



Past, Present, and Future of Contact Dermatitis Registries in the Internet Era

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Abstract

Purpose of review Digital data are invading all areas of our lives including medical practice. Digital technology grows up exponentially. Technical concerns as memory storage or processor speed are not limitations in medical data management and huge medical registries will be created in a short period of time. Epidemiological surveillance has been one of the most important issues in contact dermatitis research networks and adaptation to the new advances is mandatory.

Recent findings Digital technology can provide enough software to achieve research epidemiologic goals that were impossible 20 years ago. Legal concerns about confidentiality and simultaneous management of clinical data for daily workflow and for research are limitations of this advance.

Summary If clinicians want to update our contact dermatitis registries, it is vital to carry out two tasks: establish a standard for the variables required in the data registry and obtain Electronic Health Record programs that enable the simultaneous handling of standardized data at the clinical level and their export in real time to a referral center for epidemiologic surveillance and research.

Introduction

Contact dermatitis is an inflammatory cutaneous process produced after skin exposure to an external substance. Depending on the mechanism involved, it is classified as irritant or allergic contact dermatitis [1].

Patch testing is the main diagnostic tool to determine the substances to which patients may be sensitized and thereby possibly cause their allergic contact dermatitis. Whilst the individual result of patch testing is needed for the patient to be able to know which substances to avoid, epidemiologically, it is necessary to know the grouped data of these tests. This epidemiological

surveillance enables the establishment of the occupational or legal measures required to prevent the population being exposed to these substances. Indeed, awareness and analysis of the patch test results of each individual department is one of the main internal quality control measures for the method of performing the patch tests [2, 3•, 4, 5, 6, 7, 8].

Past

Contact Dermatitis Units traditionally recorded the results of their patch tests on spreadsheets, which later formed the basis for local, regional, and national studies [9••]. Once pooled, however, the lack of standardization resulted in a great effort to achieve homogenous data with a common format that could then be analyzed statistically [3•, 5, 10]. From a very simplistic viewpoint, we can say that the organization of the information derived from the contact dermatitis data can be summarized in two relational spreadsheets linked by a common patient identifier. One spreadsheet should contain the clinical data of patients and the other the positivities for the different allergens. With these two spreadsheets, we can extract the data needed to carry out the pertinent statistical studies.

Present

The arrival of the digital era has made access to clinical information much more fluid and efficient [9••, 11–16]. The information is no longer transcribed from paper to a file or a spreadsheet for processing [5], but rather the data are obtained from an electronic health record (EHR) [17]. To achieve maximum efficiency in medical electronic data capturing (EDC), one must assume the premise of “data loading must be just once” [18, 19]. This phrase is easy to comply with when performing billing and administrative EDC and for adequate clinical follow-up of patients. However, the raw clinical data from the EHR can very rarely be used directly for research purposes [9••, 20]. Interests in the different EDC platforms can vary and may enter into conflict. The hospital managers have as their prime interest the financial reimbursement of each clinical process. After that, there is the actual daily patient care work flow and lastly the exploitation of the data for research. Depending on the structure of the institution, there may be more or less interest in each of these levels. Unfortunately, in large hospitals, it is the economic interests of the managers that come first, and the data recorded in the EHR can rarely be used directly for research purposes.

The Departments of Dermatology, or Contact Dermatitis Units, can be divided into two large models concerning the organization and structure of the EHR: those that have their own EHR lodged locally at the Department of Dermatology (or Contact Dermatitis Unit) and those that have a general hospital-lodged EHR [9••]. In the former model, the clinical data introduced are useful for both clinical follow-up and for research, whereas in the latter

model, it is usually necessary to duplicate the entry of data, once for clinical follow-up and another time for a specific contact dermatitis registry [9••,12]. European legislation considers clinical data to be the property of the patient and health records are especially sensitive data in terms of confidentiality. Each country is gradually adapting its own legislation to make access and exploitation of clinical data stricter [21•]. It is just a question of time as each country in Europe progressively enacts this more restrictive legislation. Moreover, the implementation of any registry should consider the progressive national [22] and worldwide standardization of medical EDC to fully comply with the Health Level 7 standard concerning data transfer [23]. Accordingly, in the long term, EHR centralized at Departments of Dermatology will become less sustainable.

