Data management system (based on ESSCA experience)

Wolfgang Uter

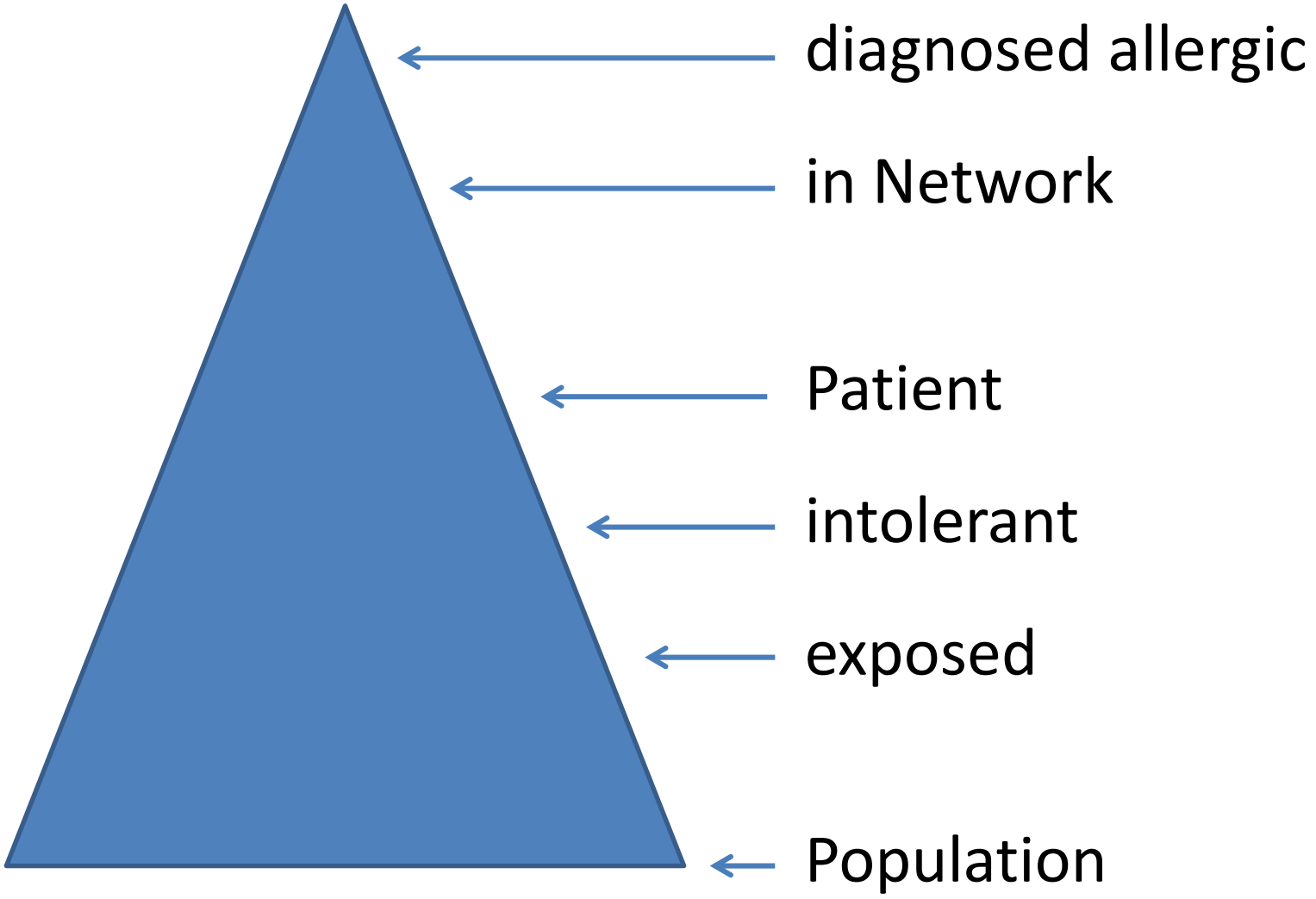
Different levels of documentation

- ESSCA or IVDK standard (local installation):
  - “Full” documentation of patch tested patients
  - Possible extensions to this
- Future ESSCA (?): Same scope, online
- EECDRG approach (online):
  - Study documentation only of eligible cases
  - N(tested) with allergen(s) is counted as denominator, split into female/male (age?)
- ‘Vigilance’ approach (online):
  - Case only documentation … with more detail

What do we want to achieve (to “validate QRA 2”)?

