Selection of clinics and testing protocols

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6 April 2016

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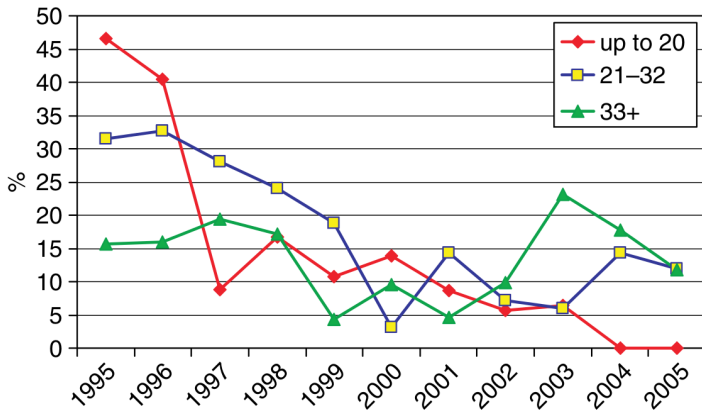
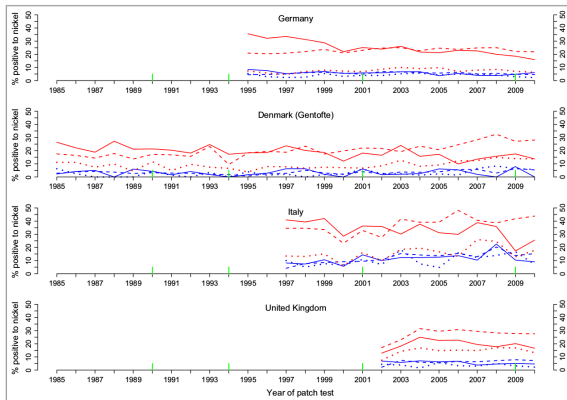# Contents

Clinical surveillance

- ▶ Patient-based epidemiology is biased by default (morbidity-driven selection)
- ▶ Assuption: largely constant selection over mid-term, less between countries/departments
- ▶ This accepted, clinical surveillance has proven its value in several instances
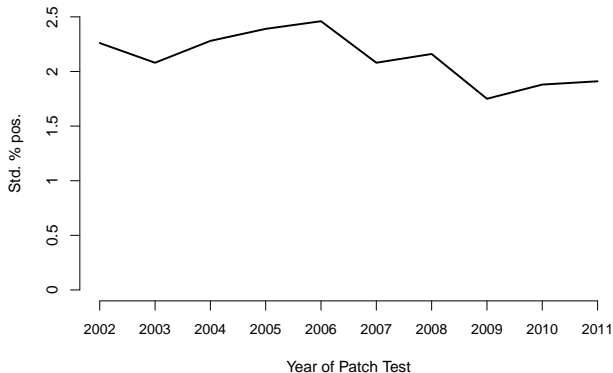
GMTG in Germany

Contact Dermatitis 2006;55:54-56.

Nickel in 4 EU countries

Brit. J. Dermatol. 2013;169:854–858.

HICC in the IVDK

Contact Dermatitis. 2012 Jul;67(1):47-9.

...2015: no further decrease

The patch test procedure

- ▶ The European Society of Contact Dermatitis (ESCD) patch test guideline[1] is applicable
- ▶ Consecutive ('unselected') patients
- ▶ Only 2 days exposure accepted
- ▶ Readings day (D)2 and D4 or D5 as minimum requirement

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[1] Contact Dermatitis 2015;73:195-221.

Technical detals

- ▶ Small (8 mm) Finn Chambers® on Scanpor® tape
- ▶ One source of patch test allergens, analytical control of stability and batch-to-batch variation
- ▶ Training rounds in standardisation of dosing and reading
- ▶ TrueVol™ dispensers (?)

Eligible departments

- ▶ Only those providing general dermatological care
- ▶ At least > 400 patients per year per department to be recruited
- ▶ As far as possible, representative regions from the EU
- ▶ Preferred: more than 1 clinician reading reactions
- ▶ Ethical vetting in the responsibility of each department (?)

Online Documentation

- A secure study server will be set up at IMBE, representing electronically the CRF
- Each participating department will receive a log-in and a manual, explaining data entry
- Regular data back-up and extraction
- Regular reporting ($\rightarrow$ Ian)