Multicenter studies on contact dermatitis have traditionally consisted of gathering spreadsheets from various centers to obtain the data needed for descriptive or analytical studies. Progress over the last 30 years in database programming has enabled this information to be collected more completely and efficiently using relational database programs, independently of whether the original data were on paper or in electronic form [11, 12, 14, 24]. These databases have now evolved to enable the data collected to be used for the clinical management of the patient as well as for scientific purposes. The best example of this synthesis is the multilingual software WinAlldat/ESSCA based on ACCESS (r)(Microsoft Corporation, USA). The European Surveillance System on Contact Allergies (ESSCA) is an expert open network conceived to establish a continuous analysis surveillance of pooled data of contact dermatitis in Europe [7, 9••, 16, 25]. The standard operating procedures of the ESSCA data center are described at http://www.essca-dc.org/doc/essca_central_SOPs_online.pdf. [26, 27]. This is now considered to be one of the most prolific working groups in contact dermatitis. Although the basic program is WinAlldat [28], it accepts data from other sources, provided they are organized in an ordered manner. The individual centers regularly send their data to a reference center entrusted with carrying out the statistical studies, the findings of which are used by researchers to draw conclusions [26].

The World Wide Web is the universally recognized transmission network [29]. Although national groups dedicated to contact dermatitis had already established research networks before the era of the internet, this technology has invaded our work space [2, 13, 24]. One of the main characteristics of the internet is that information can be transmitted easily and fluidly. Contact Dermatitis Units usually accumulate over a period of time (mostly 1 year) the patient data, which are then sent to a national reference center. Internet has allowed individual patient data to be pooled in real time at the national reference center [30]. This software is also able to report a possible adverse drug or cosmetic reaction to the National Medicaments Agency (Fig. 1). This versatility of internet may enable immediate and effective epidemiological surveillance, with no need to wait for the annual data to be accumulated and interpreted in order to assess a possible epidemiological problem [7, 9••, 16]. The great trouble with internet is data confidentiality. Health-related data lodged in contact dermatitis registries are especially sensitive. The rights of the patient to anonymity and replacement must be guaranteed. Registries must take special care to thoroughly anonymize and encrypt the data at source [21•].

Independently of the commercial program used, one of the most important aspects in the creation of database networks is the standardization of the data.

Fortunately, the method of patch testing is well established [31]. Data standardization in registries comprises two levels: one technical and the other semantic. The technical level concerns defining the minimum number of standard variables for the particular registry, the type of each variable (binary for sex, numerical for age, categorized for relevance ...), and, finally, establishing the different categories in the categorized variables [9••]. At the semantic level, all the investigators and data managers should know the meaning of each possible value of the registry data items. A particular problem in contact dermatitis registries concerns the introduction of the results of the allergens. It is necessary to record which allergens have produced a positive reaction as well as those that have resulted negative. As allergens are grouped in test series, the most efficient way to introduce the positives is to load the whole series at the same time, though the final exploitation of the data will be done by allergen [27, 28]. Whether or not the WinAlldat program is used, the ESSCA has proposed a standardized data collection worksheet that has proven very useful in the numerous studies undertaken so far. The clinical data recorded are easily understood by any researcher in contact dermatitis (Table 1) [9••, 25], and the use of the program R enables the information from the different departments to be extracted from various programs with different data for pooling and joint analysis. The 20-year experience of ESSCA has shown that any new contact dermatitis registry should be based on its minimal data sheet and categorization of data. But time passes and some minor deficiencies need to be improved. If we consider using the ESSCA minimum data sheet as the standard for future registries, there should be a clear definition of each possible value for each variable. This is especially relevant in those items related to the MOAHLFA index. What does "dermatitis" mean? Is it atopic dermatitis prior to patch testing, after patch testing, or both. What are "legs"? Is it stasis dermatitis or localized leg dermatitis [32]? The relevance categorization should also be better established. Definition of possible or probable relevance should also be clarified [33]. Another point of confusion is the allergen results. In WinAlldat, allergens are recognized by position in each test series, making extraction of the final data difficult. Although all these aspects can be resolved with minimal effort, the Achilles heel of the ESSCA Project in the digital era is that the data are accumulated at each center and uploaded yearly to the network node [28]. These data are then homogenized and analyzed, so that much time passes before conclusions can be drawn from all the data generated [9••]. Other internet-based systems have opted to upload the patient data at the time of testing directly to the centralized national registry [30]. This structure results in the reference center having the data regarding a certain issue much sooner. Likewise, including free-text items where keywords can be used enables real-time epidemiologic surveillance. Moreover, you may have a direct link to report an adverse cosmetic or drug effect to the National Medicament Agency (Fig. 1). Finally, the data collection platform in internet can be modular, with the ability to undertake prospective studies adjusted to a particular topic with an "ad hoc" design, impossible to elaborate in the retrospective studies currently undertaken [34, 35]. Today, the problem with those platforms is that it is necessary to duplicate the load of data [12, 29, 30]. The ideal registry program for contact dermatitis would enable management of the clinical data and export them to a reference center research unit in real time. Although this is feasible with the current technology, legal questions exist that make it very difficult.