- Baseline and follow-up (at 2-3 year intervals) of (3-5) newly introduced substances, e.g. for (½ or) 1 year study interval
  … the only chance to start at zero (no previous, known commencing exposure)
- Similar follow-up of “the 26 (minus x)”
  … only useful if (i) intervened and (ii) exposure can be estimated

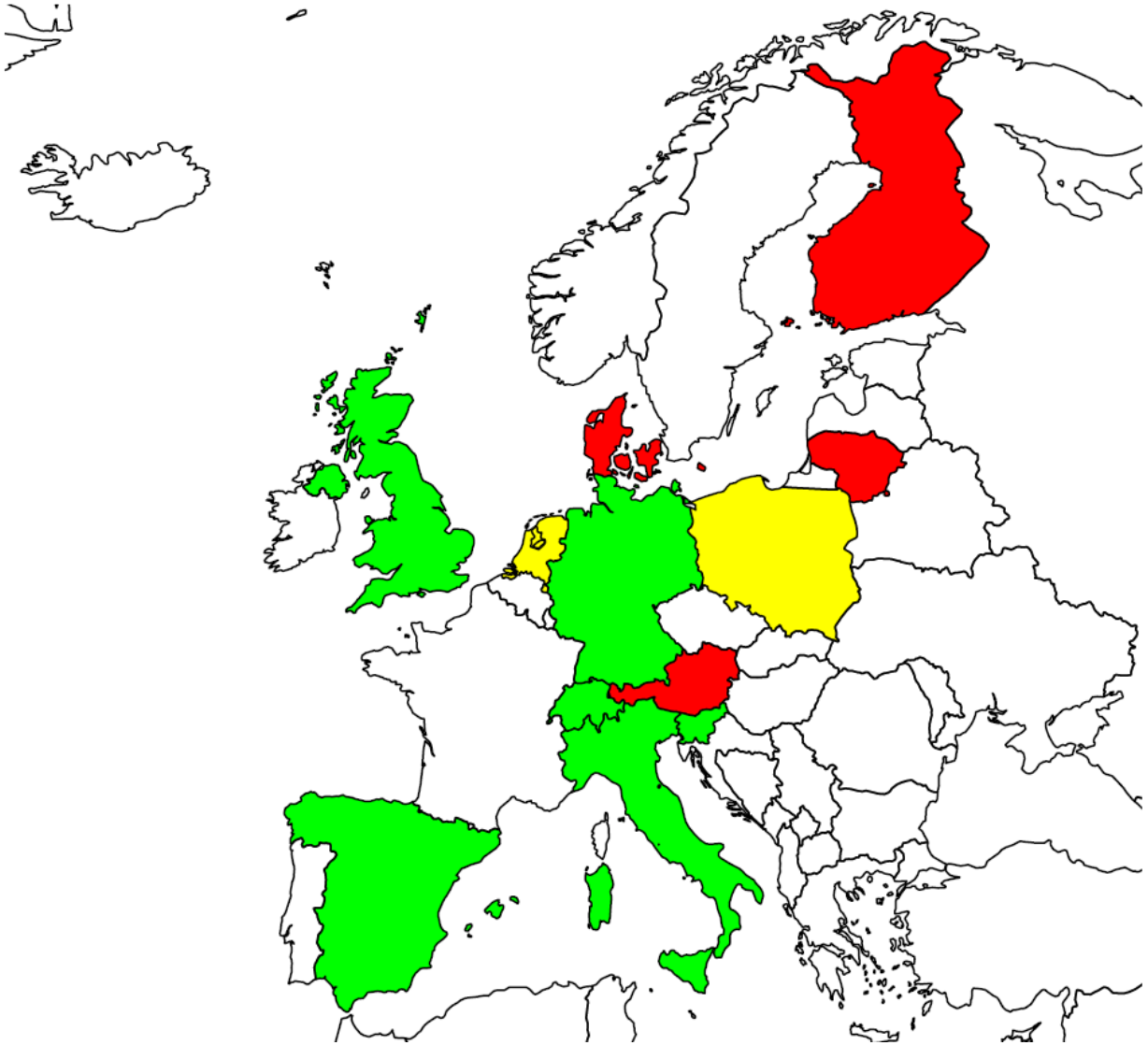
From exposure to diagnosis



ESSCA standard

- Software is available for free (MS Access needed), local installation (some local support is helpful …)
- A new .net based version is available at alpha stage – would need little person time until roll-out
- Export of pseudonymised (or anonymised) data easily possible
- All patients / full routine can be documented
- Standardised extensions can be added

ESSCA: current scope



ESSCA online (future?)

