

Original Article

Assessing Medical Prescription Forms as a Communication Tool in Trans-European Health Care

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ABSTRACT

Objective: The objective of the study was to compare the medical prescription forms in European Union (EU) countries, evaluating their convergence toward the implementation of cross-border care, as proposed by the existing EU health-care directives. It also aims to assess how the existing EU prescription models fulfill higher standards of medication prescribing quality and patient safety. **Methods:** Prescription forms from all EU countries were purposively collected. The prescription fields and other content elements were qualitatively and quantitatively analyzed. Forms were statistically compared with each other and a theoretical EU cross-border prescription form, using hierarchical cluster analysis and nonparametric testing. **Findings:** None of the EU countries' prescriptions include all the elements required by the cross-border legislation (CBL), with most countries having seven or less mandatory elements. Cluster analysis revealed that countries with similar prescription forms are geographically nearer. Important elements from the EU directive to assure patient safety are also absent such as the International Classification of Diseases, the patient's ID according to the European Health Insurance Card, and the patient's contact. However, Western and Nordic countries showed higher standardization when compared to the CBL and model. **Conclusion:** Political action is still needed to harmonize medical prescription forms between countries, serving the common goal of trans-European health care and to increase EU patients' safety using medications and other prescribed treatments.

KEYWORDS: Health-care quality, patient safety, prescription forms, trans-European care

Received: August 2017.

Accepted: November 2017.

INTRODUCTION

Medical prescription is an essential part of the communication flow between the prescriber, the pharmacist, and the patient and needed for the provision of health care.^[1] Prescribed drugs are usually written on printed forms with blank spaces that must be carefully filled with the right information, required to identify the patient, the medication, and directions for use.^[1,2] Complete and correct prescriptions are an important resource for providing efficient pharmaceutical care for the patient.^[2]

As a cognitive product, the prescription is subject to error. Pharmacists may face problems because of bad prescribing habits such as illegible handwriting, lack of information

about the duration of medication, or inadequate instructions on the administration.^[3-5] In addition, these issues can be a consequence of a high number of essential prescription elements to be placed in one blank space allowing for free writing. Such errors are not uncommon and increase the risk to patient safety.^[6,7] Thus, the aim is to standardization of prescription forms and stopping the use of handwriting.^[8] Electronic prescribing has been developed and implemented to avoid procedural errors, with more accurate prescriptions sent directly to a pharmacy contributing to less dispensing errors.^[9]

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How to cite this article: Cavaco AM, Mourato M, Ferreira S, Yeğenoğlu S. Assessing medical prescription forms as a communication tool in trans-European health care. *J Res Pharm Pract* 2018;7:22-29.

Access this article online

Quick Response Code:



Website: www.jrpp.net

DOI: 10.4103/jrpp.JRPP_17_61

A fundamental principle of the European Union (EU) is the citizens right to move across borders. When a patient with a chronic disease travels from one EU country to another with a prescription, any community pharmacy within the EU should be able to accept and dispense the necessary medication. This follows the EU slogan of “united in diversity,” opening doors to cross-border care in Europe.^[10] Over the past 20 years, excluding present migratory fluxes, the number of people that cross European borders has increased abruptly.^[11] Cross-border health care is a growing phenomenon in the EU with massive potential to develop in the next few years.^[12,13] As from 2007, the majority of patients chose to obtain health care in their own country with public spending in cross-border health care representing only 1% of the total spent on health care, although the German Techniker Krankenkasse sickness fund saw the percentage of claims for cross-border care rose from 7% in 2003 to 40% in 2008.^[11,14] It is estimated that, at least 5 times a month, a foreign European prescription is presented to 17% of pharmacists in the EU, although there are many factors (e.g., medical tourism and intra-EU migration) that may cause variations among member states.^[15]

The European directive on the application of patients’ rights in cross-border health care was created to formalize the flow of patients’ searching for health care in other countries.^[16] The implementing directive 2012/52/EU defines measures to facilitate the prescription authentication, patient and medical products identification, permission for substitution, and usage instructions so creating a list of elements to be included on a prescription to be accepted abroad.^[17] This list promoted the homogenization of how prescriptions are issued in the EU. However, as yet, there is no standard system within EU countries to share electronic prescriptions between countries, so printed forms are still needed to purchase medicines abroad.^[18] Each country has its own prescription forms, which need not that all include the same elements required by the directive. On the other hand, the EU model may also lack information or other elements that might be considered mandatory internationally to assure treatment effectiveness and patient safety. This leads to the following questions: what are the similarities between prescriptions from different European countries? Are the minimum elements required in the cross-border directive present in most medical prescriptions forms across EU countries? How would a standardized paper prescription model be recognized in any European country? Which mandatory elements were designed to minimize error?

