Development and Significance of the E-surveillance System for Contact Allergies in Slovenia

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ABSTRACT This paper describes the development and significance of on-line systems for the collection and analysis of medical data (patch test results) with a web application. Modern digital tools greatly aid in collecting, combining, and preserving the data in a way that is friendly, undemanding and time-efficient for the dermatologist. Creating a central database for the results of patch testing provides a better picture of contact sensitivity and characteristics of allergic contact dermatitis in Slovenia. An electronic database and connected network was started in Slovenia in 2010. Data from skin allergy units since 2000 has also been included retrospectively. At present (Oct 2016), the database contains the data of 19,772 patch tests performed by seven skin allergy units. Creating a central database of the results of patch testing provides a larger and therefore more credible collection of data. Immediate integration and data processing enable a current overview of contact sensitivity for each participating center as well as at the national level. Data can be easily transferred to other databases or edited with other software tools. This on-line register has worked flawlessly for more than five years. We have contributed data to the European Surveillance System on Contact Allergies (ESSCA) network database since 2012, which, along with the *Deutsche Kontaktallergie-Gruppe* system of collecting patch test data for German-speaking countries, represents the only multicenter surveillance system of patch test results in Europe.

KEY WORDS: allergic contact dermatitis, patch test, surveillance system, epidemiology

INTRODUCTION

Contact allergic sensitivity and the consequential allergic contact dermatitis (ACD) present a serious health problem. According to some studies, 20% of the population is sensitized to at least one allergen/substance from the environment (1).

Contact allergy sensitization/dermatitis is often related to an occupation. In this situation, a lack of adequate diagnosis and subsequent relapses of occupational allergic contact dermatitis may lead to work disability and represents a significant econom-

ic cost for the employer and to the health insurance system.

The diagnostic procedure of patch testing is used to determine the substance which contains potential harmful contact allergens to the individual/tested person (2). The method involves the application of standardized concentrations of the potential allergens to the patient's back. In Europe, the 30 most common contact allergens are recommended for use in basic testing, representing the so-called "European baseline series of allergens" (1,3-7).

The collection and statistical evaluation of the patch testing results for a certain population over a long time period allows the formation of epidemiological indicators (mostly time trends, subgroup analyses).

Multicenter data acquisition at a national level, i.e. establishing a large database, enables recognition of epidemiological patterns of ACD, even including allergens which are rarely the cause of contact dermatitis (8).

Based on time trends of contact sensitization, it is possible to create general preventive measures to reduce the occurrence of contact dermatitis. Examples include the Danish regulation of adding ferrous sulfate to cement, which reduced the occurrence of ACD to chrome in the building trade (9), or the European regulation limiting the use of nickel in jewelry or on labelling of cosmetic products, allowing the (allergic) consumer to select products which are free of certain additives (10,11).

Statistical processing of results and the interpretation of patch tests is carried out by practically all countries (occasionally regions) of the developed world. Additionally, various project groups were formed where larger regions or countries are combined, for example: for North America the North American Contact Dermatitis Group and the American Society of Contact Dermatitis, for Europe, the European Society of Contact Dermatitis (ESCD) and the European Surveillance System on Contact Dermatitis (ESSCA), for the German-speaking part of Europe, the *Deutsche Kontaktallergie-Gruppe* (DKG) and the *Informationsverbund Dermatologischer Kliniken* (IVDK), and internationally the International Contact Dermatitis Research Group (ICDRG).

The above-mentioned projects involve gathering the patch test results of major dermatology and allergy centers in order to create a database of 10,000 to 20,000 tested individuals per year (4). Data is collected using a variety of software tools, for example: WinAlldat/ESSCA in parts of the ESSCA network (12,13).

In 1996, the European Surveillance System on Contact Allergies (ESSCA; www.essca-dc.org) was founded as working party of the ESCD. Thanks to start-up funding from the EU, ESSCA became operative in 2002 and has since been collecting and analyzing data with the following objectives (14):

- Quality control (comparison of own results with collective and national average results);

- Subgroup analysis (e.g. children, occupational patients) (15);

- Epidemiological surveillance (the evaluation of time trends as well as regional differences in the prevalence of sensitization to certain allergens).

DATA ENTRY METHODS

In the past, the statistical evaluation of patch test results in Slovenia was carried out by a few allergy and dermatology clinics, mostly for the purposes of annual reports and less for research work.

