Proposed contents and categories of the ESSCA system

("minimal dataset")

- 3rd amendment, June 2003 -

Preface

The following paper is the final version of a draft on *contents and categories* of the ESSCA system as proposed by the members of the EDP task force. It is based on a first draft (by W. Uter, J. Albert and A. Schnuch), on a meeting in Amersham, UK, July, 22nd (D. Perrenoud, S. Shaw, W. Uter) and on a meeting in Rome, October, 4th (D. Perrenoud, S. Shaw, W. Uter, J. Wilkinson). After the first ESSCA Workshop held in April, 2003 in Gentofte, the set of data was changed; these changes have been incorporated in this document.

The structure of the underlying relational database is not topic of this paper, although it is briefly discussed.

1. Contents

Other data may be recorded in addition to the following suggested items, (i) in the future by *all* participants, or (ii) further on as "specialty" by those who already have a computer system in place and do not want to cut back the extent of their documentation. Those data we consider essential (referring both to new database systems being developed, and to the development of a structured export functions for clinics with databases already in place) are underlined. It shall be emphasized that the concept presented here is a "minimal dataset". Extensions to the "minimal dataset" are always possible on either the general or the local level, but these extensions may require some programming experience.

1.1 Center data

□□□/□□□□□/□□□□□ This is only important for "internal" ESSCA data center use; grouping and identification of centers for analyses and publications will have to be discussed individually.

- The first three characters (to first slash): 1 to 3 uppercase letters for country, corresponding to internet country conventions: AU = Austria, BE = Belgium, UK =

Britain, DK = Denmark, FI = Finland, FR = France, DE = Germany, IT = Italy, NL = Netherlands, PT = Portugal, ES = Spain, SE = Sweden, CH = Switzerland

- A maximum of 8 digits (or characters) between slashes that may contain the ZIP code number (which should be unique for a given center within a country) or a serial number.
- Another five digits (or characters) on the right may be used to uniquely identify a center if the ZIP code is not sufficient for this.

Additional descriptive information:

- Duration of application of patches (24 vs. 48 hrs.)
- Usual Reading Times
- Pre-treatment of test-sites, e.g. degreasing (yes/no/sometimes)
- Use of a refrigerator for storing patch test substances

1.2 Patient data

These contain *invariable* data for a given patient.

- sex
- identifier (best: a **unique** numerical key number, like the notes number of the respective hospital).

This data is anonymous; however, date of birth, name, address, etc. will have to be stored on a local level in order to be able to re-identify patients, should need arise. This means that data protection aspects have to be taken care of on a *local level*, according to respective legislation.

1.3 Case data (except patch test data)

Case data includes patient data, which may vary from one visit to the next. In other words, this information includes, what may be considered anamnesis information for a particular visit.

Interpretation: Understandably, interpretations of some of the questions in case dataset may differ from clinic to clinic, or even from one physician to the next. In order keep the collected data valid for comparison, it may be necessary to develop and distribute a glossary of standard operational definitions for such items as "personal history of atopic eczema".

- patient ID (see above) as a link to data mentioned in "1.2"
- age on consultation
- date of consultation
- personal history of atopic eczema ("yes, no, unclear")
- personal history allergic rhinoconjunctivitis ("yes, no, unclear")
- personal history allergic asthma ("yes, no, unclear")
- present occupation I (for all occupations: see separate catalog list)
- duration of present occupation I (months)
- present occupation II (only if applicable individually)
- duration of present occupation II (only if applicable individually) (months)
- previous occupation I (only if applicable individually)
- duration of previous occupation I (only if applicable individually) (months)
- previous occupation II (only if applicable individually)
- duration of previous occupation II (only if applicable individually) (months)
- duration of current symptoms (months)
- site affected - primary (initial) site (see separate catalog list)
- clinical pattern, e.g. "photosensitive", "exposed sites", "airborne pattern", or typical combinations of sites, such as "palms/soles", etc.
- secondary spread ("yes/no") - definition: not an extension of primary site *per continuitatem*, but a "jump" to other sites, e.g. from hand to trunk.
- final diagnosis 1
- site 1
- site 2
- site 3

  } To final diagnosis 1

- final diagnosis 2 Both diagnoses shall be selected from a catalogue of diagnoses (see table below).
- site 1
- site 2
- site 3

  } To final diagnosis 2

- final diagnosis = "other" ("yes [exclusively]", "predominantly", "contributing", "no", "unclear")
- "other" final diagnosis: free text, possibly (later, if an analysis of free text collected or local demands suggest this) - ICD 10 compatible – code number.

