An Educational Platform for Direct Communication between the National Competent Authority and Healthcare Professionals in Croatia

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***Abstract*—This article describes the OPeN system, a pharmacovigilance system developed by the Croatian Agency for Medicinal Products and Medical Devices, its current update, and gives insight into relevant information and the educational function of the application.**

Keywords - Education for Healthcare Professionals; Drug Safety; OPeN System; Pharmacovigilance

I. INTRODUCTION

The paper "OPeN: Linking the National Adverse Reactions Database with Clinical IT Systems in Croatia," presented at the Tenth International Conference on eHealth, Telemedicine, and Social Medicine (eTELEMED) in March 2018 in Rome, described the OPeN system, its functioning and role in the Croatian public healthcare system [1]. This paper describes the further investment of resources for the existing application and ongoing development of its informational and educational functions. Accordingly, this paper presents an update of the work presented at the eTELEMED conference. The educational module was planned as a result of Phase 3 of developing the OPeN system.

The OPeN system is a pharmacovigilance system developed by the Agency for Medicinal Products and Medical Devices of Croatia (HALMED). OPeN is an abbreviation of "online platform for electronic reporting of adverse drug reactions (ADRs)" (or in the Croatian language, *Online Platforma za elektroničku prijavu Nuspojava*). It is based on the Croatian National Adverse Reactions Database, maintained by HALMED. OPeN aims to achieve integration with the Croatian Central Health Information System (CEZIH), and which includes the exchange platform named Healthcare Networking Information System (HNIS), Electronic Healthcare Record (EHR), patient register, Register of Healthcare Professionals (HCPs), a messaging subsystem, online patient healthcare website, and specialized services related to e-prescriptions, e-laboratory referrals, e-booking for hospital admittance, and other interconnected functions [2].

Pharmacovigilance (PhV) as a discipline depends on spontaneous reporting, data mining and similar techniques, as well as direct reporting from clinical systems. Although Croatia is one of the top ten countries in the world for the number of Adverse Drug Reactions (ADRs) per million inhabitants, spontaneous reporting by HCPs and patients is generally recognized as an insufficient resource for pharmacovigilance protective mechanisms in public health [3]. The OPeN system is used for transferring PhV data to the national adverse reactions database, both Information technology (IT) solutions are complementary and are maintained by HALMED. Currently, OPeN is used by HALMED's internal experts and external HCPs. HCPs use the module to transfer PhV data whereas HALMED's staff use it for processing data.

This paper serves as a follow-up of our previously presented research. In Section II, we describe methods and functionalities of the new OPeN module. In Section III, we discuss the trustworthiness of the possible data sources on drug safety information. The goal of the new OPeN module and its key indicators are set and defined in Section IV. Finally, in Section V, we offer our conclusions related to the education of HCPs, reliable data sources and the role of national competent authorities (NCAs), which have drug marketing and post-marketing related mandate.

II. METHODS

In 2017 and 2018, HALMED developed a web-based application called OPeN with the aim of automating the reporting of ADRs by HCPs directly using proprietary IT systems at their workplaces. This simplifies the process of sending ADR data to HALMED. It also accelerates the process of assessing and processing ADR data given that ADRs are directly reported to the PhV department and do not have to pass through administrative channels prior to reaching the PhV department. As previously planned, Phase 3 of developing the OPeN system includes development of the educational module to serve as a platform for ongoing education of HCPs. The underlying idea is to offer HCPs the opportunity to learn about medicines at their workplace or home without the need to attending courses.

The module will feature a web interface with a login function requiring a user's first name, last name or medical license number and a password. Once a HCP is logged in, the OPeN system has been designed to identify them based on their license designation. A list of all active HCPs in Croatia has been integrated into OPeN and is updated every two weeks by the Croatian Institute for Public Health, which in cooperation with HALMED shares the information. The list of HCPs contains information on the HCP's first and last name, type of HCP (pharmacist, physician), specialization, and institution (including geographic data). Additional data, such as contact information is obtained from professional

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associations of pharmacists (Croatian Chamber of Pharmacists, CCPH) and physicians (Croatian Medical Chamber, CMC), which then enables HALMED to directly send links to target HCPs and referencing educational materials.

