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Development of a tool to assess the completeness of drug information sources for health care professionals: A Delphi study

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ABSTRACT

The aim of this study was to create a standard set of essential drug information items as a tool to assess the completeness of any type of drug information source, regardless of its length, using a Delphi consensus panel of European health care professionals. A compilation of drug-related information items was performed by searching several resources for health care professionals and a final list of 162 items was obtained. Fifty-seven experts in drug information from 23 different European countries were invited to participate in a three-round Delphi technique to obtain consensus on items considered essential and non-essential content of information. Consensus for the first, second, and third rounds was defined as ≥90%, ≥80%, and ≥75% agreement, respectively. Of the 57 experts invited, 32 completed the first round, 27 the second, and 29 the third. Consensus was achieved for 28.3% of the items in the first round, 49.3% in the second, and 58.3% in the third. The final cumulative consensus was 67.7% (n = 126) for items considered essential and 16.1% (n = 30) for items considered non-essential. The final tool obtained to assess the completeness of drug information sources was composed by 126 essential items grouped into 11 sections. This tool allows for the comparison of different information sources for the same medicine and the information content for different medicines in the same source.

1. Introduction

Selecting the most effective, safe, and economically viable medicine is complex and requires access to unbiased, complete and useful drug information (Cox et al., 2010). However, the availability of large amounts of information about new and established medicines requires a tremendous effort from clinicians to keep up with the medical literature (Haynes et al., 1986). It was estimated that primary care physicians would require more than 600 h per month, or about 29 h per weekday, to keep up with the literature relevant to their practice (Alper et al., 2004). Also, retrieval of that evidence can be a cumbersome process and being able to efficiently search the literature is an essential skill for an evidence-based practice (Doig and Simpson, 2003). Estimated time spent by physicians to find an answer to a clinical question was 12 min (Gorman, 2001). Research shows that health care professionals feel the need to perform additional searches to answer clinical questions because they find many of the existing drug information sources unsatisfactory (Jackson et al., 2007). This is not surprising given that even dosing instructions were found to remarkably vary across different drug information sources for several medicines (Khanal et al., 2014; Vidal et al., 2005). Another study found that only 30% of physicians' information needs were met during the patient visit (Covell et al., 1985).

Physicians' information needs, assessed as the number of questions arising per patient, were estimated at one question for every ten patients seen (Gorman, 2001). Several studies have been performed to reveal clinicians' specific information needs and the findings showed that most were related to diagnosis, treatment/therapy, and drug-related information (Davies and Harrison, 2007). In the specific case of clinical decision support systems, physicians expected the system to provide information on drug

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appropriateness for specific patients, dose/drug recommendations, and alternative drugs with similar effects (Rahmner et al., 2012). Drug information sources used by physicians range from paper and electronic records, databases, research literature, professional colleagues, text books, and drug labelling (Davies and Harrison, 2007; Hallersten et al., 2016). Physicians by preference continue to use traditional methods like consulting a colleague or information on paper, despite improved accessibility to e-provided information (Gorman, 2001; Coumou and Meijman, 2006; Abou-Auda, 2008; Callen et al., 2008; Hedegaard and Damkier, 2009). Pharmaceutical companies are also important drug information providers for health care professionals. According to a survey among physicians, 57% of them rely on the information of pharmaceutical companies when prescribing a new medicine for the first time (e.g., company mailings, sales representatives) (Anderson et al., 2009).

The selection amongst the various resources available is determined by the presence of features recognised by physicians as important. Cook et al. (2013). identified a set of nine features that influence users' selection of resources such as: efficiency (with subfeatures of comprehensiveness, searchability, and brevity), integration with clinical workflow, credibility, user familiarity, optimisation for the clinical question (e.g., diagnosis, treatment options, drug side effects), currency, and ability to support patient education. Also, a simple acronym – ARCA, Accessibility, Reliability, Completeness, and Applicability – has been suggested to guide the process of assessing the quality of a drug information source (Fernandez-Llimos, 2015). However, all resources suffer from shortcomings in their content. For example, even though the Canadian Compendium of Pharmaceuticals and Specialties was ranked highly among practitioners for its usefulness, accessibility, credibility, and current/timeliness (Murphy et al., 2006), other findings revealed that it displayed a strong bias in favour of the pharmaceutical manufacturers (Bell and Osterman, 1983). The American Physicians' Desk Reference contains only the limited dose information from package inserts and therefore important data from post-release discoveries are not incorporated into it (Cohen, 2001). The European Summaries of Product Characteristics (SmPCs) present important clinical pharmacology information deficits (Arguello and Fernandez-Llimos, 2007), and were considered suboptimal sources of information for dose adjustment in renal impairment (Salgado et al., 2013, 2015), drug use during pregnancy and lactation (Arguello et al., 2015), drug use in older individuals (Beers et al., 2013), drug-drug interactions (Bergk et al., 2005), food-drug interactions (San Miguel et al., 2005), therapeutic drug monitoring (Rougemont et al., 2010), overdose advice (Wall et al., 2009) or pharmacogenomics information (Reis-Pardal et al., 2016). A systematic comparison of seven commonly used online drug information databases showed that not all performed well in terms of scope, completeness, and ease of use (Clauson et al., 2007).

