دانشگاه علوم پزشکی
و خدمات بهداشتی درمانی کرمان

دانشکده بهداشت

پایان نامه مقطع دکترای تخصصی (Ph.D) رشته اپیدمیولوژی

عنوان

تحلیل نظام فارماکوویژیلانس ایران

توسط

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شماره پایان‌نامه: (۱۰/۸/۱/۷) سال تحصیلی (اسفند ۱۳۹۹)

KERMAN UNIVERSITY
OF MEDICAL SCIENCES

Faculty of Public Health

In Partial Fulfilmlment of the Requierments for the Degree of Doctor of Philosophy

Title

Evaluation of Pharmacovigilance System in Iran

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Thesis No: (10/8/1/7) Date (March, 2021)

چکیده

مقدمه و اهداف: فارماکوویژیلانس به عنوان فرآیند شناسایی و پاسخ به موضوعات ایمنی دارو تعریف شده است. ارزیابی نظام فارماکوویژیلانس به سیاست‌گذاران در شناسایی کمبودهای آن کمک نموده و می‌تواند اقدامات لازم برای اصلاح و بهبود عملکرد نظام فارماکوویژیلانس را معرفی نماید. از این رو در این مطالعه حاضر سعی گردید ابعاد مختلف نظام فارماکوویژیلانس در کشور ارزیابی شود.

روش‌ها: این پژوهش در چند بخش انجام شد؛ در مطالعه‌ای آینده‌نگر در دو بیمارستان در شهرهای رشت و کرمان بروز عوارض ناخواسته دارویی (ADR) برآورد شد. روند گزارش‌های ADR در بازه زمانی ۱۹ ساله بررسی و کم‌گزارش‌دهی با سه روش مطالعه آینده‌نگر، بررسی متون و طبقه‌بندی کشور تخمین زده شد. وضعیت فارماکوویژیلانس در ایران با استفاده از شاخص‌های سازمان جهانی بهداشت در چهار سطح ساختار، فرآیند، تأثیر و در برنامه‌های بهداشت عمومی ارزیابی شد. دو پژوهش کیفی به صورت مصاحبه نیمه‌ساختار یافته با کادر درمان و خبرگان برای تبیین درک کادر درمان از نظام فارماکوویژیلانس، شناسایی موانع گزارش‌دهی ADR و تبیین وضعیت و ویژگی‌های نظام فارماکوویژیلانس کشور اجرا گردید. یک مطالعه مرور دامنه(scoping review) برای شناسایی مداخلات ارتقادهنده گزارش‌دهی بر اساس چارچوب روش‌شناختی آرکسی انجام گرفت. در نهایت با استفاده از تحلیل SWOT (قوت‌ها، ضعف‌ها، فرصت‌ها و تهدیدها) راهبردهایی برای ارتقا نظام فارماکوویژیلانس ارائه گردید.

یافته‌ها: بروز ADR ۸۴۴/۸ در صد هزار بستری (۹۵% CI: ۶۹۷/۹-۱۰۱۳/۲) برآورد شد. روند گزارش‌دهی در سال‌های ۱۳۷۸ تا ۱۳۹۶ صعودی و میانه برآوردهای کم‌گزارش‌دهی در ایران ۷۶ درصد بود. ارزیابی برنامه فارماکوویژیلانس نشان داد که ایمنی داروها توسط مرکز ADR مورد پایش قرار می‌گیرد و این مرکز پرسنل آموزش‌دیده، بودجه و سیاست ملی برای انجام فعالیت‌های فارماکوویژیلانس دارا می‌باشد. در سال ۱۳۹۶ تعداد گزارش‌های ADR ۱۵ در صد هزار نفر جمعیت بود. ارزیابی علیتی، شناسایی سیگنال و اقدامات نظارتی در این برنامه انجام می‌شود و شرکت‌های دارویی ملزم به انجام فعالیت‌های فارماکوویژیلانس هستند. تعداد بستری‌ها و مرگ‌های بیمارستانی ناشی از داروها و وضعیت فعالیت‌های فارماکوویژیلانس در برنامه‌های