Data collection was carried out manually or by entries into a spreadsheet program where, after testing, the dermatologist documented the personal data of the individual and recorded the allergens eliciting a positive patch test reaction.

In 2007, a retrospective analysis of 5,126 patients in Slovenia was performed for the first time; the patients had been patch tested in one of three allergy and dermatology clinics either in Maribor or Izola between 2000 and 2007 (16). The results obtained by the three clinics were collected in a spreadsheet (Excel™) file; the statistical processing of the data was later performed with SPSS statistical software. However, such data collection and integration has proven to be time-consuming and complicated. Moreover, the integration of four additional allergy and dermatology centers increased the probability of errors when entering or transferring data.

Therefore, dermatologists have expressed a desire for the creation of a computer application for the establishment of a multicenter database with the following requirements:

- Easy access to the application via the web;

- Fast and uncomplicated entry of data;

- Clearly presented concepts/selections with the possibility of additional free-text comments;

- The possibility of integrating departmental data into a single national database (and, thereby, also into international databases);

- Basic data management for statistical purposes;

- Monitoring of time trends of a departmental as well as of a shared database by specific criteria;

- Data security.

The collection of patch test results is performed on a leased computer with web server Apache (17), with support for the PHP module (18) and with the MySQL database (19).

Input forms are used (Figure 1) in a mark-up language (HTML) for efficient collection of data, and are entered into the MySQL database using the scripting language PHP (20). The AJAX technology enables a regular check-up of data consistency (21). After the completion of testing procedures at the allergy and dermatology clinic, the dermatologist connects to the central server via a web browser to access the central database on the main server.

The users must first identify themselves with an assigned username and password. A dermatologist (or another authorized person) begins by entering the patient's personal data (name, surname, year of birth, sex, occupation, etc.) in the Patient Entry form, after which the patch testing results are entered (Figure 1). Due to time constraints, we have limited the number of entries to essential information on the patient, as well as limited the range of occupations (Figure 1).

Although the result collection system has remained unchanged since the beginning of its implementation, the user interface has been updated and improved several times, prompted by user requests. We have thus achieved greater transparency and acceptability of the system and easier data entry, providing sufficient clarity to avoid possible errors and misconceptions.

In order to simplify and achieve greater transparency in the entry of data into the table, instead of entering entire names (cobalt, nickel, etc.) we use abbreviations, i.e. allergen initials.

When moving the mouse pointer over the abbreviated name of an allergen, the entire name/title is displayed. For a clearer overview, each selected allergen in electronic form changes color, in addition the names of all marked allergens also being displayed at the end of the form (Figure 1).

After entering all the data of one or more patients, the entries can be overviewed and checked for accuracy using the Patient Review form. If errors occur during the entering of data by a registered person, there is an opportunity to make changes to the entered data before logging off from the system. Any subsequent changes have been disabled due to accidental or malicious false entries, and only the administrator has the ability to subsequently correct erroneous data input.

Figure 1. Display of the entry form of tested individuals and marks of positive allergens.

RESULTS

Analysis and statistical processing of collected data

The collected data is recorded in the MySQL database on the central computer server. All data can be immediately accessed with the help of the web application in order to perform a number of different statistical analyses. Processing is carried out with mathematical functions in the script language for web development, PHP (Hypertext Preprocessor).

Statistical results are displayed in text format within the tables, to allow full information availability. For a clearer overview and presentation of analyses in periodic reports, the results are also shown graphically, i.e. displaying percentages. The graphs displayed in the statistical document beside the table are created with pChart PHP library technology, where the results of the analysis are presented in further detail (22).

We have chosen parameters to display the results of the statistical on-line processing based on published reports (13, 23) of the multicenter Surveillance systems on contact allergies and formed them into three groups of data:

a) Basic information on the tested patients:

- Number of tested individuals in a given period in one or more centers, separated by sex and average age;

b) Test results:

- Number and proportion of patients with at least one positive result to the European Baseline Series ('P' measure);

- Number of positive reactions in patients (none, one or more);

- Number and proportion of positive reactions to a specific allergen;

- Proportion of positive reactions to a specific allergen by sex and age groups;

c) Trends of positive reactions over a certain time period for selected allergens;