- occupational factor(s) ("yes", "no", "partly", "unknown")
- endogenous factor(s) ("yes", "no", "partly", "unknown")
- other exogenous factor(s) ("yes [not specified]", "yes, leisure activity", “yes, environmental”, "no", "unknown")
- leisure activity/activities (list of items, possibility of multiple choices)
- "contact categories" (see separate catalog list)

1.4 Case data (patch test data)

- substance - i.e. name of the allergen
- concentration (%)
- test vehicle (PET, AQU, ALC; other abbreviations as required)
- manufacturer of test-substance (HE=Hermal, TR=Trolab, TT=True Test, CH=Chemotechnique, BR=Brial; other abbreviations, as required)
- Reading Times * Reactions (Morphology) * Interpretation:
  Concerning the documentation of patch test reactions, there is considerable concern about the mixture of morphological grading and etiological interpretation in the ICDRG system presently used. We therefore propose documenting (**A**) morphology and (**B**) interpretation separately, as follows:
  (**A**) "-" (negative), "?" (erythema only), "+" (erythema and infiltration, possibly papules), "++" (as "+", plus papulovesicles), "+++" (as "++", confluent vesicles), "f" (follicular or pustular), "pu" (purpuric), "ir" (irritant effect, e.g. soap effect, ring effect, glazing)
  (**B**) allergic, irritant, unknown.
  As a "++" reaction, for instance, will very often be interpreted as allergic (at least with the set of allergens we are going to use within ESSCA), a *default setting* of **B** as "allergic" is intended, as well as for other morphologies as appropriate. We suggest *not* to give a default for **B** for "?" and "f". The statement on B may only be necessary to be made at the final reading of patches.
  Reading Times: (D1), D2, D3, D4 etc. as appropriate for the individual case.
- relevance of positive test reactions (see separate catalog list)

Set of Allergens

As a start, it seems feasible only to include "standard allergens". Although the European standard series (see: Isaksson M et al., Contact Dermatitis 43; 2000: 41-2) is presumably tested in most centers, it is sometimes altered and often supplemented with allergens,

which are considered important locally (or nationally). Therefore, we suggest that each clinic should compile a list of 50 test substances, i.e. combinations of allergen, test concentration and vehicle. All test preparations that are used in a center and are included in this list shall qualify for communal analysis. Unique substance(Test-)-IDs for the each combination of substance, vehicle and concentration will be generated by the ESSCA Data Centre, in order to facilitate later analyses.

The "list of 50" should comprise of the 20 test-substances of the proposed "modified international standard series" (J.-M. Lachapelle et al., Contact Dermatitis 36 [1997] 121 - 123), plus eight test-substances of the extension (see separate list). The remaining 22 test-substances will be compiled according to a survey of all ESSCA members concerning the current composition of the standard series (enclosure). Please note, that substances tested in a different concentrations or with different vehicles (e.g. nickel sulfate hexahydrate 5.0% in PET), require additional entries.

Should be tested		Substance	Conc. (%)	Veh.	Manufacturer
yes	No				
		potassium dichromate	0.5	PET	
		neomycin sulfate	20.0	PET	
		thiuram mix	1.0	PET	
		p-phenylenediamine base (PPD)	1.0	PET	
		cobalt chloride ($CoCl_2$ $6H_2O$)	1.0	PET	
		Benzocaine	5.0	PET	
		Formaldehyde	1.0	AQU	
		Clioquinol	5.0	PET	
		Colophony	20.0	PET	
		balsam of Peru	25.0	PET	
		IPPD	0.1	PET	
		wool (lanolin) alcohols	30.0	PET	
		mercapto mix[1]	2.0	PET	
		epoxy resin	1.0	PET	
		paraben-mix	16.0	PET	
		p-tert-butylphenol-formaldehyde resin	1.0	PET	
		fragrance mix	8.0	PET	
		quaternium 15	1.0	PET	
		nickel sulfate ($NiSO_4$ $6H_2O$)	5.0	PET	
		Cl+Me-isothiazolinone (MCI/MI)	0.01	AQU	
		mercaptobenzothiazole (see footnote)	1.0	PET	
		Primin	0.01	PET	

2. Categories

The concept that every ESSCA partner should be able to use an individualised set of categories for sites, diagnoses, etc. can only be realised using a hierarchical "translation table", containing a "common denominator" list as a reference. Such a hierarchical table is flexible enough to accommodate different levels of detailed information. In other words, basic level of categories is in place to collect information gathered from all participating centers, while more detailed sub-categories store data from centers with more detailed documentation.