- Same scope of data recorded, e.g. using OpenClinica
- Every patient included
- Anonymised (… no identification of re-consultations possible)
- Aggregated information (e.g. age) to avoid ‘unique profiles’
- Should dispel data protection concerns
- Notwithstanding, patient consent is needed

EECDRG standard

- “Compromise”:
  - Important data only recorded for ‘eligible’ patients
  - Counting of patients in monitoring period (½ year in present study on MI exposures)
- Offered as ‘simple’ or ‘flat’ online documentation:
  - Screen forms basically just fill one row of a data table
  - Reasonably intelligent navigation is possible
  - No default local access to data once a record has been finalised
  - So far, “SoSci” has been used, “REDCap” is an alternative

Examples of screen forms

Questionnaire on MI-allergy and exposures: Form A p.1

Patient's initials

Date (DD/MM/YY)

Sex

- ○ Female
- ○ Male

Age (years)

Occupation

Atopic Dermatitis

- ☐ Presently
- ☐ Previously

Examples of screen forms (2)

1. Previously patch tested

[Please choose]

2. Known positive to MI or MCI/MI

- ◯ yes
- ◯ no
- ◯ not applicable [not tested (neither with MI nor MCI/MI)]

Next

Pause the interview

0% completed

Wolfgang Uter – 2016

Examples of screen forms (3)

Results of current patch test

Only record if positive at at least one reading, i.e., those allergens with no input will be regarded as negative (at the usual reading times of the department). If a substance (other than "other") has not been tested, please use the D2 column to document N.T. (not tested) or N.T. (S.) (not tested due to known sensitisation).

Test preparation	D2	D3/4	D5/7	Comments (You can enter free text here)
Methylisothiazolinone 0.2%	[Please choos	[Please choos	[Please choos	
Methylisothiazolinone 0.05% (500 ppm)	[Please choos	[Please choos	[Please choos	
MCI/MI 0.02% (DE only: 0.01%)	[Please choos	[Please choos	[Please choos	
Fragrance Mix I	[Please choos	[Please choos	[Please choos	
Fragrance Mix II	[Please choos	[Please choos	[Please choos	
Balsam of Peru	[Please choos	[Please choos	[Please choos	
Formaldehyde	[Please choos	[Please choos	[Please choos	

Pros and Cons ‘EECDRG’

- Relatively easy to set up
- Online data entry is well-accepted
- Can be very specifically tailored (more than the ‘ESSCA’ version)

- Excludes details of ‘all negative’ patients
- Excludes analysis of ‘study negative’ vs. ‘standard positive’ patients, e.g., FM I pos.

Vigilance

- (Cosmeto-) Vigilance is a front-line approach
- Sentinel cases (**ACD to perfumed products**) are investigated thoroughly (study checklist)
- Products are tested ‘as is’ (or as appropriate)
- Break-downs obtained from **manufacturers** are tested in appropriate concentrations
- Results are recorded centrally … and reported

Experience using a vigilance system

- REVIDAL/GERDA: network of dermatologists, several valuable publications
- IDOK@IVDK: service for all dermatologists, service for industry (SMEs, but also ‘outsourcing’ for big companies) – no scientific output so far, no added value for the community

