Drug distribution in hospitals and barcoding

The needs of traceability of medicines in hospitals

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Conflict of interest

Nothing to disclose

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Agenda

- Definitions
- Medication process in hospitals
- Medication safety, single unit and traceability
- Brief history of EAHP activities
- The EAHP statement on barcoding
- Why bar coded single unit in hospitals
- The EAHP survey 2010 on barcoding use in hospitals

Definitions
(as agreed with GS1)

- **Multiple units blister/packages**

• Package which fully encloses the drug

• Each dosage form may be individually packaged. The individually blistered identical dosage forms are attached to each other to one strip.

• The labeling is imprinted on the complete strip but not on the individual blistered dosage forms

Definitions
(as agreed with GS1)

- **Unit dose package**
  - A unit dose package contains the particular dose of the drug for **a specific patient** according to the patient-specific prescription.
  - Unit-dose packages are dispensed for one or several days by a centralized supply service unit and are labelled specifically for a patient.

Definitions

(as agreed with GS1)

- **Single unit blister package**
  - (GS1 primary package) is the one that contains one discrete pharmaceutical dosage form. i.e. a tablet, a certain volume of a liquid or that is the immediate package for a medical device like a syringe. A number of single units might be attached to each other, but are easy to separate through a perforation.
  - **Each single-unit is individually and fully labelled.**

Medicines in the community pharmacy

Marketing Company

Distributor

Pharmacists

Patient

Verification of authenticity

Medication errors and patient safety

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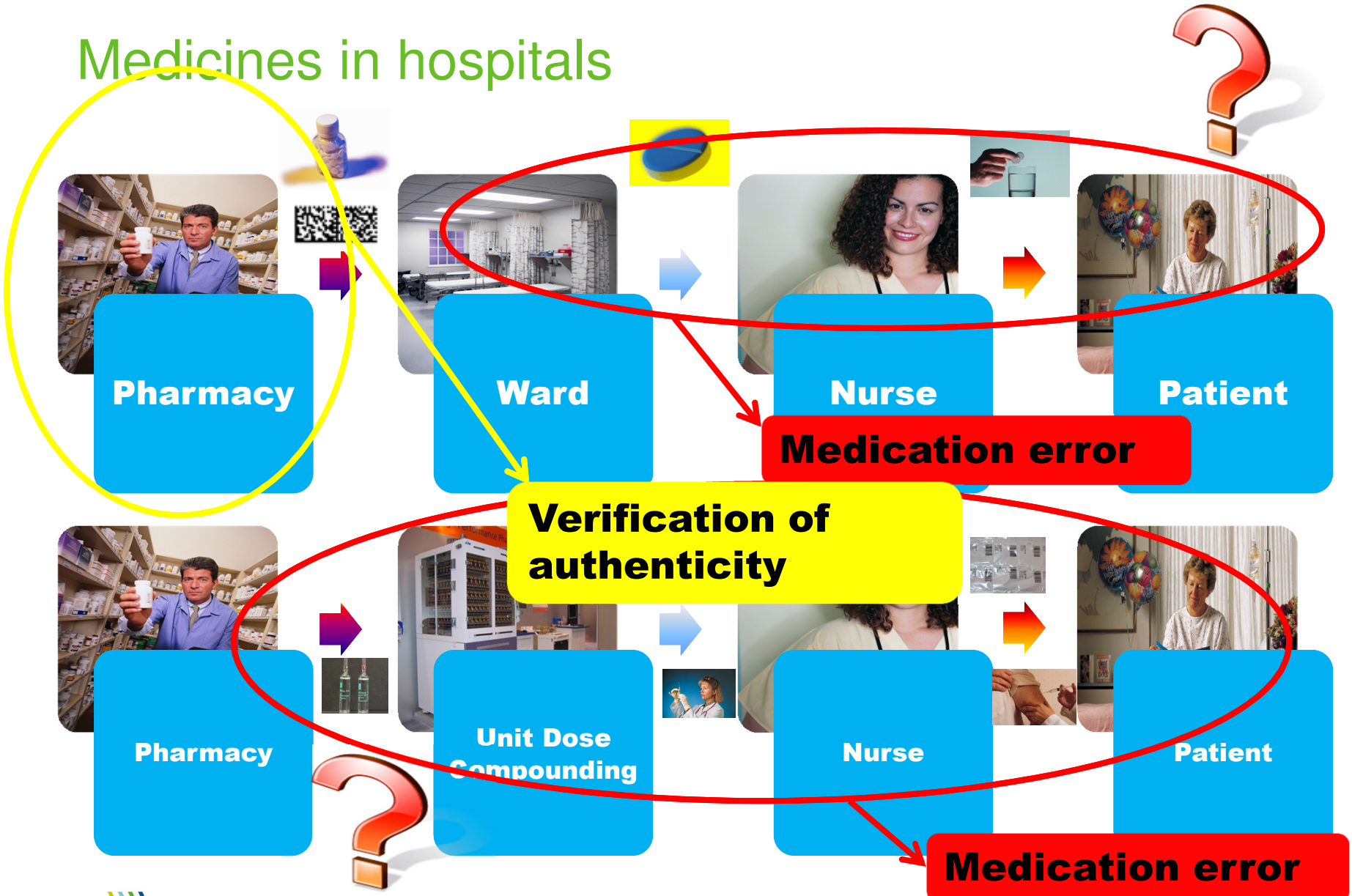
Medicines in hospitals