The basic workflow of the OPeN system is shown in Figure 1. After logging in, HCPs choose whether to access the ADR reporting or educational module. The educational module, which is the focus of this paper, contains webinars, surveys and questionnaires designed by HALMED's employees. Every test covers a different topic and is customized by staff from HALMED's pharmacovigilance department. Authors can choose from a number of questions in the particular test, type of questions (e.g., multiple choice, single choice, free text) with the ability to select the correct answer. In some cases, for specific safety issues, input may be sought from members of academia at the relevant faculties.

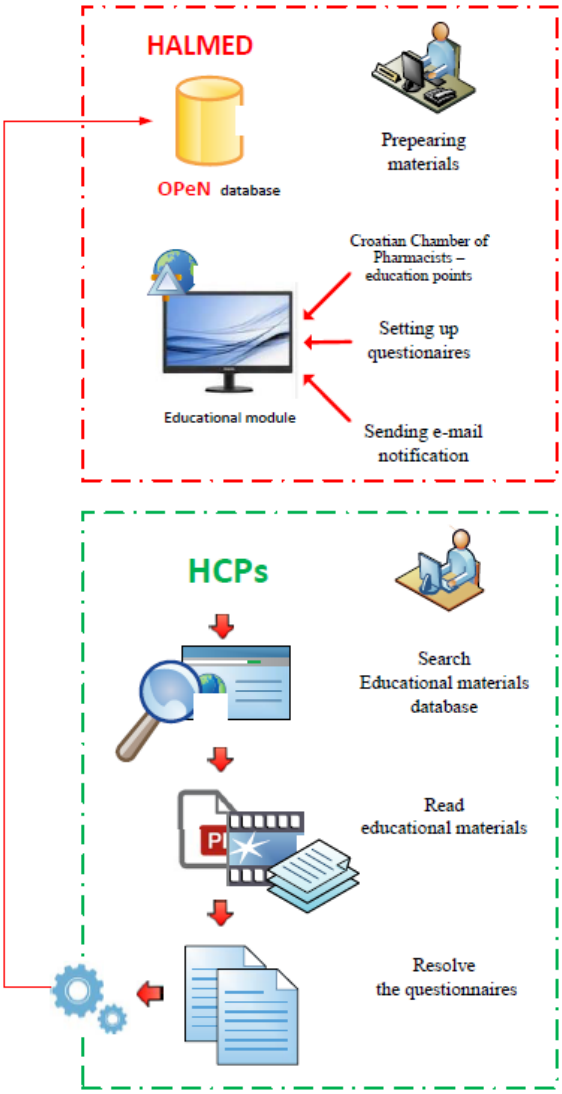

Figure 1. OPeN's educational module workflow

The involvement of academia, besides the opportunity to share their knowledge on relevant topics, additionally raises an awareness of the OPeN educational platform in an academic setting, and thus guaranteeing that future HCPs become familiar with the platform from the start of their careers. Once the test is created, a link referring to the test location is sent via e-mail to a prepared list of recipients or HCPs. The recipients are chosen based on their specialty, location or type of HCP (physicians or pharmacists). HCPs receive an e-mail with a link to the test and basic information on the topic, medicines to be covered, specific safety issues, and the like. By clicking on the link, they are directed to the OPeN educational module, more precisely, to a specific test and educational materials necessary for successful learning. Alternatively, they can log into the system and browse the educational module, without receiving a prior e-mail notification.

Every test, along with the available educational materials, is stored in the OPeN database and can be searchable by key words. Individual HCPs can view information on all available tests created by HALMED, regardless of whether they have taken the test or not. However, they can view only results from their own tests. If needed, they can retake the test any time. In certain situations, the only limited time frame given to HCPs to take the test is for particularly important safety issues requiring immediate communication and actions.

