FZZ-P16 STANDARDNA OPERATIVNA PROCEDURA ZA PRUŽANJE INFORMACIJA O LEKOVIMA I MEDICINSKIM SREDSTVIMA U AMBULANTNOJ PRAKSI

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Zdravstveni radnici, a posebno farmaceuti, pružaju informacije o lekovima i medicinskim sredstvima pacijentima i drugim zdravstvenim radnicima. Standardna operativna procedura (SOP) je razvijena sa ciljem da se informacije pružaju na jedinstven i dosledan način u Domu zdravlja „Novi Sad".

Razvoj procedure se bazirao na analizi postojećih radnih procesa, nacionalnih propisa i stručnih smernica. Definisane su aktivnosti, odgovornosti zaposlenih, obrasci za evidenciju, indikatori kvaliteta, te način periodične revizije. Aktivnosti uključuju prijem, evidentiranje, i klasifikaciju upita prema vrsti, hitnosti i složenosti; prikupljanje relevantnih podataka o pacijentu ili zdravstvenom problem; pretragu i kritičku procenu referentnih izvora; kao i formulisanje odgovora prilagođenog potrebama podnosioca. Kao referentni izvori koriste se sažeci karakteristika lekova, uputstva za lekove i medicinska sredstva, vodiči dobre kliničke prakse, stručna literatura, regulatorni dokumenti i baze podataka (npr. PubMed, Cochrane Library). Indikatori kvaliteta su broj upita, vreme odgovora, eventualne primedbe podnosioca, i doslednost evidentiranja. SOP predviđa i edukaciju zaposlenih, praćenje primene kroz interne provere, kao i sprovođenje periodičnih revizija u skladu sa regulatornim i stručnim promenama. Ukoliko se tokom obrade upita posumnja na neželjenu reakciju, neefikasnost leka ili neispravnost medicinskog sredstva, predviđeno je njihovo prijavljivanje odgovornim licima za farmakovigilancu odnosno vigilancu.

Očekuje se da primena procedure doprinese unapređenju kvaliteta pruženih informacija, jačanju sistema (farmako)vigilance i povećanju bezbednosti pacijenata u ambulantnoj praksi.

FZZ-P16 STANDARD OPERATING PROCEDURE FOR PROVIDING INFORMATION ON MEDICINES AND MEDICAL DEVICES IN AMBULATORY PRACTICE

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Healthcare professionals, especially pharmacists, provide information on medicines and medical devices to patients and other healthcare professionals. A Standard Operating Procedure (SOP) was developed with the aim of providing information in a uniform and consistent manner at the Health Center "Novi Sad".

The development of the procedure was based on an analysis of existing work processes, national regulations, and professional guidelines. It defined activities, employee responsibilities, documentation forms, quality indicators, and the method for periodic review. The activities include receiving, recording, and classifying enquires by type, urgency, and complexity; gathering relevant data on the patient or health problem; searching and critically appraising reference sources; and formulating a response tailored to the enquirer's needs. Summaries of product characteristics, package leaflets for medicines and medical devices, good clinical practice guidelines, professional literature, regulatory documents, and databases (e.g., PubMed, Cochrane Library) are used as reference sources. Quality indicators are number of enquiries, response time, potential complaints from the enquirer, and consistency of documentation. The SOP also provides for employee training, monitoring implementation through internal audits, and conducting periodic reviews in accordance with regulatory and professional changes. If an adverse drug reaction, lack of efficacy, or medical device defect is suspected during the processing of an enquiry, reporting to the personnel responsible for pharmacovigilance or vigilance is provided.

The implementation of the procedure is expected to contribute to improving the quality of the provided information, strengthening the (pharmaco)vigilance system, and increasing patient safety in ambulatory practice.