Track and Trace ⇔ Patient Safety

- Two aspects of the same problem with synergistic common interests
- The major interest of EAHP is on medication safety in the hospital setting
- By now counterfeited medicines only of less importance in hospitals but an increasing problem

History

- The General Assembly (GA) in June 2006 decided to ask the board of directors to promote single units for medicines used in hospitals
- ⇨ Working group
  - Prof. Pascal Bonnabry, Switzerland
  - Dr. Steffen Amman, Germany
  - Sophie Verbeke, Belgium
  - Dr. Roberto Frontini, Germany
- Statement of EAHP after approval by the GA in June 2007, update in **2010**
- Press release in April 2008 on the importance of single units in terms of patient safety

Statement by EAHP update 2010

Information on the single units

- The printing must be easy to read, durable and clear.
- Each single dose (unit) must contain the:
  - *trade name*
  - *application form*
  - *active substance(s)*
  - *quantity of active substance(s) ,*
  - *manufacturer's name*
  - *expiry date*
  - *batch number*
  - **barcode** including the identification of the drug (**GTIN**), the expiry date and the batch number.
    When the production facility is incompatible with an on-line printing of variable data, the barcode can **temporarily** be **limited to the identification of the drug**
  - **No serial number requested on the unit**

Statement by EAHP update 2010

- Hospital pharmacists strongly recommend the use of a **recognized international standard, like the GS1** (ex- EAN) identification system for bar codes.
- The **GS1-128 (ex- EAN-128) standard appears to be the best standard for the traceability of single dose units.**
- Taking into account the problem of the available space, we recommend printing it as a bi- dimensional barcode (i.e. **datamatrix**).

- For ampoules and vials, the same information should be provided on a label (not engraved on the glass), with additional information regarding the
- Total amount and volume (x mg = y ml) and the concentration of the solution (z mg/ml).