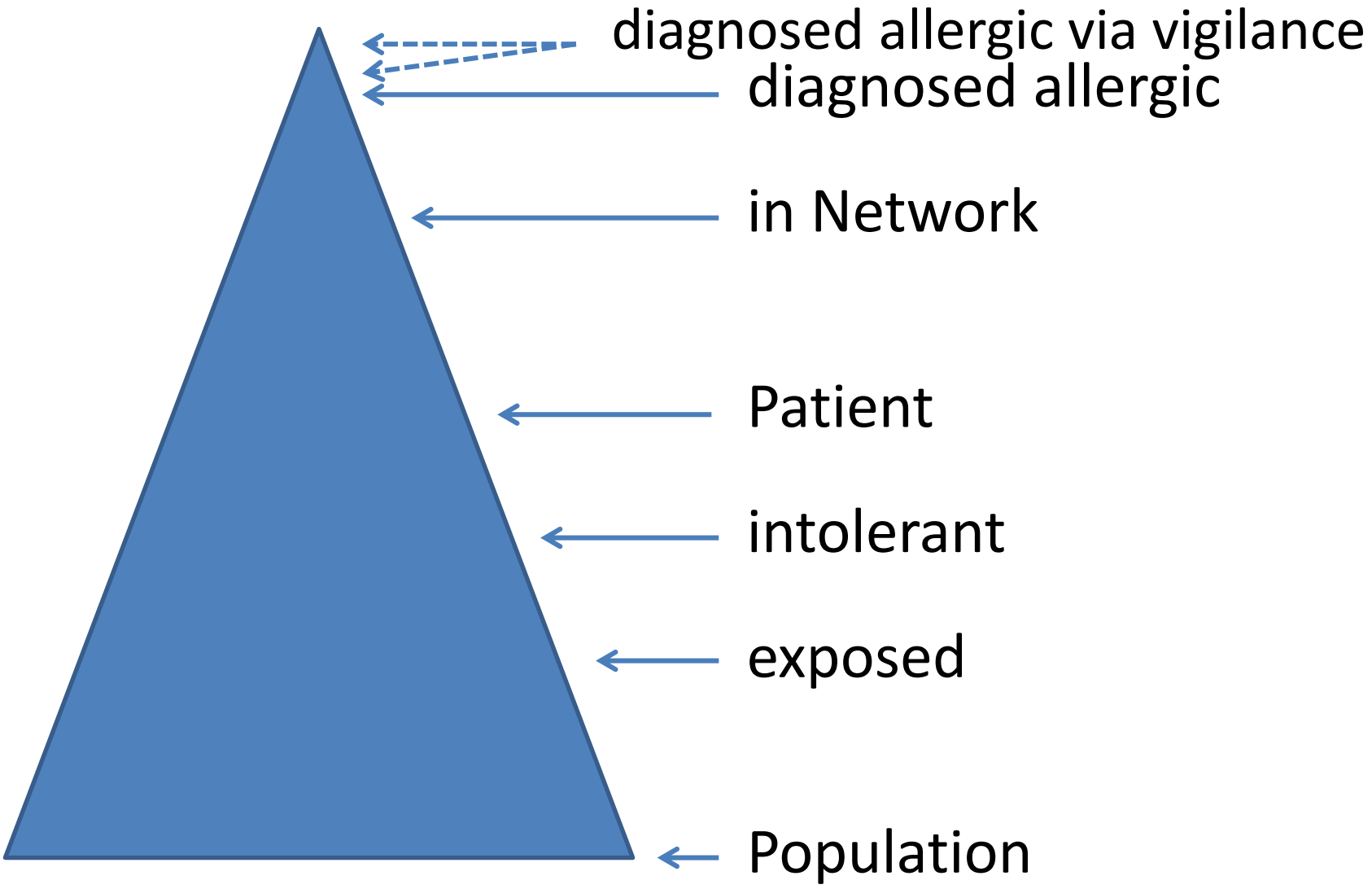
Perspectives using a vigilance system

- In view of quality problems noted with IDOK, a network of experienced dermatologists is preferable
- If new **study fragrances** are used in (a limited scope of) products, use (and intolerance) can be checked along product lists … updates needed
- In case of positive PT or ROAT with product, study fragrance(s) should be PTed

Perspectives using a vigilance system (2)

- PT concentration pre-determined in study (→ Magnus)
- Sensitivity to pick up rare allergies to study substances less than with routine PTing
- On a broader scope, perfumed products cosmetovigilcance can serve detection of new allergens

From exposure to diagnosis



Perspectives using a vigilance system (3)

- Feasibility of providing up-to-date perfumed product lists from downstream users of fragrances study substances?
- Certainly an example of pro-active post-marketing surveillance
- Will take time (as with routine – intermittent – PTing) until results are produced; inevitable in a real-world (clinical) epidemiology context