Basic statistics include the total number of patients for the selected year and the number of men and women tested, as well as their average age. This provides a quick overview (Figure 2). The test results are displayed with parameters which provide the dermatologists with the most information about the completed work; in other words, the parameters are selected in such a manner as to enable a comparison with established statistical analyses by contact dermatitis. The display indicates the proportion of patch-tested individuals with at least one positive reaction (Figure 3) and the proportion of patients with zero, one, or more positive reactions. The number and proportion of positive reactions to each individual allergen from the European baseline series is of great importance as well (Figure 4). We used a column chart with a stacked bar chart to represent the proportion of positive reactions for individual allergens by age groups and sex (Figure 5, Figure 6). A figure of the proportions of positive reactions across time can be displayed for one or more allergens (Figure 7).

Data export

For easier comparison, the online statistical analysis of data is modified to the statistical scheme which is most commonly used in analyzing data of patch testing in Europe and globally. For further statistical processing in the SPSS program (or any other statistical software), it is possible to download data from the system and transfer it onto a local computer in the selected format (e.g. Comma-Separated Value) (24). In this way, the user is not restricted to the presented set of statistical analyses in the web application but is thus able to perform other statistical analyses.

Basic data

The number of tested person – the period from 2000 to 2014: **16915**
Total male: **5185**
Total female **11729**
The average age of tested person **52.31**
The average age of tested male **52.68**
The average age of tested female **52.15**

Figure 2. Display of the basic information of tested individuals over the selected time period.

Positive	Other
6881 [40.68%]	10034 [59.32%]

Proportion of positive reactions to at least one allergen
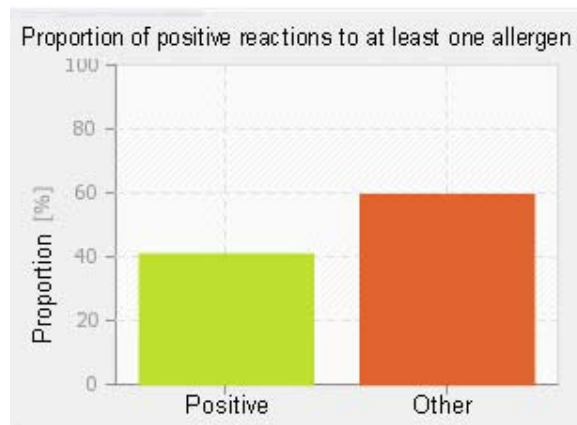
Figure 3. Display of the proportion of positive reactions to at least one allergen of the baseline series (´P´ measure).
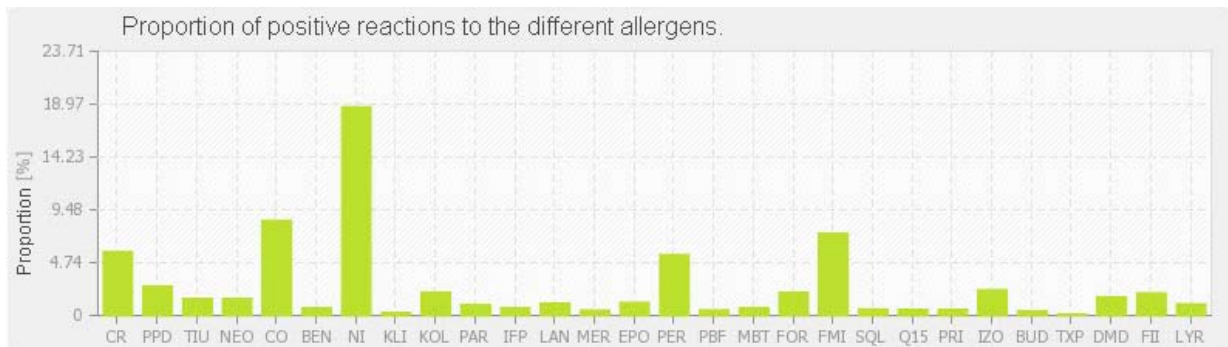
Figure 4. Display of the proportion of positive reactions to the different allergens.

Data Security

Access to the application is secured by a securely encrypted web link, and only registered users with assigned usernames and passwords can access the system. All records (accessing time and data, the name of the registered user, and all entry activities) are logged within the application and are accessible only to the authorized system operator (25). The security of the personal data entered is of the highest priority, and the patient's anonymity is fully guaranteed, in compliance with all regulations regarding the protection of personal data according to the requirements of the national information commissioner (26).