Why bar coded single units in hospitals

Medication errors*

39% 12% **11%** **38%**

* Leape LL, Bates DW, et al. JAMA. 1995 Jul 5;274(1):35-43

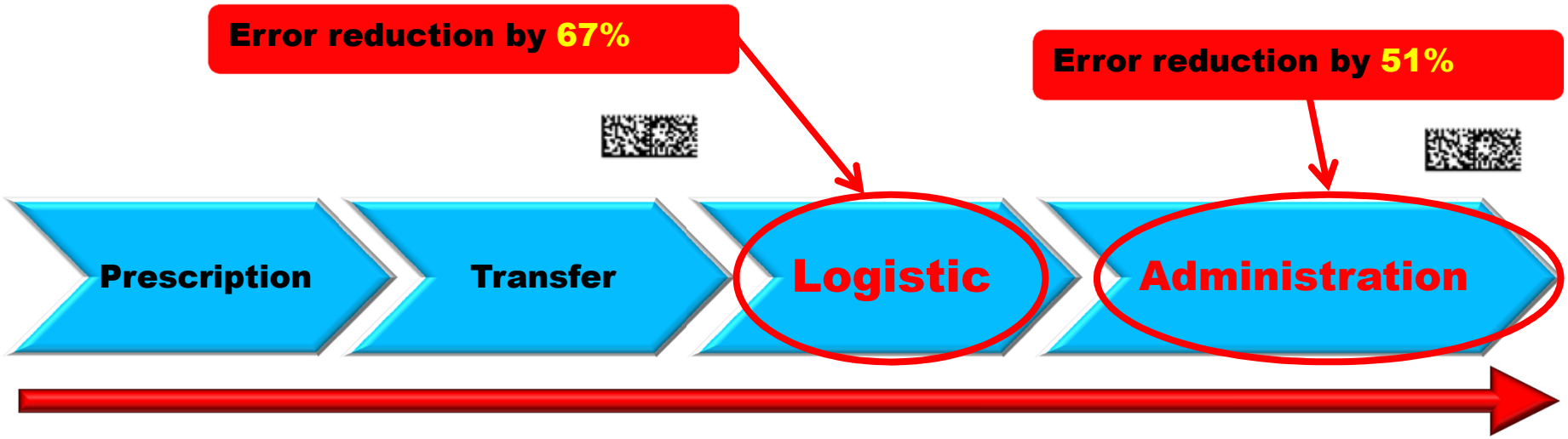
Why bar coded single units in hospitals

- To guarantee the permanent identification of a pharmaceutical product and secure its traceability within the hospital medication chain essentially **in order to prevent medication-related errors**
- **Barcode technology reduces errors by 41.4%** (11.5%⇨6.8% = **4.7** absolutely)*
- i.e. every 21st patient will have a benefit (**NNT** = 21**)

* Poon EG et al. Effect of Bar-Code Technology on the Safety of Medication Administration. N Eng J Med 2010;362:1698-707

** NNT = Number Needed to Treat

Medication errors: effect of bar-coding



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Why bar coded single units in hospitals

- **To alert faster and better manage medicines recalls**
- **To avoid risk of degradation of medical products from bulk containers** (e.g. for unit-dose automats) **because they could be sensitive to moisture, light or temperature**

Why bar coded single dose in hospitals

- **to reduce waste costs and raw material costs for repackaging in unit dose**

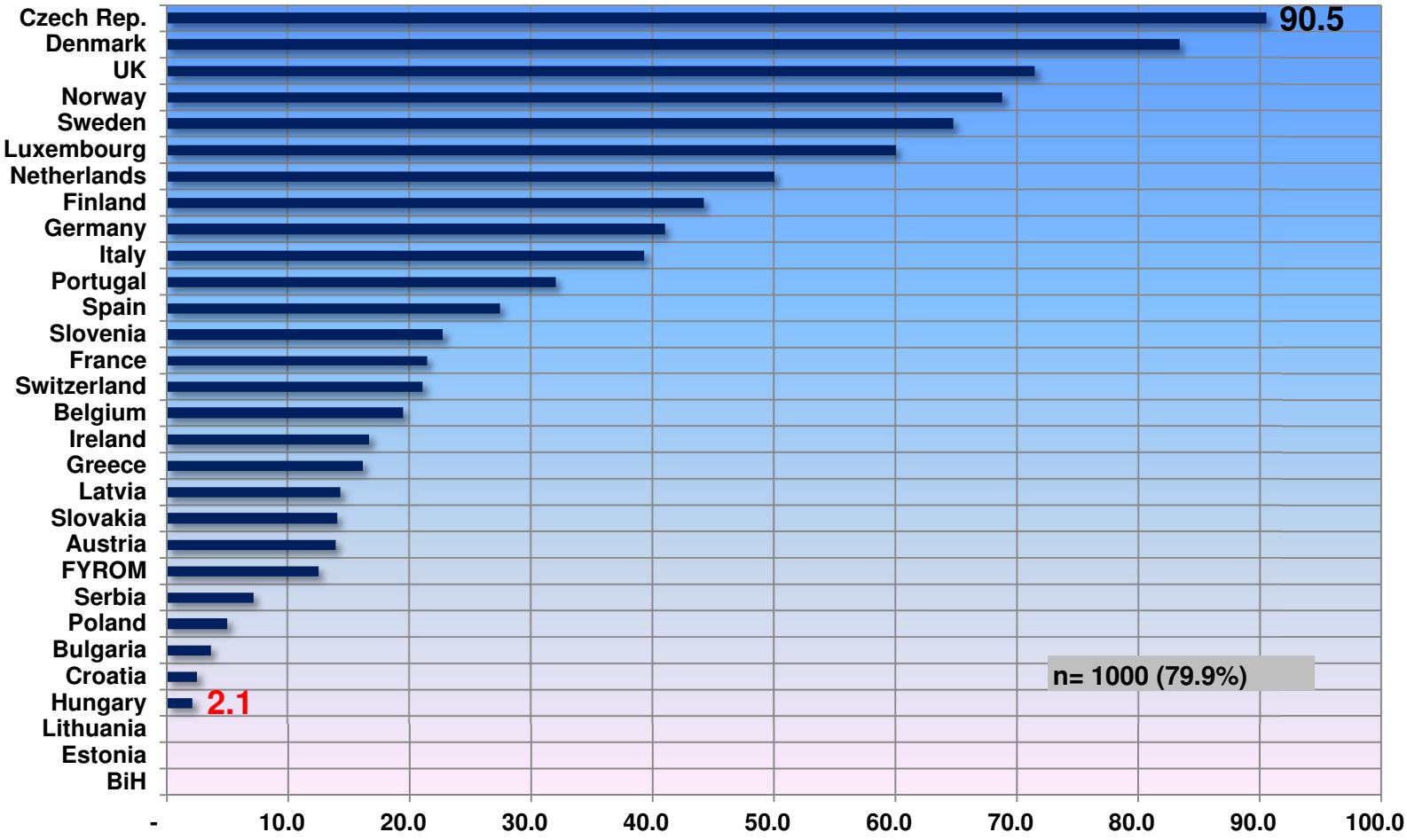
- **to reduce staff costs** (time spending on re-packaging and manually labelling)

