

THE BEAUTY OF SAS® IS MORE THAN SKIN DEEP PATCH TESTING PROTOTYPE II APPLICATIONS DEVELOPMENT

Charles Wilson, Mayo Clinic
Arnold Schroeter, Mayo Clinic

INTRODUCTION

Each year Mayo Foundation's combined facilities in Rochester, Jacksonville and Scottsdale perform over 50,000 skin patch tests, on over 750 patients. These tests are done to diagnose and treat contact dermatitis. Mayo's patch test data set is among the world's largest.

Dermatitis accounts for perhaps 25 percent of patients seen in many dermatologist's offices; half of these patients suffer from contact dermatitis (1).

CONTACT DERMATITIS: Often called eczema, contact dermatitis affects millions in the United States. Contact dermatitis results from irritations or allergies caused by over 3000 known ingredients, chemicals, substances or compounds (2, 3). This disease takes the form of inflammation, color changes, swelling, blisters, or itching, and is caused by occupational or non-occupational skin contact (3). Common examples are poison ivy and dermatitis from Nickel in ear rings.

PATCH TESTING: Patch testing is done to identify the causes of contact dermatitis. Antigens, which are small amounts of ingredients, chemicals, substances and compounds, are applied to healthy skin. At two days, patches are removed and skin is examined for two days to evaluate reactions. Reactions are scored and most are negative. Afterwards, dermatologists make historical correlation and post-test conclusions. If patients react to patch test antigens, this may or may not mean the antigens caused the dermatitis. Antigens are usually listed in a series format. These series are often associated to the occupations, locations of dermatitis, medications used or products suspected (4).

Over 15 years ago Mayo Clinic Department of Dermatology instituted its first patch testing data base. Dermatology, working with Mayo statisticians and programmers, used SAS® exclusively. From 1980 through 1992, over 3000 patient-observations were entered. Analysis of this data is an important contribution to dermatology. This data is used and referenced in a number of professional publications (4). However, drawbacks became apparent.

PROBLEMS IDENTIFIED

Anticipating a need for more advanced and refined computerization, with additional biostatistical features, these four major problem groups were identified:

- I. **FORMS:** Usage, space and communications problems exist with current forms.
- II. **DATA MANAGEMENT:** Methods gathering, entering and retrieving data reveal multiple problems.
- III. **ANTIGEN DUPLICATION:** Duplicate antigens are common throughout multiple series; locating them is difficult. Duplicate notation is inconsistent.
- IV. **STAFFING:** Human resources are wasted with redundant and repetitive tasks. Excessive time is spent communicating grading and form methodologies, which are often misunderstood by dermatology and other medical personnel.

DEVELOPMENT OVERVIEW

Between January of 1994 and January of 1995, future goals, details of past dermal biostatistics and review of options within Mayo for applications development, were discussed. Literature revealed further insight.

A visit to a Mayo scratch testing lab previewed an existing skin testing, with form printing application.

All of this illuminated the needs, desires and goals unique to Mayo dermatology patch testing procedures.

The scratch testing application and the proposed patch test system, to be developed within Mayo, did not have the desired dermatologic biostatistical capabilities.

SAS software is used frequently at Mayo. After discussing potential solutions with Mayo statisticians, SAS appeared to be the answer to our patch testing problems; if costs, features and time met department parameters.

A packet containing goals, summary and examples of forms for a proposed patch testing computerization plan was compiled and presented to the department.

The plan gained approval in early 1995.

In March of 1995, written agreements were reached with SAS to develop a comprehensive patch testing application that would function within the SAS 6.10[®] PC environment.

PATCH TESTING PROTOTYPE I

During the pre site visit, preparation stage, on-site work was greatly diminished because communications and the mailing of background information to SAS Consulting[®], and SAS Consulting using standard and electronic mailing of code to Mayo.

The first prototype was developed between March and November of 1995. This included a site visit of two and a half days, which ending November 9, 1995.

Patch Testing Prototype I, a comprehensive, low-cost, user-friendly application, became functional for testing on November 9, 1995.

PATCH TESTING PROTOTYPE II

The Patch Testing Prototype I product functioned well, effectively solving problems communicated to SAS.

Yet, after testing the product, a few unforeseen problems surfaced.

After problem definition and possible enhancement-solutions were identified, a new contract was written.

Problems were solved by SAS Consulting with enhancements to Prototype I; this developing into the Patch Testing Prototype II product now used.

Prototype II developed with off-site consultation.

- All code was mailed on diskette.
- Communications by e-mail and phone.
- Debugging, testing and minor code changes done by Mayo Dermatology.

TESTING AND FACILITATION SUCCESS

Patch Testing Prototype II became functional for testing in March of 1996. Fictitious patients in various series and antigen scenarios were tested. Some additions were made to data set variables.

