

Measurement of a possible patch-testing outcome indicator

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Background: Clinical performance measurements often employ outcome indicators to express the extent to which health services achieve a given clinical result.

Objective: The objective of our study was to develop an outcome indicator of patch testing. We identified and measured as a possible indicator the ratio of patients with allergic and/or photo-allergic contact dermatitis clinically cured/improved as a result of identification of relevant allergens.

Patients/Methods: Patients with positive reactions considered relevant to their current dermatitis were interviewed by telephone 2 months after patch/photo-patch testing in order to assess their clinical outcome in relation to the recommended elimination of supposedly relevant allergens.

Results: Over a 4-year period positive reactions were seen in 1397 out of 2857 tested patients. Relevance was considered current in 578 subjects, and 506 of them were interviewed.

Remission/significant improvement following allergen(s) contact avoidance was reported by 431 patients, the outcome indicator (431/506) thus scoring 85.2%. Among the 75 patients who reported no improvement, 41 had not avoided contact with the offending substance(s), 17 had other persistent concomitant skin conditions, and 17 were unchanged despite elimination of the alleged relevant allergens.

Conclusions: The ratio of relevantly patch-test-positive patients resolved/improved after allergen avoidance is a useful patch-testing outcome indicator.

Key words: Allergic contact dermatitis; follow-up; outcome indicator; patch test; performance measurement; perspective study; relevance. © John Wiley & Sons A/S, 2010.

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Developing ways to measure the clinical performance of health care services has become a major concern for health care providers in recent years (1, 2).

In 2003, in the context of a large project concerning quality improvement undertaken by the Azienda Ospedaliera Universitaria San Martino of Genoa, using internationally accredited approaches to quality management (3), we were asked to develop an outcome indicator appropriate for contact allergy work. In practice, the ability of contact clinic professionals to spot relevant patch test reactions is a crucial diagnostic step that can directly influence the clinical outcome of patients with allergic

contact dermatitis. A simple outcome indicator of patch testing could thus be the percentage of tested patients whose dermatitis resolved/improved following the identification of relevant allergens. However, not all patients referred for patch testing actually have allergic contact dermatitis but have a variety of different diagnosis and the prevalence of these needs to be determined.

Materials and Methods

Between January 2004 and December 2007, 2857 consecutive patients were referred to our contact clinic for patch and/or photo-patch testing. Referral

sources included general practitioners (12%), doctors in general dermatology clinics (53%), consultants or registrars in our own department (27%), and other specialists (8%). All patients were routinely submitted to careful history taking based on specially designed questions. Patient details, including information about possible sources of allergen exposure, present patch test results, concomitant or previous investigations and likely differential diagnosis, were prospectively recorded.

2750 patients were patch tested to the Società Italiana di Dermatologia Allergologica Professionale ed Ambientale (SIDAPA) baseline series, with additional series or own materials added where suggested from the history. Allergens were applied to healthy skin on the backs using Haye's® Chambers (HAL Allergen Lab.B.V., Alphen aan den Rijn, The Netherlands), and left for 2D. Allergens were from F.I.R.M.A. S.p.A.® (Firenze, Italy) and Brial® (Greven, Germany). Readings were undertaken at 2D and 3D. An additional reading at D5 or 7 was performed in specific cases when the D3 reading was negative but the history was suggestive of contact allergy to allergens known to give late positive reactions (4). Reactions were scored according to the criteria of the International Contact Dermatitis Research Group (5). When needed, repeated open application tests (ROATs) or use tests, as well as prick tests, were also performed (6).

In a number of patients referred for standard patch testing, patch tests were supplemented by photo-patch testing to one or more specifically suspected substances (mainly ketoprofen). 117 patients underwent complete photo-patch testing, performed according to standard methodology (7).

At the end of patch testing, the clinical relevance of positive reactions was determined based on individual clinical history and pattern of dermatitis. Relevance was defined as current (the patient was exposed to the allergen during the current episode of dermatitis), past (past episode of dermatitis from exposure to the allergen), or unknown (unexpected result, possibly due to unidentified or sub-clinical exposure). In turn, current relevance was defined as certain, probable, or possible, based on the degree of evidence of the dermatitis being caused by a given allergen (8). Allergic reactions relevant to present dermatitis were divided into primary cause or aggravating factor. All patients with positive reactions were given thorough explanations about the nature of their allergy and the possible sources of exposure to the offending allergens.

