ISCH COST Action TD1206

Development and Implementation of European Standards on Prevention of Occupational Skin Diseases (StanDerm)

FOUNDATIONS OF CONTACT ALLERGY SURVEILLANCE

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StanDerm Workshop Krakow, 13 October 2016

Conflicts of interests

- Accepted travel reimbursement and partly honoraria for presentations to cosmetic industry associations
- Lecture fee by Almirall/Hermal
- Participation in honoraria to A. Schnuch for expertises for allergen registration produced for Brial

What are “foundations”?

- Generally agreed principles?
- Indispensable standards?
- Binding conventions?
- … ?

“Foundations” as defined here

- Adherence to pertinent international **guidelines** (e.g., STROBE, patch test guideline)
- Use of well-defined **catalogues**
- **Independence** (transparency) of reporting

Guidelines: STROBE

- **ST**rengthening the **R**eporting of **OB**servational studies in **E**pidemiology [1)]
- Sensible criteria of what to include in the reporting of epidemiological studies
- Based on a broad consensus

[1)] strobe-statement.org/

Guidelines: Case reports

- Support of transparency and accuracy of **CA**se **RE**ports [1)]
- A generic guideline from 2013
- An adaptation for *Contact Dermatitis* is in print

[1)] http://www.care-statement.org/

Technical patch test quality requirements

Contact Dermatitis • **Education & Debate**

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Contact Dermatitis

Thoughts on how to improve the quality of multicentre patch test studies

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- Detailed checklist … and score
- Very relevant for dedicated patch test studies, e.g., dose finding, new allergens

Guidelines: Patch testing

Contact Dermatitis • **Review Article**

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European Society of Contact Dermatitis guideline for diagnostic patch testing – recommendations on best practice

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Catalogues: Occupation (job title)

- **I**nternational **S**tandard **C**lassification of **O**ccupations [1)]
- Version upgrade from ISCO-88 to ISCO-08, applied to ESSCA, transition 2013/14
- A few mapping issues …
- Type of job + level of skill (unnecessary?)

[1)] http://www.ilo.org/[…]

Catalogues: Industry (employer)

- **I**nternational **S**tandard **I**ndustrial **C**lassification of All Economic Activities (ISIC, UN)
- Statistical Classification of Economic Activities in the European Community (NACE, EU)
- …
- So far not included in ESSCA – important? [1)]

[1)] Part of UK Epiderm project

Catalogues: Diagnoses

- **I**nternational **C**lassification of **D**iseases (ICD, WHO)
- ICD-10 did not offer sufficient detail
- ICD-11 will!
- … even in terms of composite classification along with causative agents

Catalogues: Anatomical Sites

- ICD-10 would offer some gross categories, but
- Proprietary (hierarchical) lists are used, e.g., in ESSCA: 9 ‘must’ and 49 ‘optional’ levels of detail
- (Common) combinations should be included

Catalogues: Substances

- For cosmetic ingredients, INCI [1)]
- For active ingredients (medicines), INN
- CAS nr. always a good idea
- … beyond?
- ESSCA has a catalogue of > 3000 substances, multilingual
- ICD-11 will include the most important substances

[1)] http://ec.europa.eu/growth/tools-databases/cosing/

Catalogues: “Contactants”

- Product categories …
  - *causing contact dermatitis*
  - *of a product patch tested (‘as is’, diluted, break-down)*
  - *of a diagnosed allergen, which is currently relevant in that product category*
- Have proven a useful filter
- Not many “official” lists exist

Catalogues: MOAHLFA index

- Very popular shorthand description of (probably) the most important patient descriptors
- Simple %age of
  - *Male patients*
  - *Patients with occupational dermatitis*
  - *Patients with atopy/atopic eczema*
  - *Patients with hand, leg, face dermatitis*
  - *Patients age 40+*

MOAHLFA index: needs for clarification

- Standards for definition of **o**ccupational dermatitis 👍
- **A**topy or atopic eczema?
- **H**and OK, but where does the **L**eg start?
- Does **F**ace include the scalp, the lips, …
- A consensus paper seems warranted!

How to join all this information?

- ‘Classically’ in a medical letter or medicolegal evaluation as free text
- In a CRF, information is structured, ±standardised, but partly also reduced
- Particular problem:
  Relation allergen – diagnosis – site – history may be multiple

Suggested representation of final evaluation

- Presented in Amsterdam
- Currently evaluated in a pilot study
- Data from 62 patients from 9 departments (n=1-21) already included

Final evaluation

Time[1]	Diagnosis[2]	Occ.[3]	Site[2]	Allergen/Irritant[4]	Contactant[2]	Eval. based on[5]
[…….]	[…….]	[…]	[…….]	[…….]	[…….]	[…….]
[…….]	[…….]	[…]	[…….]	[…….]	[…….]	[…….]
[…….]	[…….]	[…]	[…….]	[…….]	[…….]	[…….]
[…….]	[…….]	[…]	[…….]	[…….]	[…….]	[…….]
[…….]	[…….]	[…]	[…….]	[…….]	[…….]	[…….]

Transparency/ independence of reporting

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Quality in epidemiological surveillance of contact allergy

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- Discussion of necessary level of detail of reporting, before quality is doubted
- Addressing some other important aspects

Biostatistical and epidemiological aspects

- Misclassification (e.g.,“false-positives”, “false-negatives”)
- Error and the role of sample size (planning)
- Statistical testing vs. (effect) estimates with confidence intervals
- Bias (e.g., selection effects) and strategies against it (stratification, adjustment)

Potential conflicts of interests

- Information to editorial team, e.g., along International Committee of Medical Journal Editors (ICMJE) forms [1)]
- Also information of readers is important!
- (Inappropriately) strict “quality standards” may filter evidence until none is left to avoid (costly) risk management action
- Judicious evaluation by multi-disciplinary expert panels is recommended

[1)] http://www.icmje.org/