HALMED's employees have at their disposal additional functionalities, such as the ability to post various types of educational material (videos, films) to the module, and placing links to documents published on the HALMED website. The authors of the test set a threshold for passing the test, where each person that passes the test is awarded ongoing education points as a HCP. The grade system is proposed to and then agreed with the boards of HCP chambers.

HCPs will also be able to track the number of continuous education points they received on the OPeN platform, including points awarded in the ADR reporting module.

One of the main features of the OPeN education platform is the ability to analyze test results and assess the outcome of educational activities. All results can be analyzed for an individual HCP and also based on aggregated data (e.g., test results for physicians or pharmacists, specialist or non-specialists, hospitals or primary care, and other comparisons). This leads to precisely targeting knowledge gaps, better knowledge on medicines for HCPs and hopefully better patient safety.

III. DISCUSSION

Up to date, accurate and practical information is necessary in ensuring that drugs are prescribed safely and effectively. It also promotes improvements in prescribing practices, minimises harm to patients and facilitates decision making based on valid information [4]. Generally speaking, HCPs should have immediate access to high quality evidence-based

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information on medicines. This may include prescribing information or critical safety information on medicines.

HCPs have at their disposal various sources of information on medicines; however, not all sources are equally regarded as useful or relevant. There is usually the issue of credibility of the source, or updates and redundancy. Information on medicines can be communicated by different stakeholders including the pharmaceutical industry, scientists, regulators, professional chambers, learned societies, and the like. According to Molimard et al. [5], communicating information on medication often utilizes tools and messages that are not adapted to the target audience. This is further hindered due to a lack of knowledge in communication techniques and the fact that communication on safety information is subject to regulatory or legal requirements [5]. Various factors related to communication strategies, such as trust in the sender of information, may influence the acceptance of information [6].

According to a study published by Piening et al. [7], HCPs indicated that they preferred safety information to be issued by the Dutch regulatory agency (MEB), the Dutch Pharmacovigilance Center or their own professional associations via e-mails, in medical journals and using electronic prescribing systems - as the preferred channels for the distribution of information on drug safety.

The results of project SCOPE which aims to describe and improve pharmacovigilance practices in the EU indicate that current safety communication practices seemed to be broadly similar among European medicinal products regulators, i.e., NCAs [8][9]. NCA safety communication is mainly restricted to communicating safety issues directly through bulletins or newsletters and indirectly through approval and coordinating the dissemination of dear healthcare professional communication (DHPC) and educational materials [8]. DHCP and educational materials cover significant safety issues and are usually distributed by the pharmaceutical company following NCA content approval. Both communications are distributed to individual HCPs and may also be made available on the NCA website [8]. Awareness of the existence of these materials varies among HCPs in different EU member States (MSs) and even among different types of HCPs (e.g., general practitioners or cardiologists).

In Croatia, there are 3,800 active pharmacists and almost 14,500 physicians. HALMED has been actively involved in providing important safety information to HCPs at seminars, workshops and congresses, safety committee meetings as well on its website. The drawback of seminars, workshops and congresses has been the fact that they are resource intensive, whereas the difficulty in presenting information on the website is limited impact and reach based on our website analytics and metrics. In general, actions undertaken by HALMED have been somewhat restricted in terms of one-way safety communication to HCPs without the ability of measuring the impact of such activities. Upon consideration of all these factors, HALMED decided to develop an on-line platform for HCPs in order to enhance direct communication with HCPs and provide them with information on medicine-related fundamental safety issues. We are not aware that a similar platform exists in other EU member states. With regards to Croatia, there are a few educational platforms for HCPs, with “Pliva Zdravlje” being one of the most popular (https://www.plivazdravlje.hr/). This particular platform is operated by a local pharmaceutical company and covers topics relevant to physicians and pharmacist, while not necessarily related to medicines. However, some physicians view this platform as lacking credibility, something that is not be the issue with the HALMED education platform [7].