Most of the studies that assessed the quality of the various drug information sources available used *ad hoc* created tools and methods (Arguello and Fernandez-Llimos, 2007; Clauson et al., 2007; Spyker et al., 2000). To enable comparisons of the content of different drug information sources, both online and printed, the same tool should be utilised across different sources. However, to date, no such tool has been developed. The aim of this study was therefore to create a tool to assess the completeness of any type of drug information source, by identifying the essential content of information, using a Delphi consensus panel of health care professionals.

2. Methods

A three-round Delphi technique was used to obtain consensus on the essential content of information that should be included in any type of drug information source for health care professionals, irrespective of its length. For the purpose of this study, the term health care professional refers to someone who is qualified and legally allowed to provide health care to patients.

2.1. Initial pool of information items

An initial pool of drug-related information items was created by performing several exploratory searches in different drug information sources. First, a literature search was conducted on PubMed to identify articles that used checklists to evaluate the content of drug information sources in specific areas of knowledge (e.g. the study by Spyker et al. (2000). which evaluated the clinical pharmacology content of drug information sources). Second, official guidelines from drug regulatory agencies were reviewed to identify further items (e.g. *Notice to Applicants* describing the information to be included in SmPCs (European Commission, 2009)). Finally, other drug information sources including reference books, product monographs, compendia (e.g. Physician's Desk Reference) and webpages targeting health care professionals were also reviewed to identify drug-related items that should be included in a drug information source for health care professionals.

After merging all the items gathered, the research team eliminated duplicates and thoroughly discussed the inclusion of each information item in the 'initial pool'. In addition, each item was clearly defined to produce a glossary (Online Appendix 1). The list of items was organised following the typical structure and sections of a drug reference book. At the end of this process, the initial pool of items to be assessed in the first Delphi round included 162 information items, organised in the following 11 sections: Characteristics of the Medicinal Product (24 items), Use of the Medicinal Product (31 items), Contraindications (6 items), Adverse Reactions (23 items), Interactions (10 items), Overdose (3 items), Pharmacodynamic Properties (13 items), Pharmacokinetic Properties (41 items), Preclinical Safety Data (5 items), Evidence (2 items), and Prescription Data (4 items) (Online Appendix 1).

2.2. Selection of the Delphi panel

The Delphi technique is a consensus method based on the agreement of experts about a given subject (Linstone and Turoff, 2002). A convenience sample of experts in the area of drug information from different health care settings (hospitals, community pharmacies, and both academic and research institutions) was recruited, including as many different European countries as possible to ensure that a broad spectrum of opinions and views were explored (Keeney et al., 2001). The research team initially selected 57 professionals as experts in drug information from 23 different European countries: Austria (2), Belgium (2), Croatia (2), Czech Republic (1), Denmark (5), Finland (3), France (3), Germany (3), Greece (2), Hungary (2), Ireland (2), Italy (1), Lithuania (1), Malta (2), Netherlands (4), Poland (2), Portugal (3), Serbia (2), Slovenia (3), Spain (3), Sweden (3), Switzerland (3), and the United Kingdom (UK) (3).

Experts were invited by e-mail between October and November 2009 and only those who expressed their interest to participate were sent the questionnaire in English. Upon acceptance to participate in the study, the questionnaire in MS Microsoft Word® format was sent by e-mail, as well as a link to a web page with the glossary (containing the definitions of the items also in English) to assist with questionnaire completion. During each Delphi round, experts were asked if they considered each of the drug-related information items to be 'essential content of information'. Essential content of information was defined as: "The essential information needed for clinical practice. Items selected as being