Every center's data categories will need to be related and translated with the hierarchal table to later facilitate communal data analysis. This relation and translation is only required once, and is perhaps best carried out by each individual partner, and not by the data centre. New reference categories can be created as needed.

[1] Mercaptobenzothiazole should probably be chosen instead (solely), as its sensitivity seems to be better than that of the mix (J. Geier, O. Gefeller, Amer. J. Contact Dermatitis 6 [1995] 143 - 149)

2.1 Sites

The following is an example of site categories from four centers as they would be relate to the hierarchal table. The first column contains the essential categories, while the second column contains categories for supplemental information included in the next two levels of the hierarchal table. Each ESSCA partner will need relate the local categories to the reference lists, and provide this information to the ESSCA Data Center.

Reference "must"	**Reference "can"; two additional levels**	Center A (A. Bircher)	Center B (P. Elsner)	Center C (S. Shaw/ J. D. Wilkinson)	IVDK (Germany)
Hand, not specified		Hand		hand	hand/hands
Entire Hand			entire hand		
	Palm		palm		palm
	P., central			central palm	
	P., periph.			periph. palm	
	Back of Hand		back of the hand	dorsal hand	back of hand
	Finger	Finger	finger		
	Finger, palmar			palmar finger	
	Finger side			finger side	finger sides
	Fingers, interdigitally		F., mainly interdigitally	interdigital	
	Fingers, dorsally		F., mainly dorsally	dorsal finger	
	Fingertip			fingertip	
Head, not specified		Head			
	Face	Face	face	face, facial area	face
	Periorbital			Eye	periocular
	Lid	Lid	eyelid	eyelid	
	Scalp		scalp	scalp	scalp
	S. Margin			margin	
	S. Centre			centre	
	Ear, not specified	Ear	ear	Ear	
	Ear canal				ear canal
	Earlobe				Earlobe
	Mouth, Lip	Mouth		mouth	
	perioral				
	Oral mucosa			oral mucous	
Neck, not specifed		Neck	neck	neck	Neck
	Neck Front			front	
	Neck Back			back	
	Neck Side			side	
Trunk, not specified		Trunk			Trunk
	Trunk Back		tunk back	trunk back	
	Trunk Front		trunk front	trunk front	
	ano-genital			Ano-genital	ano-genital

	genital		genital		
	perianal		perianally		
	Groins			groin	Groin
	Axilla		axilla	axilla	Axilla
Arm			upper limb	Arm	Arm
	upper arm	upper arm	upper arm	upper	
	elbow			elbow	
	elbow flexure			elbow flexure	
	lower arm	lower arm	lower arm	forearm	
	Wrist			wrist	
	W. extensor			extensor	
	W. flexor			flexor	
Leg			lower limb	Leg	Leg
	upper leg	upper leg		thigh	
	popliteal fold			popliteal fold	
	knee			knee	
	lower leg	lower leg		lower leg	
Foot, not specified		Foot	feet	foot	Foot
	Toe	Toe		Toe	
	Dorsum			dorsum	
	Sole			sole	Sole
Flexures, not specified					Flexures
	elbow flexure			elbow flexure	
	popliteal fold			popliteal fold	
Genera-lised			generalised	generalised	generalized
			disseminate d		
not specified, none		none		Not certain	other site
				exposed site	

2.2 Diagnoses

The representation of diagnoses, with their individual conceptual background (e.g.: "dyshidrotic hand eczema" vs. "atopic palmar eczema", or "atopic dermatitis (eczema??)" with or without "atopy" (what is atopy?), morphological vs. etiological classification, is a considerable problem. It is suggested that diagnoses, including combinations of diagnoses which are quite frequently encountered, are recorded as suggested above (see section 1.3: Case Data). - Keep in mind that ESSCA is not intended to be a comprehensive clinical documentation system, but a patch test surveillance system. Partners wishing to use a certain set of diagnoses (e.g. ICD 9 or 10 compatible, as

available from the British and the German Dermatological Societies, respectively), may do so *in addition* to providing the ESSCA set diagnoses.

