National pharmacy practice standards and evidence based guidelines in pharmaceutical care; development and methodology in Hungary

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Background
Country-specific pharmacy practice standards based on Good Pharmacy Practice (FIP) provide the professional background and framework for high quality pharmacy services. Evidence based clinical guidelines are defined as systematic statements developed to assist decisions by health care providers on appropriate healthcare for specific pathological conditions. The development of standards and evidence-based guidelines in pharmaceutical care is essential in order to ensure patient safety and also cost-effective pharmacy-management practice.

Aim
To give an overview about the method development, in order to form standards, and evidence-based guidelines in the field of pharmaceutical care.

Method
A careful combination of the GPP and the country-specific environment was the first step of standard development; followed by an extensive consultation with pharmacy organisations and practitioners, mapping the critical points regarding pharmaceutical care process. „Swiss cheese model” was used to reveal the patients safety risk points of the process. Finally, the main domains of standards were determined by root cause analysis (RCA). Guidelines’ topics were selected regarding the prevalence of health care conditions present in the community pharmacy. The classic process of guideline development, consistent with AGREE criteria were followed. Where external evidence based pharmaceutical care guidelines were available, adaptation was preferred after critical appraisal. Development process in lack of external guidelines was based on the systematic literature searching method in order to find the available evidences. Standards and guidelines were reviewed by a multidisciplinary expert group and refined by a “pilot study” before release.

Results
According to the results of RCA, pharmaceutical practice standards were formulated on 12 domains. These are in accordance with FIP/GPP recommendation. Guidelines (16) were developed for the most common cases of self medication (common cold, acne, low-back-pain, allergic rhinitis, GERD) and for common public health problems (metabolic disorders, asthma, COPD, BPH). Safe medication in pregnancy and in geriatrics were among the selected topics as well. The structured questions in the evidence–based pharmaceutical care guidelines developed by our expert team focus on the following fields: (1) the patient asking for an OTC (self medication) or the patient brings a prescription; (2) adequate and safe use of medicine; (3) improve the adherence of patients; (4) need for referral.
Unfortunately, only a few external evidence-based pharmaceutical care guidelines were found in the literature, therefore recommendations from medical guidelines were adapted in many cases.

**Conclusion**
The adaptation of the evidence-based guideline development into the field of pharmaceutical care was aggravated by numerous methodological issues.