The aim of this study was to compare the existing content of medical prescription forms from European countries,

including the mandatory elements proposed by the EU cross-border directive, allowing to achieve an optimized formula for adoption by all EU member states.

METHODS

This documental cross-sectional descriptive survey was initiated by the construction of a MS Excel 2013 database including the most frequent and customary prescription forms used by general practitioners in European countries. The blank forms were obtained between November and December 2015 by contacting by mail the main health-related institutions of all fifty European countries such as the Ministry of Health, drug regulatory bodies, and physicians’ and pharmacists’ associations. It was not possible to identify patients, professionals, and/or places of issue (e.g., hospital, health center, or private practice) from the forms collected.

Different kinds of prescription forms were received: ordinary, special, working accident, and multiple prescriptions. From all the prescriptions, some were real forms and others were samples including some from the country’s legislation. The database included a total of 236 different prescription elements and fields. To evaluate the quality of the forms, we only considered well-defined elements, i.e., not those that might be referred in each country legislation, but with no specific field to fill in the prescription form. Legislative elements that might be handwritten by the prescriber in available blank spaces were not considered in this study. This was decided to increase database accuracy since there is no way to predict if the prescriber will, or will, not mention less defined information.

A final and straightforward database was extracted from the initial one, comprising prescription models (cases) and their elements (variables) considered by research team consensus as the most useful for the next analytical steps. Prescriptions were selected using only real and most complete forms (when several were available from one country), achieving one single form representing each country. The elements (variables) were chosen according to the required elements in the implementing directive 2012/52/EU^[17] and other fields assessed by the research team to be relevant to study objectives, especially from the patient safety perspective. Variables were coded as binary, with 0 meaning the absence and 1 presence of the element in the prescription.

A prescription index was created by qualitatively weighing or scoring each variable, with perceived varying importance for elements presence/absence, according to the cross-border legislation (CBL) and the deemed importance to the communication quality between the prescriber and the dispenser. The variables present in legislation received a three-point score, others received

2 or 1 point, depending on their importance to increase prescription intelligibility or to facilitate professionals' exchange. This is presented in Table 1.

For instance, concerning the patient ID (variable/line A), if a prescription form has the field "name/surname," 3 points were attributed since this element is required for cross-border prescriptions. If containing only "name," the weight was 1 point, and if missing both these fields, it received 0 points on this variable. Another example is the patient ID line B: When the date of birth was present, the prescription received 3 points; when including patient age, it received 2 points. Even though the field "age" is not an element in the CBL, it clearly contributes to the prescription intelligibility making it equivalent to the cross-border requirements. For the age variable, if the prescription contained both "age" and "date of birth," it received 5 points (2 and 3 points, respectively), while both elements' absence corresponded to 0 points.

After all scoring, it was possible to obtain a total sum score for the CBL elements and a prescription index by summing up all elements' scores. The minimum score possible was zero, or in practical terms with at least one identifier (such as the "physician name") scoring 1 point. The maximum score for a flawless form is 41 points, i.e., the maximum value for the prescription index.

This dataset was submitted to hierarchical cluster analysis, mapping the different prescription forms in

similar groups. The clustering strategy comprised of Ward's method, chosen for its good performance with binary variables,^[19] while the squared Euclidean distance between subjects/clusters was used as the similarity measure. The hierarchical cluster analysis was performed with SPSS statistics software (version 22, SPSS, Chicago, IL, USA). Differences in prescription index between clusters were also performed using the nonparametric Kruskal–Wallis test, followed by multiple comparisons of the means,^[20] with a Type I error probability (α) of 0.05.

