzed. Key findings can be summarized as follows:

►Overall, the published data on the topic is scarce.
►The inspection of medical prescriptions may result on a bureaucratic obstacle to accessing optimal treatments according to patients', physicians' and pharmacists' views[4,5].
►Although it may reduce pharmaceutical expenditures, the evidence for its long-term influence is not conclusive[6,7].
►The use of an inspection system as a method for controlling pharmaceutical expenditures does not affect medical decisions on the best therapeutic option for the patient[8].
►There are discrepancies amongst professionals, health authorities and the pharmaceutical industry on its final clinical or economic purpose[9].

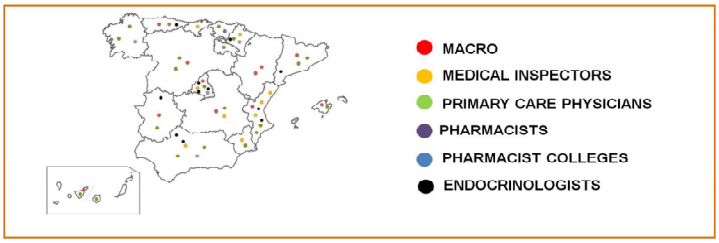
Review of current legislation. A total of 17 websites were searched. Only 6 Autonomous Communities (Andalucía, Aragon, Canarias, Valencia, Extremadura and Galicia) offered information easily accessible to the public. No information on the regulation of the inspection system of medical products was available for 11 Autonomous Communities .

Results. Semi-structured interviews

A total of 58 professionals (n=11 macro-level; n=9 meso-level; n= 32 micro-level) were interviewed until data saturation **(Figure 2)**, including:
A total of 58 interviews were conducted **:**

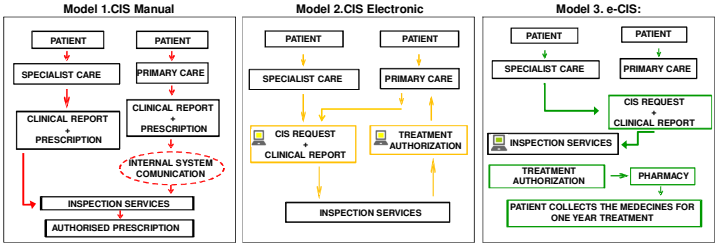
► 11 regional health authorities (macro-level)
► 9 medical inspectors (meso-level)
► 6 primary care pharmacists, including a representative of the pharmacist colleges (meso-level)
► 21 primary care physicians (n=9 urban area; n=12 rural area); 11 endocrinologists (micro-level)

Figure 2. Geographical location of the decision makers interviewed.



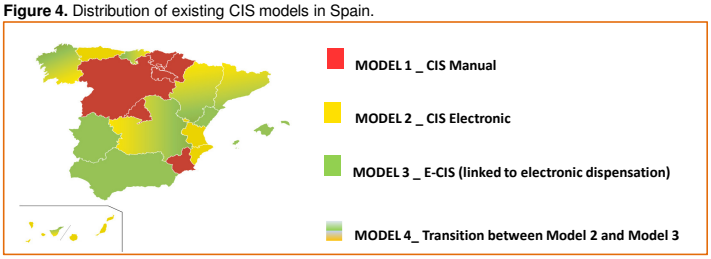
Three CIS models where identified across Spain **(Figure 3)** based on the nature of the system the inspection of prescriptions takes place: **Model 1:** manual system, **Model 2:** electronic system, and **Model 3:** electronic system of inspection, authorization and dispensation of medical products (e-CIS)

Figure 3. Existing CIS models in Spain.



The three CIS models are unevenly distributed across Spanish regions **(Figure 4).** Most Autonomous Communities are at a transitional phase to linking the inspection of the prescription and dispensation of treatments through an electronic system.

Figure 4. Distribution of existing CIS models in Spain.



Key findings.

► While health managers at the micro level of decision (primary care physicians and endocrinologists) perceived the inspection system of medical products mostly as a method for controlling expenditures on drugs, managers at the macro- and meso-level (regional health authorities, pharmacists, medical inspectors) mainly saw it as a way for guaranteeing a more adequate, safer and efficient use of medicines according to clinical needs.
► Clinicians argued in favor of a more effective training of medical professionals on the rational use of medicines and on the implementation of more operative clinical pathways rather than on an inspection system of prescriptions.
► Criteria for imposing the need of inspection of medical products seemed unclear and unsystematic to many participants.
► An electronic system of inspection of prescriptions has been extensively implemented in the primary care sector compared to the specialist care sector.
► Several advantages for the electronic systems of inspections were identified (speeding up of the process, friendly use of electronic tools, access of treatments for a year, less time consuming for patients)

Conclusions

► **Available scientific and regulatory information on the inspection system** of specifically defined groups of medical products **is limited**.
► **Most regions in Spain move towards implementing electronic systems that link the prescription**, authorization and dispensation of medical products.
► **Discrepancies exist amongst health managers acting at different levels** of decision **on the ultimate aim of the inspection system of prescriptions**.
► The characteristics of such **discrepancies** are to be explore in study **phase 2.**

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References: [1]Royal Decree 946/1978; [2] Ley 29/2006 de Garantías y Uso Racional de los Medicamentos y Productos Sanitarios; [3]Derecho y salud 2006; 14(1): 25-44.; [4] Aten Primaria 2006;37(5):278-86. [5] Av. Diabetol 2005;21:315-321; [6] Gestión clínica y sanitaria 2005; 7(3):88-95.; [7]Pharmacoeconomics 2007;25:637-48; [8] Clin Ther 2004;26:1518-32.; [9]Informe INESME: 2004; 34ip. Disponible en: http://inesme.com/pdf/visados.pdf . Accedido el 4 de abril de 2010.