After the data has been entered, all the data is visible and accessible to the dermatologist until he logs out of the system. After logging off, the personal data on the server is encrypted into an anonymous form. As the system is intended only for gathering information for epidemiological analysis of patch test results personal data, the dates of birth, place of residence, and names of patients are irrelevant.

In addition to the data protection provided by the host server system, the administrator of the system provides regular scheduled back-up in case of host server failure.

DISCUSSION

The huge progress of information technology has resulted in electronic health records in many areas of medical care for different purposes such as clinical studies and science research, as well as electronic health records which are structured to permit the prescription of new, expensive medicaments only if the patient fulfils the criteria predefined by the health insurance institutions.

The development of our electronic patch test register was not requested by any authorities but was rather the result of the need to help dermatologists performing patch testing in the daily management of patients with contact dermatitis. We have tried to develop user-friendly patch test registry software to document the relevant parts of a patient's history and patch test results following the "minimal add-on" strategy (minimizing the amount of data entered). In this way, the storing of data would be the least time-consuming and consequently more patch testing units would join the register. Due to these characteristics of the registry, all Slovenian patch test units participate in the network, and thus it can be regarded as a national network. It is a permanent multicenter network with the possibility of surveillance of sensitization prevalence in patch-tested patients across time.

Since 2012, we have been contributing our data to the ESSCA network, which involves the data obtained from 12 European countries (59 departments). So far the data from 114,330 consultations have been
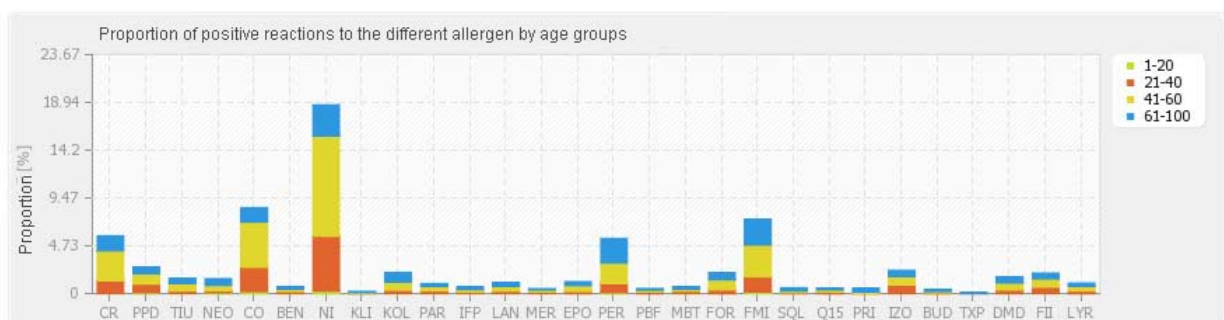

Figure 5. Display of the proportion of positive reactions to the different allergen by age groups.
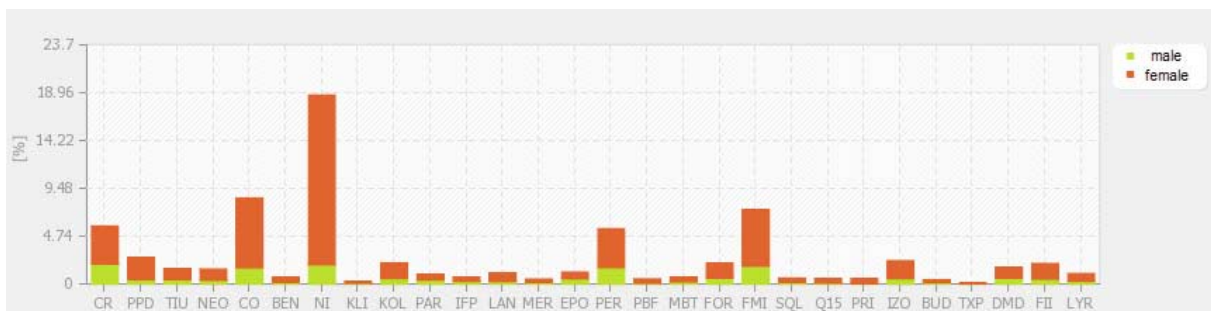
Figure 6. Display of the proportion of positive reactions to a specific allergen by gender.

collected between 2002-2014, of which 15,610 consultations were contributed from Slovenia (27).