RESULTS

The initial contact with health and professional organizations obtained 59 prescription forms from 30 different countries, 26 from the EU, and 4 outside the EU. Missing EU countries were Romania, Greece and Luxemburg, adding a Scottish form and two-third party countries (Norway and Switzerland), for which the CBL also applies. As well, two other non-EU European countries (Montenegro and Serbia) were included as external control cases. The final database comprised of 29 prescription forms, from 29 individual countries, plus a virtual prescription form representing the fields required by the CBL.

Considering only the variables present in the directive, there are 13 variables to be evaluated, with the CBL case scoring 39 points, which is the maximum cases' score. None of the prescription forms assessed meet all the

Table 1: Prescription elements and weights/scores calculation

	Scores		
	1	2	3
Patient ID			
A	Name*	-	Names/surnames
B	-	Age*	Date of birth
C	EHIC*	-	-
D	Phone or email*	Phone + email*	-
Authentication/validation of the prescription			
E	-	-	Issued date
Prescriber ID			
F	Name*	-	Names/surnames
G	Specialty*	-	Qualification
H	-	Email/phone/fax	Email + phone + fax
I	Country name	Address	Address + country name
J	-	Doctor stamp*	Doctor signature
Prescribed products ID			
K	Active substance	-	DCI/brand
L	-	-	Pharmaceutical form
M	-	-	Quantity
N	-	-	Strength
O	-	-	Dosage regimen
P	-	ICD*	-

Elements marked with an *Are not present in the CBL. EHIC=European Health Insurance Card number, ICD=International Classification of Diseases, ID=Identification, CBL=Cross-border legislation

estimated required elements, with all prescriptions failing at least four elements, i.e., reaching a ceiling score of 30 points. In the case of the French prescription, there were the most elements than in the cross-border case, reaching 27 points or 9 variables in 13. The prescription presenting the least required elements was Bulgarian, with only one element present. From the all EU countries' prescription samples, 8 had 3 or less required elements, 14 varied between 4 and 7 elements, and only 4 presented >7 elements. When considering the non-EU prescriptions too, there were 9 prescriptions with 3 or fewer elements, 17 prescriptions between 4 and 7, and 4 with >7 elements.

When considering the prescription index (i.e., legislation and additional elements), there was an overall increase

in scores because of many forms being absent from the cross-border obligatory elements but presenting equivalent or other important elements. One example of this is "date of birth," three countries were missing, but they presented the analogous "age." Anyway, the French still was the most complete prescription; the Polish form became the one with the lowest prescription index. These results are presented in Table 2.

The hierarchical cluster analysis produced the dendrogram represented in Figure 1. It was possible to identify three countries' clusters with neighbor prescription classification: Cluster 1 has the highest cluster membership (13 countries), while Cluster 2 has the lowest number of countries (7 countries). To help understand the cluster analysis results, Figure 2 presents a