Table 1. Variables to be included in the Registry

Basic variables	Type	Comment
Country	Integer (Pseudo)	International phone code
Province/state	Integer (Pseudo)	Postal code
Date of test	Date	
Patient identifier	Integer	Anonymous; encrypted
Consultation identifier	Integer	Anonymous, identifier of consultation
Age	Integer	Year; post analysis dichotomized into < 40 and > 39 as source of MOAHLFA
Sex	Binary	
Occupation	Integer (Pseudo)	After the ISCO-08; present occupation; consider previous occupations Consider time in present occupation and previous occupation
Occupational factors	Binary	Source of MOAHLFA
Atopy	Binary	Atopic dermatitis present. It is mandatory a previous definition. Source of the MOHALFA
Anatomical site (s)	Category	Consider initial localization as category and/other localizations. Source of MOAHLFA; definitions required
Time of symptoms	Integer	Time of symptoms previous to the study; months
Allergen category	Category	Product categories of possible contactants
Allergen tested	Category	Codified from a general table or a series table. Baseline series necessary
Positive allergens	Category	Possible results of each contactant. Positive as well as negative For statistical purposes only consider last reading
Relevance of positive allergens	Category	Causal relationship between the dermatitis and the positive test
Final diagnose (s)	Category	One or various
Additional variables		
Own products	Free text	Consider using categories: commercial fragrances, cosmetics, topical drugs...
Test method	Category	Usually patch test. Consider ROAT, Prick.
Series tested	Category	
Intermediate test lecture(s)	Category	
Internet additional variables		
Prospective module	Category (with subcategories)	Able to introduce a series of items for a period of time.
Causal Interpretation	Free text	Interpretation of results Use keywords for real-time surveillance.
Cosmetic/drug severe side effect	Link	Direct link or to a table to be exported to the Drug National Agency Other links may be suitable for other registries.

Page ☐ Save as Complet **Next** Log Out

Occupational Factors ☐ Yes ☐ Partly ☒ No ☐ Unknown Occupational Dermatitis. "Partly" means that work worsens the dermatitis but is not its cause. Required.

External Factors ☒ Yes ☐ Environmental ☐ Leisure activities ☐ No ☐ Unknown Other exogenous factors (No Occupational). Required.

Contact Categories (Max. 3)

☐ Tools (metal, wood, plastic)	☐ Medical : Drugs, external	☐ Metal others as coins ...	☐ Glues
☒ Clothing, textiles	☐ Medical : Drugs, internal	☐ Food (and additives), skin contact	☐ Plastics
☐ Clothing : Shoes, boots	☐ Medical : Material , suture , gel ...	☐ Plants (Not food)	☐ Office Material
☐ Clothing : Gloves	☐ Medical : Desinfectants	☐ Pesticides, herbicides, ...	☐ Leather (other)
☐ Cosmetics : Leave on products	☐ Medical : Dental Prostheses	☐ Cleaning agents (detergents)	☐ Rubber (other)
☐ Cosmetics : Rinse off products	☐ Medical : Dental Filling (Amalgams ...)	☐ Building material	☐ House dusts
☒ Cosmetics : Hair Products	☐ Medical : Metal Implant	☐ Woods	☐ Cutting fluids (water based)
☐ Cosmetics : Nails	☐ Metal (worked with)	☐ Paints, laquers	☐ Neat oils, greases
☐ Cosmetics : Perfume , deodorants	☐ Metal jewellery	☐ Solvents	☐ "Other" chemical
☐ Not classified			