Why bar code in hospitals

- **To make the process of compounding and reconstitution more safe**

The EAHP survey 2010 on barcoding use in hospitals

Use of EAN codes for stock management



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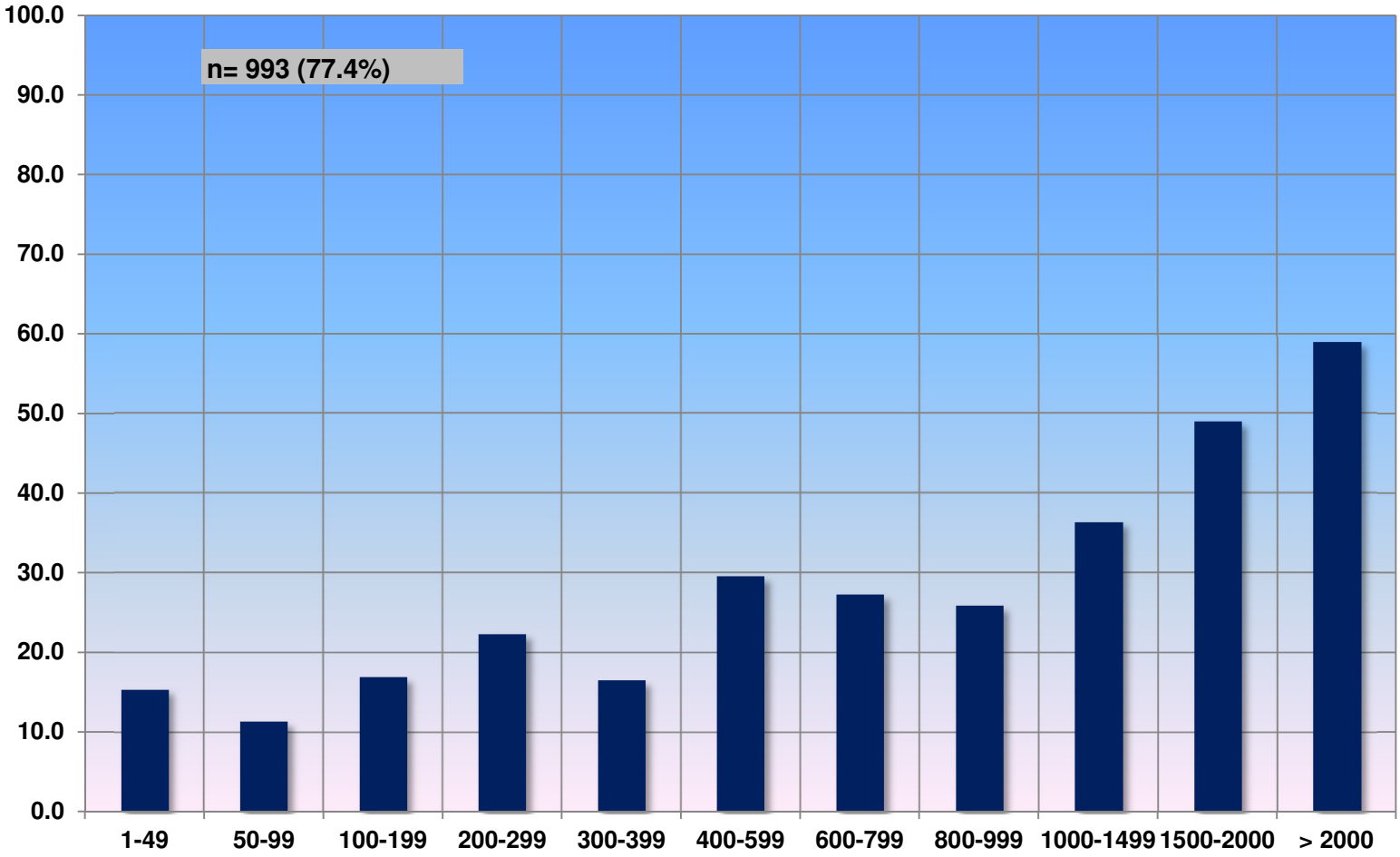
Use of EAN codes for stock management



