Creation of a better medication safety culture in Europe: building up safe medication practices

Recommendations of the Council of Europe Expert Group on Safe Medication Practices
Plan

- Initiatives for safer medication practices in Europe
- Impact of INNs on medication errors prevention
- Still room for improving the safety of INNs
Council of Europe initiatives for improving patient and medication safety

- **20-22 October 1999** - pan-European Seminar Strasbourg
  “The pharmacist at the crossroads of new health risks: an indispensable partner for their management”

- **21 March 2001** - Council of Europe Resolution ResAP(2001)2 of the Committee of Ministers concerning the pharmacist’s role in the framework of health security

- **21–22 November 2002** - Council of Europe Expert Meeting
  Medication safety Den Haag, The Netherlands

- **November 2002** - Establishment of the Committee of Experts on Management of Safety and Quality in Health Care by the Public Health Committee

- **April 2003** - Establishment of the Expert Group on Safe Medication Practices by the Committee of Experts on Pharmaceutical Questions

- **24 May 2006** - Council of Europe Recommendation Rec(2006)7 of the Committee of Ministers to member states on management of patient safety and prevention of adverse events in health care

- **19 March 2007** - Launch of the report of the Expert Group on Safe Medication Practices on the website of the Council of Europe in a preliminarily version
Promoting safer medication practices in Europe

- **European Union:**
  - Project SIMPATIE “Safety Improvement For Patients In Europe”
  - Luxembourg Declaration on Patient Safety (5 April 2005)
  - No safe medication practice initiatives announced

- **Council of Europe:**
  - Strong cooperation between the Committee of Experts on Management of Safety and Quality in Health Care and the Expert Group on Safe Medication Practices
  - Adoption of common glossary of terms related to patient and medication safety
  - “Medication safety, a specific strategy to promote patient safety” is a full part of the Recommendation Rec(2006)7: Appendix E
Report structure

- **Introduction**: scope of the report
- **Chapter I**: how to prevent errors by learning from medication errors
- **Chapter II**: how to measure and evaluate medication safety
- **Chapter III**: how the design of medicine products used in Europe can be developed to improve the safety of these products in use
- **Chapter IV**: methods for improving safe medication practices
- **Chapter V**: how drug information practices contribute to medication safety
INN impact on preventing medication errors

- INNs: basically designed for patient safety
- Safe medication practices recommendations based on INNs use
- Use of INNs for safer labelling and packaging of European medicines
INN built-in safety

- A unique name globally recognised allows:
  - the identification of medicines,
  - the communication and exchange of information

- In-use safety based on several principles involving human and cognitive factors:
  - standardisation,
  - simplification,
  - understanding of a similar therapeutic activity, a specific mode of action or a chemical or biochemical feature on the basis of a common stem.,
  - differentiation for improving communication, etc.

- mitigating factor when medication errors occur
Promoting the use in practice of INNs instead of trademark names

- Overdosing due to the use of several trademark names for the same active pharmaceutical substance
- Health professionals: the use of INNs reduces knowledge-based errors and memory failures
- Patients understanding of INNs help them to:
  - recognise a dispensing or administration error
  - inform health professionals about their treatment
- Need for helping patients and health care practitioners to understand and use INNs, instead of relying only on trademarks
The Medicines in Europe Forum campaign

1. The INN is clearer and less confusing
   Nicole would like to understand the INN system
2. Using INN reduces the risk of overdose
   Three doses of the same drug: too much for Julieta!
3. The INN: one drug, one name, everywhere in the world
   A holiday trip ends in hospital
4. Placing INN on drug packaging reduces the risk of error
   The INN on drug packaging: practical and safe!
5. The INN system helps patients to avoid side effects
   Avoiding rechallenge with a contraindicated drug
6. Using INN reduces the risk of confusion
   Fewer drugs make for a safer home medicine cabinet
7. The INN helps to prevent allergic drug reactions
   Leo’s spots: due to a drug
8. Identifying the INN on drug packaging
   Ask your pharmacist to highlight the INN on your medication packaging
9. The INN is a drug’s true name, a generic is a copy of drug
   The generic name is not the same as the INN
10. The INN is the only reliable way of identifying a drug
    Starting treatment without delay
11. Non informative brand names sometimes hide combinations of several drugs
    With the INN system you know exactly what drug(s) you’re taking!
Safe medication practices
INN related recommendations

