

Identifying over-the-counter high-risk medications: development of a national high-risk medication list

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1. Introduction

High-risk (high-alert) medications bear a risk of causing significant patient harm when used erroneously (1). However, the current literature on high-risk medications mainly concerns prescription medications.

Although over-the-counter (OTC) medicines are considered to be relatively safe, others can cause significant harm (e.g. ASA, paracetamol) (2, 3). In addition, some patient groups, such as elderly patients and patients with chronic conditions, may be more prone to harm.

Furthermore, some prescription medicines can be affected by drug-drug interactions with OTC-medication resulting in grave consequences.

According to our knowledge high-risk medication lists for OTC medication have not yet been introduced in Finland or other countries.

2. Aims

To develop a national OTC high-risk medication list which includes a check list of key safety risks and actions for identifying patients at risk in community pharmacies.

3. Method

International and national literature on medicines information on, and risks associated with, OTC-medicines were reviewed.

Based on the identified literature material and experiences from developing high-risk medication lists for hospitals, a national OTC high-risk medication list comprising a check list for identifying patients at risk was developed by a group of national medication safety experts in spring 2017.

5. Conclusion

Our project represents international pioneering work in the field of OTC medication safety. Educational material for pharmacies will be developed to facilitate the implementation of the use of the list in community pharmacies.

The work will continue by expanding the list to cover also high-risk medications during pregnancy and medicines associated with misuse and abuse potential.

References

- Institute for Safe Medication Practices (ISMP). ISMP list of high-alert medications in community / ambulatory healthcare. 2011.
- National program for over-the-counter medication. Finnish Medicines Agency (Fimea) Publications 1/2015.
- Saedder EA ym. (2014): Identifying high-risk medication: a systematic literature review. Eur J Clin Pharmacol 70: 637-45.

4. Results

An OTC-medication high-risk list was developed and will be available in community pharmacies (Table 1).

The list includes the identified high-risk OTC-medicines, potential consequences when these medicines are used in error, conditions and patients with increased risk, and a set of questions to identify risk patients.

Table 1: Over-the-counter high-risk medications

OVER-THE-COUNTER HIGH-RISK MEDICATIONS				2017
Substance	Main risks and other aspects to consider:	Consequences:	Patients at risk and risk conditions:	Discuss with the patient:
Acetylsalicylic acid (ASA): analgesic and composite products (≥ 300 mg)	Main risks: ◦ Combination with other anticoagulative medications ◦ Combination with medications increasing risk of haemorrhage (other NSAIDs, corticosteroids, SSRI and SNRI medications)	→ Haemorrhage → Gastrointestinal haemorrhage	Patients at risk: ◦ Elderly (> 65 years) ◦ Children (< 16 years) ◦ Pregnant women (particularly first and last trimester)	Ask: ◦ Who is the user of the medication? ◦ Do you have any chronic diseases (particularly diseases affecting the kidneys or heart, or asthma) or regular medications (particularly anticoagulants)? ◦ Do you have any allergies to medication?
Acetylsalicylic acid (ASA): antithrombotic products (50-250 mg)	◦ Pre- or post-operative use of ASA (incl. dental surgery) ◦ Pre- and post-operative interruption of antithrombotic ASA and initiation after the procedure (according to physicians instructions) Other aspects to consider: ◦ Interactions with antihypertensive and cardiac insufficiency medications ◦ Interaction with lithium ◦ Allergic reactions and hypersensitivity (i.e. asthmatics) ◦ Not to be used for children in viral infections	→ Haemorrhage → Haemorrhage, thrombosis → Decreased efficacy of other medications → Increased efficacy of lithium → Dyspnoea → Increased risk of Reye's syndrome	Risk conditions: ◦ Renal, hepatic or cardiac insufficiency ◦ Haemorrhagic diseases ◦ Cardiovascular diseases (hypertension, hypercholesterolaemia, diabetes, smoking) (ASA ≥ 300 mg) ◦ Asthma (10-20 % of asthmatics are hypersensitive) ◦ Gout	◦ Have you had a gastric ulcer or any gastrointestinal bleeding? Do you suffer from heartburn? Antithrombotic products: ◦ Has the medication been prescribed by a physician? Recommend: ◦ Do not use ASA simultaneously with other NSAIDs. ◦ ASA is not recommended for treatment of pain or fever in children. ◦ Antithrombotic ASA should be administered 2 h before other NSAIDs (if concomitant use is necessary).
Ibuprofen, ketoprofen, naproxen	Main risks: ◦ Combination with anticoagulative medications ◦ Combination with haemorrhage increasing medications (ASA, other NSAIDs, corticosteroids, SSRI and SNRI medications)	→ Haemorrhage → Gastrointestinal haemorrhage	Patients at risk: ◦ Elderly (> 65 years) ◦ Pregnant women (particularly first and last trimester) Risk conditions: ◦ Renal, hepatic or cardiac insufficiency ◦ Haemorrhagic diseases ◦ Gastric ulcer or gastrointestinal haemorrhage ◦ Cardiovascular diseases (hypertension, hypercholesterolaemia, diabetes, smoking) (ASA ≥ 300 mg) ◦ Asthma (10-20 % of asthmatics are hypersensitive)	Ask: ◦ Who is the user of the medication? ◦ Do you have any chronic diseases (particularly diseases affecting the kidneys or heart, or asthma) or regular medications (particularly anticoagulants)? ◦ Do you have any allergies to medication? ◦ Have you had a gastric ulcer or any gastrointestinal bleeding? Do you suffer from heartburn? Recommend: ◦ Ibuprofen is the most recommended of the OTC-NSAIDs. ◦ Do not use one NSAID simultaneously with other NSAID. ◦ Explain the dosing and measuring of oral liquid solutions for children. ◦ Antithrombotic ASA should be administered 2 h before other NSAIDs.
Paracetamol / acetaminophen	Main risks: ◦ Overdose ◦ Simultaneous use of several paracetamol products ◦ Simultaneous excessive alcohol consumption ◦ Simultaneous use with warfarin (paracetamol dosage > 2 g/day)	→ Hepatic toxicity → Haemorrhage	Patients at risk: ◦ Alcoholics / patients with high alcohol consumption Risk conditions: ◦ Chronic pain (simultaneous use of several analgesics containing paracetamol) ◦ Epilepsy	Ask: ◦ Who is the user of the medication? ◦ Do you have any chronic diseases or regular medications? Recommend: ◦ Do not exceed the recommended daily dose. ◦ Do not use with alcohol. ◦ Explain the dosing and measuring of oral liquid solutions for children.
Potassium chloride	Main risks: ◦ Severe renal insufficiency ◦ Simultaneous use with potassium-sparing diuretics Other aspects to consider: ◦ Irritating for mucosa ◦ Simultaneous use with ACE-inhibitors and ATR-blockers in patients suffering from renal disease	→ Hyperkalemia (cardiac arrhythmia, neuro-muscular symptoms) → Mucosal damages → Mild hyperkalemia	Patients at risk: ◦ Elderly (> 65 years) Risk conditions: ◦ Renal insufficiency ◦ Heart diseases ◦ Diabetes ◦ Stenosis oesophagi	Ask: ◦ Who is the user of the medication? ◦ Has the medication been prescribed by a physician? ◦ Do you have any chronic diseases or regular medications? Recommend: ◦ Swallow the tablet whole, take it with meals or with a full glass of water or other liquid. Do not take immediately before going to bed or lying down. ◦ Regular measurements for blood potassium levels are important.

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