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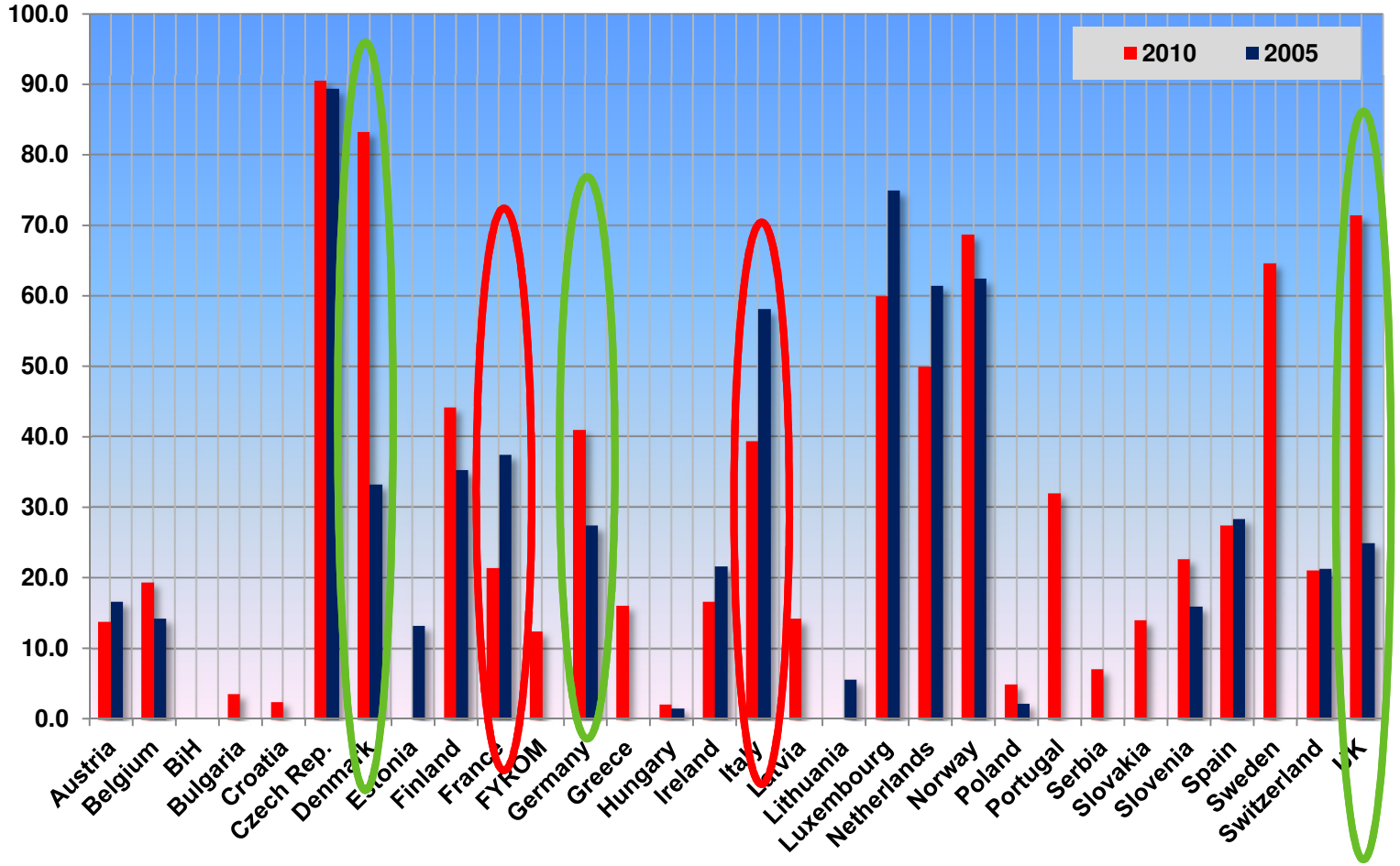
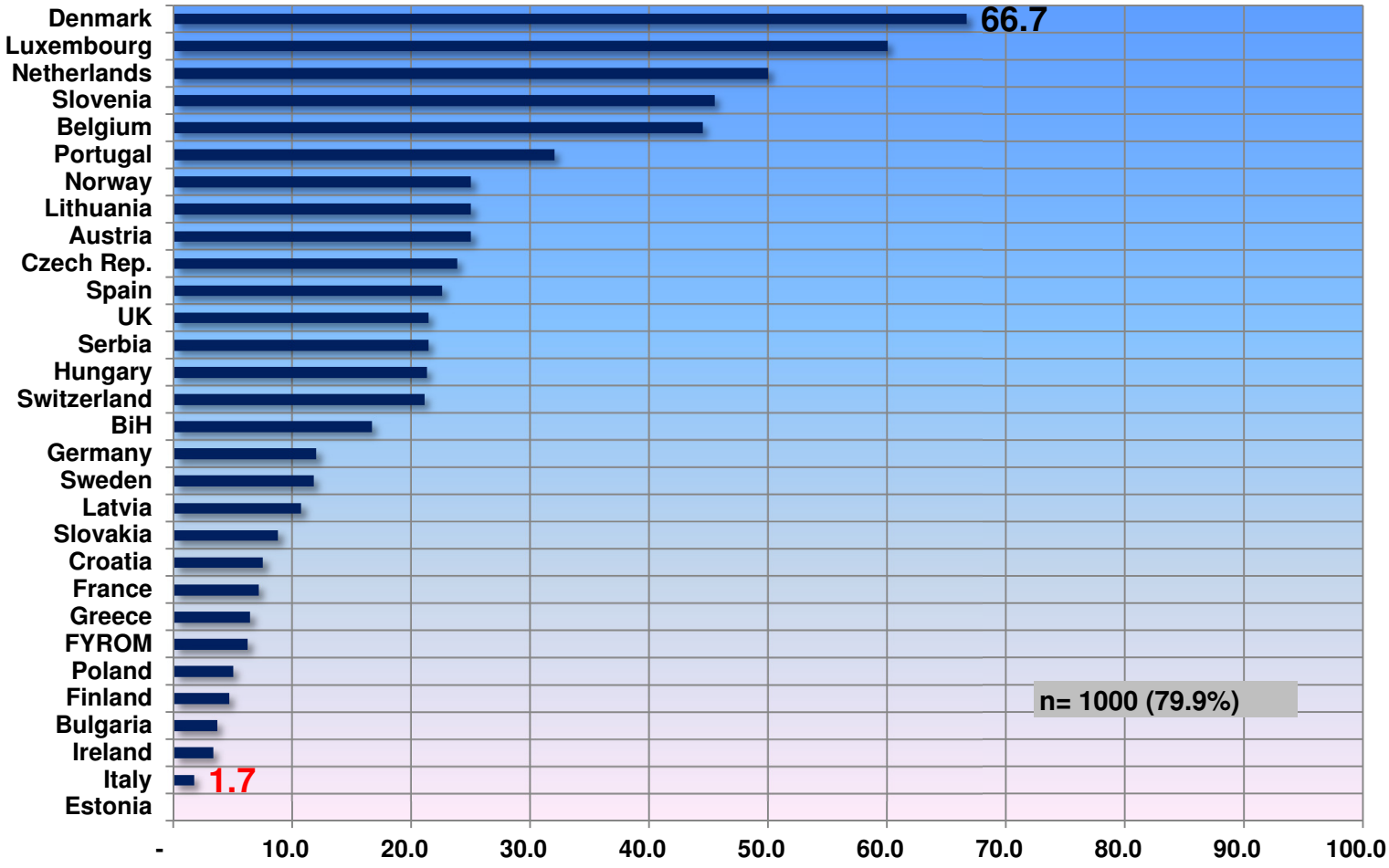