Table 2: Prescription elements and scores

	Country	Patient ID				Authentication/ validation of the prescription	Prescriber ID					Prescribed products ID					Scores		
		A	B	C	D		E	F	G	H	I	J	K	L	M	N	O	P	CBL
EU	Austria	3	0	0	0	3	0	0	0	0	5	0	0	0	0	0	0	9	11
	Belgium	3	0	0	0	3	3	0	0	0	5	0	0	0	0	0	0	12	14
	Bulgaria	1	2	0	0	0	1	0	0	2	5	0	0	0	0	0	0	3	11
	Croatia	3	3	1	0	3	0	1	2	2	3	0	0	0	0	0	2	12	20
	Cyprus	1	0	0	0	3	1	1	3	2	0	0	0	0	0	0	0	6	11
	Czech	3	0	0	0	3	0	0	0	0	5	0	0	0	0	0	0	9	11
	Denmark	1	0	0	0	3	1	0	0	0	3	3	3	3	3	3	0	21	23
	Dutch	1	3	0	0	3	1	1	2	2	3	3	3	3	0	3	0	20	28
	England	3	5	0	0	3	0	0	0	0	3	0	0	0	0	0	0	12	14
	Estonia	1	2	0	0	3	1	0	0	3	5	3	3	0	3	3	2	21	29
	Finland	1	3	0	0	3	3	0	0	0	5	3	0	3	3	3	0	24	27
	France	3	2	0	0	3	1	3	3	2	3	4	3	3	0	3	0	27	33
	Germany	3	3	0	0	3	0	0	0	0	5	0	0	0	0	0	0	12	14
	Hungary	1	3	1	0	3	1	1	0	0	5	0	0	0	0	0	2	9	17
	Ireland	1	0	0	0	3	0	0	0	0	3	0	0	3	3	3	0	15	16
	Italy	3	0	1	0	3	0	0	0	0	5	0	0	0	0	0	0	9	12
	Latvia	3	0	0	0	3	3	1	2	2	5	0	0	0	0	0	2	12	21
	Lithuania	3	3	0	0	3	0	0	3	2	5	0	0	0	0	0	0	15	19
	Malta	3	0	0	0	3	1	0	0	0	3	3	3	3	3	3	0	24	25
	Poland	0	0	0	0	3	0	0	0	0	3	0	0	0	0	0	0	6	6
	Portugal	1	0	0	1	3	1	1	2	0	3	3	3	0	3	3	0	18	24
	Scotland	1	0	0	0	3	0	0	0	0	3	0	0	0	0	0	0	6	7
	Slovakia	3	3	0	0	3	0	0	0	0	5	0	0	0	0	0	2	12	16
	Slovenia	3	3	0	0	3	3	3	3	2	5	0	0	0	0	0	0	21	25
	Spain	3	3	1	0	3	0	0	0	0	3	3	3	0	3	3	0	24	25
	Sweden	1	0	0	0	3	1	3	2	2	3	3	3	0	3	3	0	21	27
	NonEU	Montenegro	3	3	0	2	3	3	0	2	0	3	0	0	0	0	2	15	21
		Norway	1	0	0	0	3	1	1	0	0	5	4	0	3	3	2	18	26
		Serbia	3	3	0	0	3	0	0	0	0	5	0	0	0	0	2	12	16
		Switzerland	0	0	0	0	3	1	1	3	2	5	0	0	0	0	0	9	15
EU cross-border prescription		3	3	0	0	3	3	3	3	3	3	3	3	3	3	0	39	39	

CBL=Score that only include the elements requested in the CBL, Index=Score that include all the elements. EU=European Union, ID=Identification, CBL=Cross-border legislation

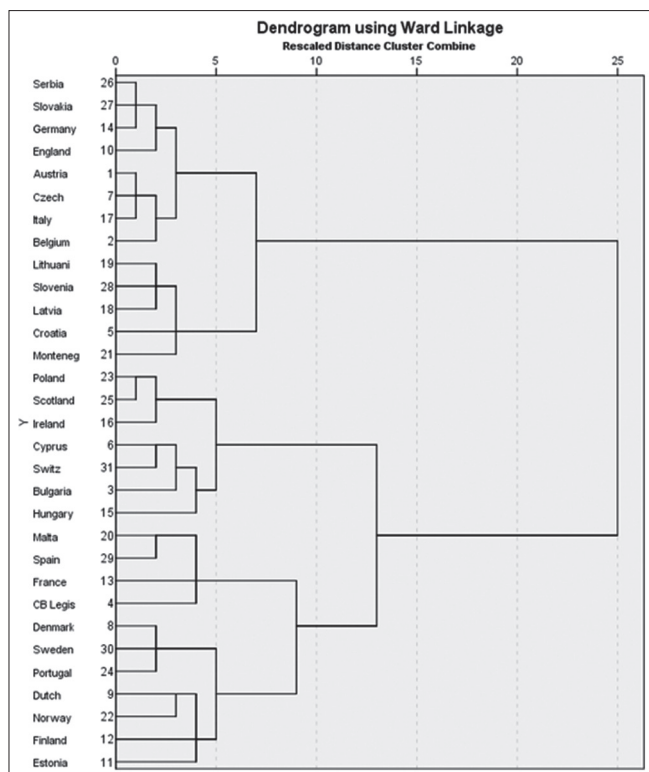


Figure 1: Dendrogram of countries' prescription forms

Europe map with the geographic distribution of countries in each cluster. Cluster 1, which is the largest cluster, has most countries located in central Europe. Cluster 2 comprised of Ireland, Scotland, Eastern European countries, and Switzerland. The Nordic countries, Iberian Peninsula, France, The Netherlands, and Malta were in the Cluster 3.