Presently, only the Slovenian network and the Information Network of Departments of Dermatology IVDK (comprising Austrian, German, and Swiss departments) contribute multi-department data to the ESSCA data center, thereby rendering it to a meta-network (26).

Quality control in multicenter networks is essential. Differences in the spectrum of allergens diagnosed in different centers should be compared to the group's average to identify possible methodological variations.

Due to the limited capacity of data analysis and quality control of the data of our registry, feedback in the form of standardized internal ESSCA reports presents a great opportunity for upgrading the data analysis and in particular the possibility of cooperation between contributing units of our registry and from other countries.

For example, comparison of the ´P´ measure (proportion of patients with at least one positive reaction to the baseline series as used in the department) shows that two of the six contributing units have a rather lower ´P´ measure with no apparent differences concerning sex and age, which indicates a par-

ticularly uneven and quite liberal indication for patch testing in Slovenia (28). Identified divergences are an excellent starting point for a unified selection of indications, technical implementation, and interpretation of results at a national level.

The presented electronic patch test network was created and currently exists as a voluntary project. Subsequent maintenance and planned upgrades of the registry will exceed the possibilities of voluntary work, and it will therefore be necessary to find independent financial support of our project in the future.

CONCLUSION

The objectives of creating an E-surveillance system on contact allergies were to provide multicenter collection of patch test results, immediate (regular) analysis and comparison of data, and monitoring of epidemiological trends over a given period of time.

The application is designed for the needs of dermatologists, whereby the main focus was rapid and easy data entry, data security, and the possibility of transferring and processing data to another central system. The application has worked flawlessly for five years, and it is used by all Slovenian units where patch tests are performed. The retrospective data from the
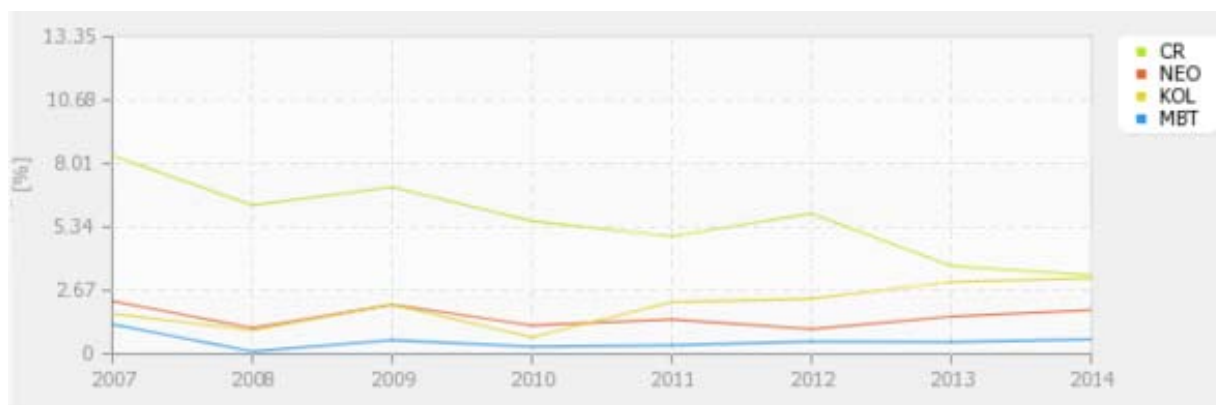

Figure 7. Display of time trend of the proportion of positive reactions to selected allergens for a selected period.

period of 2000-2010 were also entered in the register, which has enabled us to gain a realistic national epidemiological overview of contact allergy sensitization for the period from 2000 to 2015.

Transferring data to other systems has proven simple, as is evident from the recent transfer of data to the ESSCA network database (27).

The data is useful for further analysis and comparison with data collected in other countries (28-31). The web application is created in a manner that enables easy updates and upgrades.

Due to positive experience after several years of use, the application will be upgraded with further parameters useful for epidemiological analysis of patch test results with the MOAHLFA index and to design a similar application for a specific series of patch tests (cosmetic, hairdresser, dental, etc.) as well as for skin prick tests results, while at the same time paying close attention to keeping the application uncomplicated and time-efficient for the user.

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