بهداشت عمومی قابل بررسی نبود. هزینه‌ها و مدت زمان بستری بیمارستانی مرتبط با دارو نسبتاً زیاد بود. دانش و آگاهی کادر درمان در زمینه شناسایی و گزارش‌دهی ADR مطلوب نبود. ضعف در فرآیند گزارش‌دهی، عدم آگاهی، محیط کاری و خصوصیات فردی از موانع اصلی در گزارش‌دهی ADR بودند. از دیدگاه خبرگان نواقص گسترده‌ای در ساختار، زیرساخت‌ها و امکانات، فرآیند گزارش‌دهی، همکاری‌های بین بخشی، جلب مشارکت کادر درمان و شرکت‌های دارویی، نظارت و پیگیری، ارزیابی و تحلیل گزارش‌ها و عملکرد وجود دارد. استراتژی هایی برای ارتقا ساختار برنامه، فرآیند گزارش‌دهی و همچنین بهبود اثرات و عملکرد برنامه فارماکوویژیلانس پیشنهاد شدند. ضمن اینکه مداخلاتی همچون آموزش، پایش فعال و ثبت کامپیوتری گزارش‌ها و مشوق‌های مالی می‌توانند در ارتقای گزارش‌دهی ADR مؤثر باشند.

بحث و نتیجه‌گیری: این مطالعه نیاز اساسی برای تقویت نظام فارماکوویژیلانس ایران را نشان داده است. نظام فارماکوویژیلانس می‌تواند با تسهیل فرآیند گزارش‌دهی، آموزش و اطلاع‌رسانی، افزایش همکاری های بین‌بخشی و جمع‌آوری داده‌های ایمنی از منابع مختلف نسبت به وضعیت داروها و عوامل خطر مطلع شود و اقدامات لازم و به موقع برای حفظ ایمنی بیماران و کاهش خطر را انجام دهد. مشارکت کادر بهداشتی و درمانی، شرکت های دارویی، دانشگاه های علوم پزشکی، پژوهشگران و عموم مردم در گزارش‌دهی و فعالیت‌های فارماکوویژیلانس به سلامت عمومی و بهبود ایمنی در مصرف داروها کمک خواهد نمود.

واژگان کلیدی: فارماکوویژیلانس، نظام های گزارش‌دهی عوارض ناخواسته دارویی، عوارض جانبی و واکنش‌های ناخواسته مرتبط با دارو، گزارش‌دهی داوطلبانه رخداد ایمنی بیمار

Abstract

Introduction and Objectives: Pharmacovigilance has been defined as the process of identifying and responding to drug safety issues. Evaluating the pharmacovigilance system helps policymakers identify its deficiencies and recommends measures to remedy and improve the pharmacovigilance system's function. Therefore, different aspects of the Iranian pharmacovigilance system were evaluated in the present study.

Methods: This study was conducted in several parts; The incidence of adverse drug reaction (ADR) was estimated in prospective studies in two hospitals in Rasht and Kerman. The ADR reports trend was assessed over 19 years, and three methods, i.e., prospective study, literature review, and country's stratification, estimated its underreporting. The status of pharmacovigilance in Iran was evaluated using WHO pharmacovigilance indicators in four categories: structure, processes, outcomes, and pharmacovigilance in the Iranian public health programs. Two qualitative studies were carried out. Semi-structured interviews were conducted with healthcare professionals and experts to understanding their view of the pharmacovigilance system and identify the barriers to ADR reporting and explain the Iranian pharmacovigilance system's status. According to Arksey and O'Malley's methodological framework, a scoping review was conducted to identify interventions that improve ADR reporting. Finally, strategies to strengthen the pharmacovigilance system were presented using SWOT (strengths, weaknesses, opportunities, and threats) analysis.