Clusters were subsequently tested to assess possible differences in relation to the prescription index score, and a significant result was obtained ($H = 21.092, P < 0.001$). As shown in Figure 3, prescriptions in Cluster 3 feature a score distribution significantly higher compared to Clusters 1 and 2.

DISCUSSION

This study aimed to study medical prescription forms within countries that are bound to prescription sharing mechanisms, enabling cross-border care. It was also intended to explore the prescription filling spaces unequivocally related to patient, prescriber, and medicines so that a flawless information flow is achieved, thus helping avoid common interpretation or transcription errors. In published literature, there are several examples of this issue.^[21-24]

Scores and the prescription index calculation were a simplified method to verify how well the analyzed prescriptions match the elements assumed as necessary

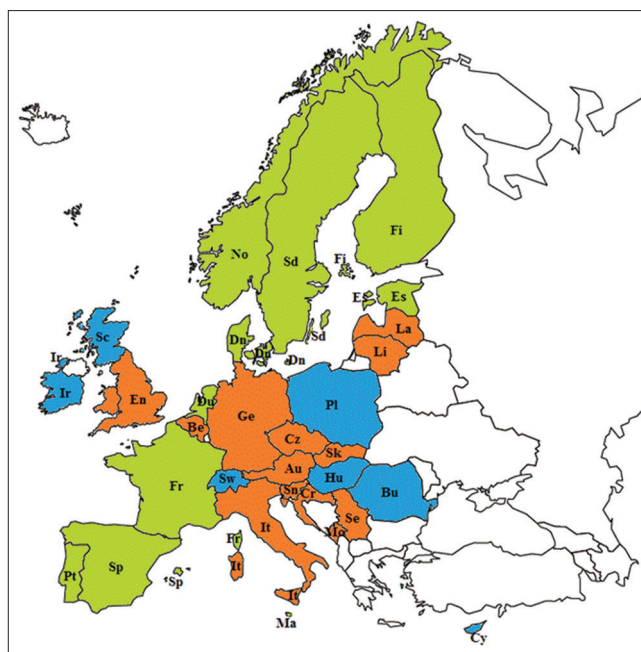


Figure 2: Geographical distribution of countries in each cluster: Clusters 1, 2, and 3 are colored in orange, blue, and green, respectively

for quality and safe practice, compared to the gold standard of CBL.^[17]

Findings suggested that none of the prescriptions included in the study comprise all the elements required by the CBL and additional elements, with most countries showing seven or less required elements. The first implication of this finding is the mismatch between practice and legislation, with implications for patients' access to medication in the EU area. For instance, community pharmacies can refuse to dispense medicines that are solicited through another EU country prescription due to lacking or mismatched information. The intended easier circulation of people within the EU space, who might have a health condition, is also conditioned by differences not so hard to solve. However, more importantly from a clinical perspective is the hindered communication between the prescriber and the dispenser, which increases possible hazards for the patient. Patient, physician, and especially drug information limitations are particularly relevant with possible cultural and language barriers in cross-border care.

The EU mapping of similar prescriptions shows an interesting distribution since it was not expected to find the usually demanding Nordic countries, which are recognized by a greater focus on patients' safety culture, matching the Southern countries of France, and especially Spain and Portugal, while Italy runs on similar models as the central EU countries. This central Europe group seems to be less demanding on information exchange between medicine prescribers and dispensers.