The EAHP survey 2010 on barcoding use in hospitals

Use of barcodes at point of care



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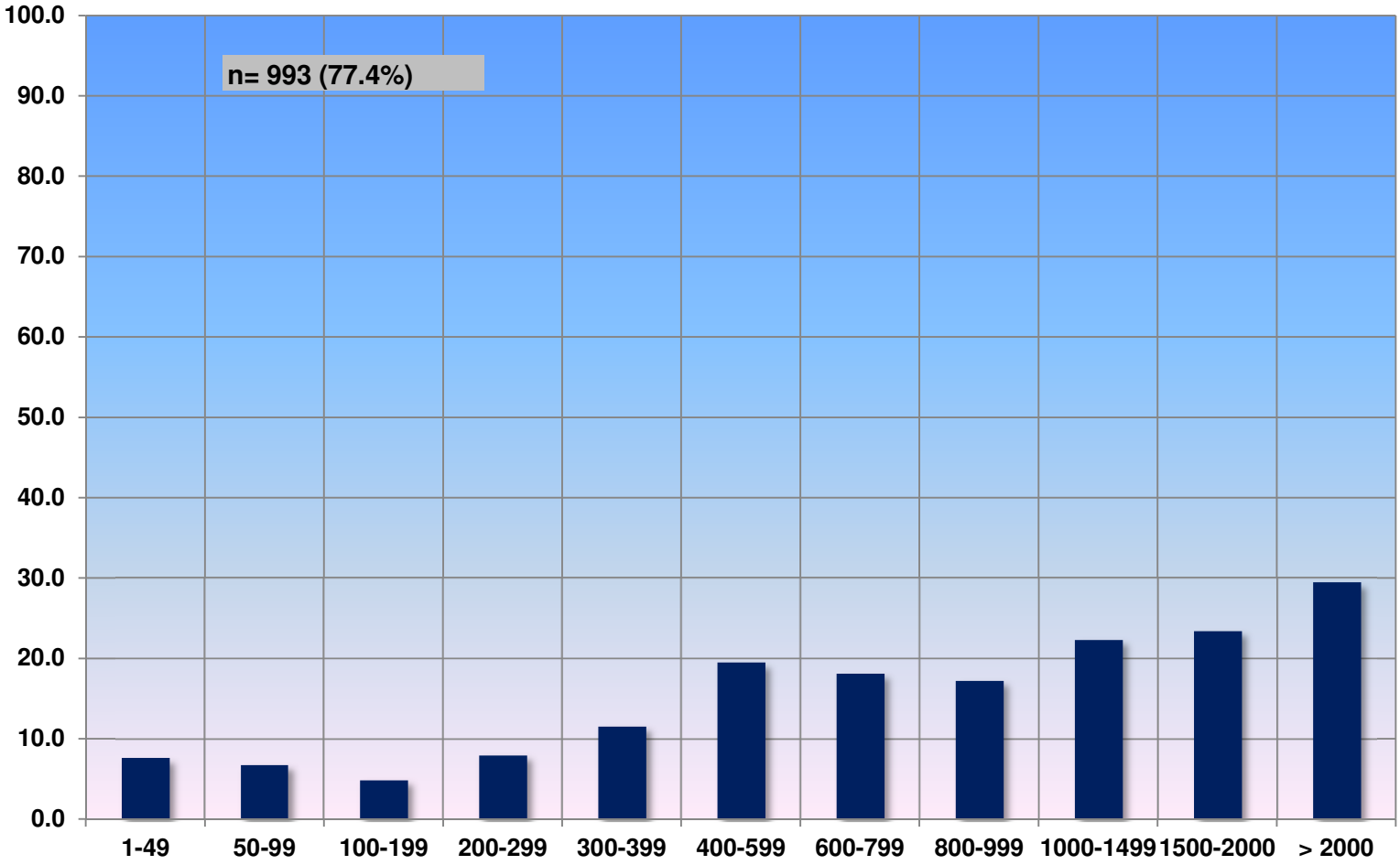