The application was presented to staff in several phases. Dermatologists attended the final pre-facilitation conference on June 28, 1996.

Patient survey and working forms methods was refined. July 2, 1996, the first patient was processed using Prototype II. The first history form was printed on July 8, 1996.

Successful completion of Prototype II included these enhancements:

- User-friendly data entry screens.
- Ability to key in a list of miscellaneous, non-series, in-stock or non-stock antigens or products.
- Font size increases, in view of an aging population and projected reading difficulties with smaller fonts.
- Miscellaneous graphics changes.
- Development of macros, sending some data to the printed history form, all to PC memory, and all to mainframe SAS data sets, as backup.
- Elimination of handwriting on Patch Testing Forms
- System categorization of patch test antigens and identification of duplicate antigens.
- System categorization of patch test antigen series in a numerical format, for unique identification.
- Administrator capabilities to add, edit and update patch test antigens, and to add new series.
- Functional connection with SAS Assist[®], allowing lay-staff dermal biostatistical options.
- Labor-saving default negatives; most patch tests are negative. Scoring not negative needs changing.
- Printing Mayo's 6 ³/₄ x 9 ³/₈ or 8 ¹/₂ x 11 forms.

MICRO-MANAGING PROBLEM GROUPS

The unique set of defined problems, identified before and during the development of Prototype II, are an interesting example of solution micro-management. Minute details that appeared remotely problematic, were noted, discussed and prioritized, then presented to SAS Consulting for solution.

These problems, separated into the four general groups, show successful problem-management leading to successful, cooperative, applications development.

PROBLEM GROUP I-FORMS:

Usage, space and communications problems exist with current forms.

Past patch testing procedures within Mayo Dermatology were characterized by forms equal to, or surpassing, the quality, diversity and appearance of those found in patch testing in the United States.

However, as Mayo dermatology prepares to embrace of computer technology, the three versions of these printed forms used from 1980 to 1996 revealed these problems:

- Mayo's history form, 6 $\frac{3}{4}$ " by 9 $\frac{3}{8}$ " is an unusual printer and application size.
- Repetitious information, including date, physician's name, pager number, code of person completing the form, patient sex, age, occupational code and in-patient status is often handwritten on forms.
- Most skin tests are negative or have no results. Yet this repetitious information must be noted in each skin test and each daily scoring.
- The average number of tests per patient would require only the space on the front and back of one Mayo history-size form, however, an average of over two forms are used per patient.
- Forms are placed in the Mayo history pocket, wasting precious space within this unit with multiple forms and some non-tested patch test series. Forms have several sets or series of skin tests on one form. Most of the time the patient is patch tested for half or fewer of the antigens listed.

- Patch test series are pre-printed on forms with a minimum of two patch test series on each form. Series are printed on 22 different forms, with at least two patch test series per form. The two or more series listed on each form are not often tested together. One series called Carba Mix, is made up of only four antigens. Using that series, you must use a whole form, crossing off four series not tested.
- While unused patch test series must be crossed off, used series must be highlighted for communication. An incipient problem arises because patients see one or more series is crossed-off. Patients may not understand why all tests appearing on forms were not done. Especially if they were negative to skin tests and desired answers to their dermatitis.
- Except for handwritten editing, patch testing is bound to the series of patch test antigens listed on existing forms. Creation of new series would require approval of new forms. Once printed, changes require considerable effort because of needs to have the forms re-approved with any changes.
- Except writing up the current forms by hand, there is no way to prepare forms in advance. Patients sometimes cancel or do not arrive, wasting forms.

FORMS SOLUTIONS:

Prototype II solved all defined forms problems.

Laser printed history forms are used, there is no handwriting on these forms.

Up to 145 patches can fit on the front and back of the laser-printed form.

Although an unusual size, the option of a B5 envelope is very close in size, Prototype II prints the form.

Prototype II has system default negatives. Also, the system locates and notes duplicates. This increases communication of test results.

Printing of work sheets can be done in advance of patch testing to save time when the patient arrives. Worksheets guide personnel through the setup of patch test. Since no antigens or series need to be crossed off, time is saved, and communications are improved.

PROBLEM GROUP II-DATA MANAGEMENT

Although Mayo Department of Dermatology began using mainframe SAS data sets, including versions 5 and 6 starting in the 1980s, lack of defined requests and attention to retrieval goals, hindered requests for patch testing dermatological biostatistics.