REPORT SEVERE ADVERSE EFFECT : The report sheet will appear after checking "Yes"

Is there any severe effect after the contactant exposure? ☐ Yes ☒ No ☐ Unknown **SEVERE EFFECT DEFINITION**

- Produces death	- Produces severe or permanent disability
- Presents an immediate life risk	- Produces congenital malformations
- Needs or prolongs hospitalization	- Severe events that may conduce to the previous situations if not treated

Related Findings Text Field. "Key words" may be used.

Interpretation

Fig. 1. Screenshot of the Registro Español de Investigación en Dermatitis y Alergia Cutánea. The single arrow presents a link to the Spanish Drug Agency. The double arrow presents a free text variable where "keywords" can be loaded for an immediate epidemiological problem (Reference 30).

Future

Digital technology is advancing exponentially [36], such that problems existing a few years ago, like massive data storage or processor speed, are becoming less important than data processing [17]. To have homogenous data requires accepting an EDC standard for all centers in all countries in all continents. Here, we should be grateful to the ESSCA for their minimal datasheet. From the author's own personal viewpoint, the items and their categorization are admirable, though if we wish to establish a standard valid throughout the world, the allergen codes should also be standardized. A possible solution to this issue is to standardize all the commercial allergens available. Categorizing these allergens would just require adding a prefix to the commercial codes of the allergens. For example, Chemotechnique® allergen COS-001 could be CH-COS-001 worldwide [37]. At some point after data collection, the equivalent contactants from the different manufacturers would be pooled together. A point of special relevance in contact dermatitis is "occupation." In this case, we have to be guided by the universally recognized standards of ISCO-08. Its coding, graduated in 4 digits, is perfect to adjust the professional categories. Although it is based on payment and not on exposure, it is the recognized standard in all

occupational registries worldwide. In the ISCO 08, a common exposure, as in the Construction Industry, is separated into managers or laborers according to the different payment scales. This represents additional work after the data collection [38].

Another point of interest is the direct uploading of data for simultaneous use in both the clinical setting and research [20]. In the same computer used for clinical follow-up, screen forms must be developed in order to simultaneously store data in the institutional database and export the data to a central contact dermatitis registry accessed via the Internet. As mentioned above, technically, this is quite feasible, but at the present time, there are legal problems concerning patient confidentiality that make it extremely difficult. Whilst this situation persists, the centralized registries must be able to store individual patient data as well as import aggregated data from any contact dermatitis unit.

Finally, we are in the era of "big data" [36]. All health registries accumulate vast amounts of data necessitating mathematical management that exceeds the skills of the clinicians [39]. So far, most studies on contact dermatitis have been based on comparing the frequencies between patient groups or over periods of time. This large amount of available data enables us to establish mathematical models that are more useful than just the simple comparison of frequencies [40]. Validated mathematical models with a considerable number of variables, which would have been impossible 20 years ago, should be explored [3•, 41]. Predictive models may be the mathematical approach with the greatest application in contact dermatitis [42]. These models establish the pondered likelihood of having a positive test in relation to the factors studied. The positive test can be for a specific allergen or any of the categories on the minimal datasheet, such as occupation or localization. Other possible mathematical models can be based on time or geographical issues [43], with important consequences in the taking of decisions to improve our clinical practice, population health, and the entire health system.

Conclusion

Information management is invading our contact dermatitis clinics. If we wish to progress satisfactorily in this field, it is vital to carry out two tasks: establish a standard for the variables required in the data registry and obtain EHR programs that enable the simultaneous handling of data at the clinical level and their export in real time to a referral center for epidemiologic research.

Compliance with Ethical Standards

Conflict of interest

Leopoldo Borrego declares that he has no conflicts of interest.

Human and animal rights and informed consent

This article does not contain any studies with human or animal subjects performed by any of the authors.

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- Of major importance

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