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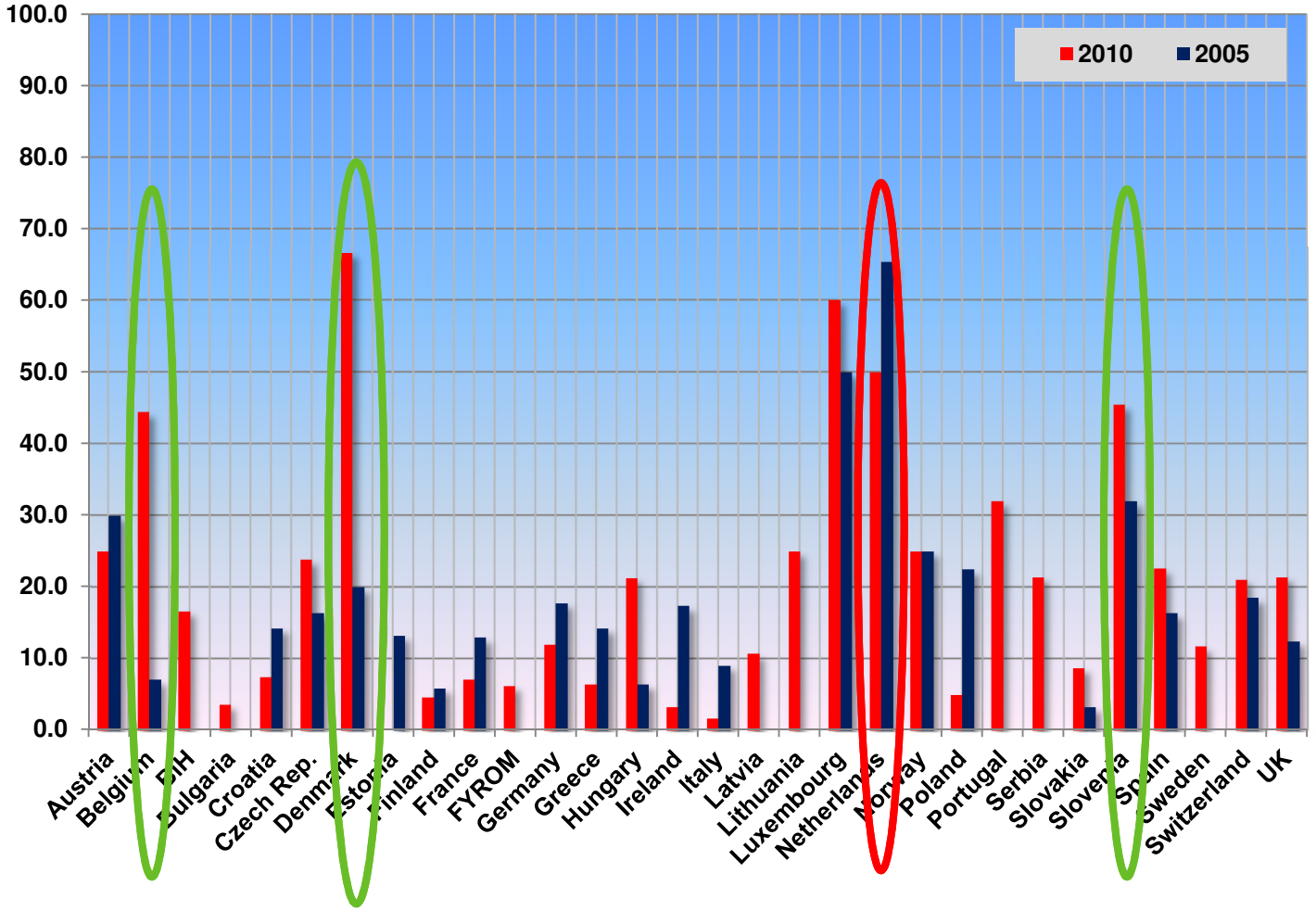
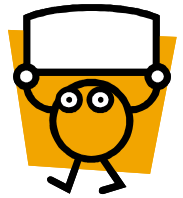


Take home messages



- **The use of barcodes is useful in fighting counterfeited medicines as well as in enhancing patient safety**
- **The use of bar coded single (dose)units reduces medication errors by 41.4% and is an important contribution to patient safety in hospitals**
- **EAHP requests the regulators to make bar coded single units mandatory for hospitals**
- **EAHP requests industry to pack all medicines for hospitals in bar coded single units**
- **Bar code technology is sufficiently in use across European countries despite some regional differences**

Thank you very much for your attention!