Results: ADR incidence was 844.8 per 100 000 admissions (95% CI: 697.9-1013.2). The ADR reporting trend increased from 1999 to 2017, and the median of estimated percentages of

underreporting was 76.0%. The pharmacovigilance program's evaluation also showed that drug safety is monitored by the Iran ADR Center and has a national policy, trained staff, and a statutory budget. In 2017, the number of ADR reports was 15 .0 per 100 000 population. Causality assessment, signal detection, and regulatory actions are performed in this program, and pharmaceutical companies are required to administrate pharmacovigilance activities. Moreover, the number of hospital admissions and deaths due to drug reactions and the status of pharmacovigilance activities in public health programs could not be assessed. The length and cost of hospitalization related to drugs were relatively high. The knowledge and awareness of healthcare professionals about ADR identification and reporting were not desirable. Weakness in the reporting process, lack of knowledge, work environment status, and personal characteristics were the main obstacles in ADR reporting. From the experts' point of view, there are widespread shortcomings in the structure, infrastructure, facilities, reporting process, cross-sectoral cooperation, the involvement of healthcare professionals and pharmaceutical companies, monitoring and follow-up, evaluation and analysis of reports and performance. Strategies were suggested to improve the program's structure and reporting process and promote the pharmacovigilance program's impact and outcome. Besides, interventions such as education, active monitoring, and computerized reporting registration and financial incentives could help amend ADR reporting.

Conclusion: This study has shown a crucial need to strengthen the pharmacovigilance system in Iran. The pharmacovigilance system can be informed about the status of drugs and risk factors in society by facilitating the reporting process, training and noticing, increasing inter-sectoral collaborations,

and collecting safety data from various sources. It should take necessary and timely measures to sustain patient's safety and risk minimization. Participation of healthcare professionals, pharmaceutical companies, medical sciences universities, researchers, and the general public in reporting and pharmacovigilance activities will contribute to public health and improve drug usage safety.

Keyword: Pharmacovigilance, Adverse Drug Reaction Reporting Systems, Drug-Related Side Effects and Adverse Reactions, Voluntary Patient Safety Event Reporting

فهرست مندرجات

فصل دهم: نتیجه‌گیری

فهرست جداول

فهرست نمودارها

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فهرست منابع:

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بسمه تعالی

تاریخ ۹۷/۲/۲۶

شماره ۱۰/۸/۱/۷

پیوست .....

صورتجلسه دفاع از پایان نامه

دانشگاه علوم پزشکی کرمان

مدیریت تحصیلات تکمیلی دانشگاه

جلسه دفاعیه پایان نامه تحصیلی خانم ملاحت خلیلی کیسمی دانشجوی دکتری تخصصی (Ph.D) رشته اپیدمیولوژی دانشکده بهداشت دانشگاه علوم پزشکی کرمان تحت عنوان " تحلیل نظام فارماکوویژیلانس ایران" در ساعت ۷:۳۰ روز دو شنبه مورخ ۹۹/۱۲/۱۱ با حضور اعضای محترم هیات داوران به شرح ذیل:

سمت	نام و نام خانوادگی	امضا
الف:استاد(ان) راهنما	آقای دکتر علی اکبر حقدوست آقای دکتر حمید شریفی	
ب: استاد(ان) مشاور	خانم دکتر بیتا مسگرپور خانم دکتر مهرناز خیراندیش	۱۱ اسفند ۹۹
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ج: عضو هیات داوران (داخلی)	خانم دکتر آرمیتا شاه اسماعیلی	
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ه :نماینده تحصیلات تکمیلی	آقای دکتر حمیدرضا توحیدی نیک	

تشکیل گردید و ضمن ارزیابی به شرح پیوست با درجه عالی و نمره ۱۹,۹۸ مورد تأیید قرار گرفت.

مهر و امضاء معاون آموزشی

۱۴۰۰-۱-۱۴