- Mayo Derm lacks a user-friendly system to enter data into SAS data sets. When entering data, the desired series may be on the 20th screen, while patient information is on the first.
- Dermatologists busy with clinical duties had little time for study data organization, and a designated patch test data administrator not assigned. Further, miscommunication in type of analysis, studies and data exists between dermatologists and statisticians.
- A tedious method of ordering correlation and statistics from statisticians in another department can hinder obtaining timely information. These statisticians followed Mayo guidelines, sometimes putting dermatology requests of a low priority.
- Hand calculating periodic patch totals is tedious and subject to human inaccuracies.
- Completion of patch testing forms by hand, and entering data later, diminishes incentive to perform the task of data entry.
- To continue using SAS as the software of choice and to access, import and upgrade data from the two former versions of SAS used.
- Filling out forms by hand and then data entering them later is duplicated staffing resources
- Staff time is required for the writing of over 20, 000 negative scores each year.

DATA MANAGEMENT SOLUTIONS

Prototype II solves all data management problems.

The application has user-friendly data entry screens.

Former data sets in SAS versions 5 and 6 can be accessed and converted. Inclusion and comparison are conceivable of all data back to 1980.

Although miscommunication of type of analysis, studies and data may still happen, SAS ASSIST allows lay-staff to experiment and produce correlation and other dermatologic-biostatistics in with an ever increasing level of precision and knowledge.

We can now enable lay staff to learn and use SAS Assist. Awareness and understanding of the lay-user potential of SAS Assist, created stimulus to gather an expanded set of data.

We are now able to subset and expand the type and number of variables in data sets with ASSIST, and able to merge data sets for correlation.

PROBLEM GROUP III-ANTIGEN DUPLICATION

Duplicate antigens are common (there are over a hundred duplicate antigens in 50 different series) throughout series.

These specific problems result from this:

- Antigens are often in several series at Mayo and other dermatology facilities. Because of this, duplication is easy to overlook.
- When setting up more than one series per patient, it takes needless time and attention to locate and note duplicates.
- There are no methods to note, mark or identify duplicates or deletions on forms.
- Duplication of skin tests may cause over-charging
- Inconsistent spelling of antigen names and using antigen synonyms may increase duplication.
- Human error and lack of knowledge of these where these duplicates are within series can cause ordering problems.

ANTIGEN DUPLICATION SOLUTIONS

Duplicate search and noting function in Prototype II:

Finds duplicates and notes them with a consistent, simple, and department approved method.

Prevents accidental overcharging of patients.

Communicates identified duplicates and deletions.

Can be used to seek out duplicates for designing new patch test series. These series may be used together and can be used without having duplicate antigens.

PROBLEM GROUP IV-STAFFING

Although human resources are wasted with redundant, repetitive and needless tasks, problems and solutions to these are scattered throughout the three other defined problem groups.

Human resource savings will be hard to calculate because although there may be less form-completion time, there will be more computer hours.

Furthermore, although there are savings in the tasks and methods with Prototype II, the intended method and attention paid to data gathering and accuracy may commit additional staffing to tasks not formerly done.

MAYO PATCH TESTING. LOOKING AHEAD

Prototype II use in Rochester precedes future use in other facilities. Standardization of series, antigens and procedures are goals we hope will be easier to accomplish with the use of Prototype II in all Mayo Dermatology facilities.

Location comparison biostatistics and general geographic correlation will be made easier with SAS ASSIST and SAS MAP®.

When Prototype II began use, Mayo Dermatology also began using a new method of scoring patch reactions and other new numerical scoring of survey answers, which are data set variables.

While these scoring problems were not steps in the development of Prototype II, their facilitation in conjunction with the Prototype is strategic.

We believe some of the numerical scoring methods and numerical quantifying of data may prove to be new to the procedure of dermatology patch testing.

Since numerical grading is logical and quantifiable. Numeric variables in the data set should hypothetically allow more precise correlation between variables.

CONCLUSION

Patch Testing Prototype II is one of a kind in dermatology patch testing.

One form replaces an average over two per patient.

With this great tool, patch test forms are easy to read; communicating patch test results clearly to medical personnel.

Only series and antigens tested appear on this form.

Savings in human resources are accomplished with system location of antigen duplicates, system assignment of default negatives, and ability to prepare forms in advance of busy days without printing a worksheet until the patient arrives. These features relieve users of some mundane tasks.

Furthermore, Mayo dermatology can collect and study biostatistical data, greatly contributing to the diagnoses, understanding, and treatment of those afflicted with allergic and irritant contact dermatitis.

REFERENCES

1. Fischer, T. & Maibach H., Improved, But Not Perfect. Patch Testing. American Journal of Contact Dermatitis, 1:73, 1990.
2. Hogan, Daniel, et. al. (1994). Occupational Skin Disorders, New York: Igaku-Shoin.
3. DeGroot, A. (1986). Patch testing. New York: Elsevier.
4. Guin, Jere (1995). Practical Contact Dermatitis, New York: McGraw-Hill, p. 41.

Author may be contacted at:

Charles Wilson
Mayo Clinic
Department of Dermatology
MA_E5B Patch Testing
200 First Street SW
Rochester, MN 55905