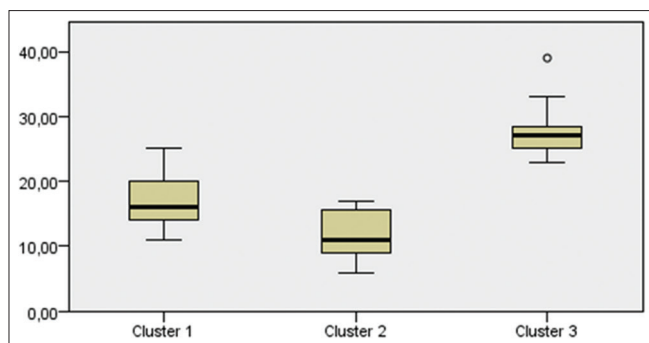


Figure 3: Prescription index comparison between the three clusters using nonparametric Kruskal–Wallis test

Surprisingly, Scotland and Ireland differ from Great Britain, where the National Health Service is usually considered as a reference health-care system.

If prescribers want to accomplish the required cross-border elements, they can handwrite information outside of the designated fields or by adding separate written notes. Having more than one information support does not contribute to the correct handling of prescriptions and medicines use. One alternative to prevent this issue is to develop a specific and common prescription form for cross-border healthcare, preferably using a dedicated official website and/or app developed under EU control and using certified automatic translation according to the location. New important elements should be present such as International Classification of Diseases, patient's European Health Insurance Card number (other ID), and patient contact details. This solution, if adequately resourced, such as shared medicines databases, could immediately suggest equivalent prescribed drugs, using georeferencing options.

Some of the new aforementioned elements are not required in the present directive. However, it is believed that, through information technology, these can be effortlessly managed, contributing to better communication between all involved, including reimbursement systems and other legal issues (e.g., counterfeit prescriptions) but especially the patient. One possible paper-based example of a generic cross-border prescription form is provided in Annex 1. This proposal would need further validation regarding its robustness as an effective communication tool, as well as the reduction of the two main prescription-related risks: unintended medication errors, especially those resulting from the act of writing and prescription fraud, i.e., the use of falsified prescriptions to access controlled drugs.^[25,26]

A limitation of this study was not being able to confirm if the prescription models, received and used in this study, were the most representative or frequently used

forms for daily primary care prescription. Some forms might respect regulatory obligations, but the actual use in practice might be simpler, especially when no e-prescription systems are in use. Furthermore, from the 28 EU countries, it was not possible to obtain prescriptions from Greece, Romania, and Luxembourg. Furthermore, online translating tools were used which might introduce some error in the translating process, particularly for abbreviations and acronyms.

Prescription elements were weighted according to the research team perception of their importance in practice, patient safety, and the clinical context of this study. Other specific approaches in elements weighting (e.g., health-care management, policy, or economic variables) might ascribe different scores and values to the same elements, thus producing different results. Furthermore, no in-depth qualitative assessment of the elements' presence/absence implications for patient outcomes was accomplished.

Although there is a political willingness toward the standardization of the prescription model in Europe, significant practical differences still exist regarding the information required to issue a medical prescription. This indicates the need to develop and implement a standard e-form, recognized in any EU country, to facilitate prescription communication between providers in different countries. The impact and outcomes of the prescription variability within selected EU countries, as well as the pilot study of a shared computer application, are next important research steps.

AUTHORS' CONTRIBUTION

Afonso Cavaco contributed in study design, including methodology and data analysis, as well as manuscript writing. Miguel Mourato and Sofia Ferreira were responsible for data collection and analysis, as well as manuscript writing. Selen Yeğenoğlu participated in the study design and manuscript revision.

Acknowledgments

Authors would like to thank all colleagues that contributed to their own countries' prescription form specimens.

Financial support and sponsorship

Nil.

Conflicts of interest


There are no conflicts of interest.

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ANNEX

	Prescription Form Cross-Border Healthcare	_____
		(Country Name)
Patient Information		
First Name(s): _____ Surname(s): _____		
Birth Date: __/__/____ European Health Insurance Card: _____		
Phone: _____ Email: _____		
Rp.		
DCI/Brand: _____ ICD code: _____		
Active Substance: _____		
Pharmaceutical Firm: _____ Strength: _____		
Number of Units (quantity): _____		
Posology/Dosage Regimen: _____		
Prescriber Information		
First Name(s): _____ Surname(s): _____		
Qualification: _____ Phone: _____		
Email: _____ Fax: _____		
Address: _____		
_____ (Prescription date)		
_____ (Prescriber Signature)		_____ (Prescriber Stamp)

Annex 1: One model proposal for cross-border health care