The HALMED platform is planned to be an extension of the already existing ADR reporting system for OPeN. The OPeN education module acts as an IT infrastructure providing two-way communication with HCPs. It also enables hosting of webinars, questionnaires and surveys as ongoing education on medicines for HCPs. Webinars are developed by employees at the HALMED pharmacovigilance department along with members of academia from relevant faculties. Topics covered include information on important safety issues regarding medicines such as restrictions on indications, severe adverse reactions, change to the benefit-risk ratio, and the like.

Expected benefits for HALMED include:

- Establishing closer cooperation with HCPs by providing a two-way communication platform
- Increasing the reach of safety communication on medicines
- Rationalization of internal resources
- Establishing HALMED as a trusted source of safety information
- Promoting the importance of medicine safety monitoring, including ADR reporting
- Measuring information uptake by measuring both process and knowledge indicators
- A convenient and modern education format appealing to younger HCPs
- The ability to measure demographic characteristics of respondents, establish a correlation with their knowledge in order to adapt and focus the safety message
- The ability to additionally focus on educational activities based on analysis of the results of taken tests
- Reduced administrative burdens – consecutive education points are automatically assigned to individual HCPs after completion of assignments, webinars and tests
- Increasing cooperation between HALMED and all areas of the Croatian health system, starting with academia where future HCPs receive their education and right through to professional chambers and the Institute of Public Health, thus ensuring that stakeholders cooperate on important safety issues

Expected benefits for HCPs include:

- Drug safety information provided by trusted source
- Up to date information on medicines safety

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- Convenient communication and education format – electronic communication, the ability to set MS Outlook reminders
- Convenience of receiving education at one's own pace, without physically attending courses. This is especially convenient for HCPs in remote locations, like islands or rural areas
- Customized overview of educational history
- Continuous education points

IV. RESULTS

Our aim is to establish a drug risk management system, able to face and respond to public health challenges in terms of safe drug use, with particular emphasis on issues such as antimicrobial resistance and vaccination hesitancy. With the help of HALMED's online tools, HCPs are informed about the latest safety information on safe drug use.

We have set ourselves a rather ambitious goal. In 2020 we plan to reach a minimum of 30% of all HCPs in Croatia. In 2021, our plan is to reach a minimum of 50% of all HCPs in Croatia through webinars, questionnaires and surveys using our platform. Further development of this tool will provide us with the opportunity to:

- Participate in national and international initiatives dealing with safe drug use, especially vaccine hesitancy and antimicrobial resistance
- For every additional risk minimization measure, an explanation will be provided via video or audio by a member of HALMED's PhV team
- Every emerging safety issue will incorporate a video or audio recording
- Based on our platform and authority, we will endeavor to increase vaccine coverage
- We will facilitate development of the vaccination information center on our platform
- Our platform enables us to support policies to combat antimicrobial resistance

Key performance indicators that indicate success include:

- Increased public trust in HALMED's competence
- An increase in the number of queries about safe drug use, especially vaccines and antimicrobial resistance
- Successful cooperation with national institutions and bodies, healthcare workers and patient associations
- An increased number of public campaigns with participation from HALMED, especially on issues regarding antimicrobial resistance and vaccination hesitancy

V. CONCLUSION

Development of an additional software educational module is an update and expansion of the existing OPeN system. As we had reasonably presumed based on previous cooperation with HCPs, and based on the study of Piening et al. shows, HCPs consider NCA to be a more reliable source of various material on drugs, which also includes educational material, when compared to other sources. Moreover, HCPs have begun using HALMED's online website, and are becoming acquainted with its interface and usability. HALMED has had a lot of experience in educating HCPs, and this function is derived from its mandate. Therefore, its modernization through the use of a modern portal tool, such as OPeN, was an obvious option. The expansion of the educational function of OPeN will help HALMED achieve the stated benefits and key performance indicators, take advantage of the stated opportunities and strengthen its role in the national health domain. Finally, the benefits for HCPs, in receiving a quality education in an efficient manner, will result in benefits to patients, improved patient care, and consequently, patient health.

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