- Providing the INNs on all medication orders/prescriptions
- Considering the possibility of name confusion when new medicinal products are added to the own or collective medicines formulary
- Ensuring the widespread use of INNs by educational programmes
- Verifying the prescription medicine in front of the patient, spelling INNs
- Highlighting systematically the INN on the drug packaging or on the dispensing label
- Encouraging the reporting of errors and potential look and sound-alike medicinal product names
Better use of INN for improving the safety of European medicines

European Medicines Agency, National Medicines Agencies and other related stakeholders are recommended:

- to update the national and European legislative framework in order to require complete and unambiguous labelling of every single unit of use of all licensed medicines products (e.g. tablet, vial and nebules), including the INN,
- to require design features for packaging and labelling of medicine products including prominent positioning of the INN,
- to require the pharmacists dispensing medicines for ambulatory patients to put a dispensing label on the medicine package when it is dispensed, and the drug companies to allocate space for a dispensing label with mention of the INN.
Still room for improving the safety of INNs

- LASA medication errors related to INNs
- Better designing medicines names for safety
- Learning from medication errors
- Improving cooperation for safer INNs
Unsafe INNs

- Less reported confusions between INNs than with trademarks, but high mix-ups recurrence related to error-prone INNs.
- Focus on high risk active substances
  - vincristine # vinblastine
  - daunorubicin # doxorubicin, etc.
- Case studies on current acute problems:
  - hydromorphone # morphine (USA, Canada)
  - epinephrine # ephedrine
  - adrenaline # atropine

*adrenaline (epinephrine)*
Managing confusions error risks

- As an additional safety barrier, using both the INN and the trademark name on prescriptions is recommended in case of medicines with a high risk of confusion errors (redundancy control);
- Generating computerised reminders and alerts when prescriptions for error-prone medicines are issued;
- Highlighting the parts of the names that are different in bold, colour, and/or capital letters (“tall man” lettering e.g. doBUTamine, doPAmine; ePHEDrine, EPINEPHrine; hydrOXYzine, hydrLAzine);
- Separating at risk products in storage areas in the pharmacy as well as in patient care areas. Warning professionals of the risk of confusion with stickers; etc.
Designing medicines names for safety

European Medicines Agency, National Medicines Agencies and other related stakeholders are recommended to establish standardised procedures for assessing the risks of all proposed trademark names including:

- a risk assessment and evaluation by the manufacturers, for possible sound- or look-alike confusion with existing marketed medicines, including user testing
- a review of the risks of proposed trademark names by the medicine agencies as a part of the normal marketing authorisation application
- publication of official assessment criteria for trademark names

Checking the lack of potential confusion between new INN applications and existing medicine names by consulting various databases is not enough:

- systematic comments of proposed INNs during the 4 month objection period should be stimulated, at least by the National Centres on Safe Medication Practices
- risk assessment techniques similar to methods used to assess medicines trade names should be applied by the WHO INN Programme and national nomenclature committees
- at risk INNs safety review should be processed by health care practitioners and patients
Learning from medication errors

European Healthcare Organisations and other related stakeholders are recommended to:

- establish **medication error reporting systems (MERS)** including primary care as well as hospital settings at local, national and European levels.
- delegate the responsibility for the management of local medication use systems in both primary and secondary care to **multidisciplinary safe medication practices committees**.
- establish a recognised **national focal point for safe medication practices**, in a collaborative and complementary way with pharmacovigilance systems.
European Health Authorities should:

- build a **European network of national MERS**:
  - mandate the co-ordination between MERS to a permanent network pertaining to the Council of Europe, further as a structure belonging to the European Directorate of the Quality of Medicines;

- ensure that all **medication error reports** related to its relevant missions, such as naming, labelling, packaging, advertising of medicinal products, are **shared with the European Medicine Agency and national regulatory agencies**;

- ensure that all medication error reports related to the recommended International Nonproprietary Names (INN) are shared with the World Health Organisation (WHO) **INN Programme**.
Networking for safer INNs

- The Council of Europe pragmatic approach: a Network of European National Safe Medication Practice Centres