Code (example)	Text	ICD 10
1	Allergic contact dermatitis, not elsewhere classified	L23.9
1001	Allergic contact dermatitis - exclusively	L23.9
1002	Allergic contact dermatitis - predominantly	L23.9
1003	Allergic contact dermatitis - contributing	L23.9
2	Irritant contact dermatitis, not elsewhere classified	L24.9
2001	Irritant contact dermatitis - exclusively	L24.9
2002	Irritant contact dermatitis - predominantly	L24.9
2003	Irritant contact dermatitis - contributing	L24.9
3	Atopic eczema / dermatitis syndrome	L20.9
4	Seborrheic dermatitis	L21.9
5	Nummular dermatitis	L30.0
6	Stasis dermatitis	I83.1
7	Photoallergic Dermatitis	L56.8
8	Phototoxic Dermatitis	L56.8
9	Burn, thermal or chemical	T20-T32
10	Psoriasis	L40.0
11	Mycosis	B35-B49
12	Parasitosis	B85-B89
13	Contact urticaria, not elsewhere classified	L50.6
13001	Contact urticaria, immunological	L50.6
13002	Contact urticaria, non-immunological	L50.6
14	Urticaria	L50.9
15	Airborne dermatitis, not elsewhere classified	L23.8
15001	Airborne dermatitis, contact allergic	L23.8
15002	Airborne dermatitis, irritant	L23.8
16	Atopic (palmo)(plantar) eczema	L20.8
17	Dyshidrotic eczema, pompholyx	L30.1
18	Stomatitis, contact allergic	K12.1
19	Stomatitis, irritant/toxic	K12.1
20	Cheilitis, contact allergic	K13.0
21	Cheilitis, irritant	K13.0
22	Cheilitis, not further specified	K13.0
23	Protein contact dermatitis	L23.8
24	Xerotic eczema (exsiccation)	L30.8
25	Exanthem (non urticarial)	R21
26	Amalgam allergy, to be excluded	Z01.5
27	Denture allergy, to be excluded	Z01.5
28	Eczema / Dermatitis, not further specified	L30.9
29	Drug intolerance	L27.0

30	Contact allergy, to be excluded	Z01.5
31	Glossodynia	K14.6
32	Hyperkeratotic (tylotic) eczema	L24.9
33	Lichen ruber	L43
34	Perioral dermatitis	L71.0
35	Prurigo	L28.2
36	Pruritus sine materia	L29.9
37	Contact allergy, no clinical correlate	T78.4
99	"other" diagnosis, not elsewhere classified	
9901	other diagnosis - exclusively	
9902	other diagnosis - predominantly	
9903	other diagnosis - contributing	

2.3 Occupation

Most international classifications, like the NACE for industries or the ISCO for occupations, are not completely suitable for ESSCA purposes; they require considerable modification. The following list is derived from the ISCO-88 COM, which is used also by the European Union's statistical office (Eurostat, Luxemburg). This catalogue has been partly kept to a minimum level of classification, partly been extended, as necessary and required, respectively, from a dermatological point of view (See separate Excel spreadsheet "occup_01-02.xls").

2.4 Relevance of positive test reactions

A statement on the clinical relevance does contain important information and is regarded as an essential aspect of a qualified diagnostic work-up. As an option, two additional dimensions are suggested: a statement (i) as to whether the relevant reaction is relevant occupationally or not, and (ii) on the degree of certainty of the "must" statement (obviously except "unknown" relevance).

Reference "must"	*	Reference "can"	*	Reference "can"
current relevance		occupational		Certain
past relevance		non-occupational		Probable
unknown relevance				Possible
active sensitization				Unlikely
cross reaction				Not
not allergic (irritant)				

2.5 Contact Categories

Apparently, few ESSCA partners use "contact categories". We propose including these categories *including these* as definers of probable sources of contact dermatitis (as allergens or irritants).

Reference "can" (?)
clothing, textiles
house dusts
shoes, boots
cosmetics, creams, ...(leave on products)
soap, shampoo, ... (rinse off products)
hair cosmetics
nail cosmetics, artificial nails
perfume, deodorant, ...
food (additives), referring to skin contact, not ingestion
drugs, external
drugs, internal
medical mat. (sutures, gel, ..)
disinfectants
metal (worked with)
metal jewellery
metal implants
metal (other, like coins)
tools (metal, wood, plastic)
dental filling (e.g. amalgam)
dental prostheses
cutting fluids (water based)
neat oils, greases
solvents
"other" chemicals
cleaning agents (detergents)
building material
woods
plants (not food)
pesticides, herbicides, ...
paints, lacquers
Glues
gloves (various materials)
leather (other)
rubber (other)
Plastics
office material
"not classified"