At the end of every working week, the contact clinic staff, comprising a consultant, a registrar, and a nurse, briefly reviewed the patients' patch test results, history, clinical presentation, and differential

diagnoses. Based on these data, the possible diagnosis of patients with negative or non-relevant positive reactions was classified following the flow chart shown in Fig. 1.

Patients identified as having positive patch test reactions relevant to present dermatitis were scheduled to be interviewed by telephone within two months of patch testing. Interviews, carried out by the registrar, were structured so as to identify possible biases due to difficulties patients might have had in understanding the explanations/instructions received at the end of patch testing and in identifying allergen sources and avoiding allergen exposure in everyday life. They focussed on the following questions: Is your dermatitis better? Did you find patch testing useful and our explanations clear enough? Do you remember the name of the substance(s) you are allergic to and the sources of exposure? Was it difficult to avoid exposure? If yes, why? Are you still using topical steroids or other medications?

The mean interview time was 10 min per patient. Patients who could not be contacted after five attempts (at different times of the day during at least two different days in a two-week span) were considered lost to follow up. Patients who declared themselves unimproved were invited to come back for clinical examination. Based on the results of the interviews, current relevance of positive reactions was re-evaluated and the rate of patients resolved/improved, thanks to patch test identification of relevant haptens, was calculated.

Results

Patch and/or photo-patch test results are summarized in Fig. 2. ROATs, performed in 37 patients, resulted positive in 16 cases, dubious in 2 and negative in 19. Use tests, performed in 13 patients, were positive in 5 cases, dubious in 4, and negative in 4.

Overall test results were either negative or non-relevant in 2279 patients (80% of total tested patients) whose likely clinical diagnoses are shown in Table 1.

Of the 578 patients with positive reactions relevant to their present symptoms, 390 were female and 188 male, 5–89 years old, with a mean age of 46. Overall, out of 966 positive reactions scored as relevant, 759 (78.6%) were to standard allergens, 144 (14.9%) to non-standard allergens and 63 (6.5%) to photo-allergens. Multiple relevant reactions were seen in 197 patients. Sixty-three out of 430 patients tested with their own products/materials were relevantly positive to one or more of them. The responsible allergens were unidentified in 39 cases. In a

few cases, break-down testing with product ingredients allowed identification of rare allergens (9–11). Current relevance was considered certain in 170 patients, probable in 179, and possible in 229. Exposure to relevant allergens was occupational in 75 cases (13%). In 86 (15%) patients contact allergy appeared to be the aggravating factor of other concomitant skin disorders.

506 out of 578 patients answered our interview, while 72 (12.4%) were lost to follow up: 231 (40%) patients reported complete remission and 200 (34.6%) significant improvement of their dermatitis following allergen(s) contact avoidance (Table 2). In 75 (13%) patients the dermatitis was unchanged or worse: 41 of them had not avoided contact with the offending substance(s), 18 for occupational reasons, the others mainly due to lack of compliance or poor understanding of the instructions received. Exposure was unavoidable in two cases (one airborne, the other from a tattoo). Clinical examination revealed that 17 out of the 75 'unimproved' patients still suffered from some other concomitant skin affection, while the allergic contact dermatitis component was no longer present. In 17 patients the clinical picture was actually unchanged despite careful elimination of the suspected allergens, and the diagnosis of present contact allergy from these substances was reviewed as wrong/unlikely. The outcome indicator, calculated as the ratio of patients with alleged relevant reactions healed/improved after allergens avoidance (431/506), scored 85.2%. Most patients, including some of the unimproved ones, considered patch testing useful and appreciated the interview as a positive additional aspect of care.

Discussion

Clinical performance evaluations often rely on the measurement of outcome indicators. An indicator expresses the extent to which health services achieve a given clinical result and is generally defined as a proportion, for example the proportion of hypertensive patients in whom blood pressure control has been achieved, thanks to a given intervention strategy (1). As outcomes are influenced by definitions, data quality, patient case-mix, clinical quality of care, and chance, all sources of variability need to be considered in both developing and using indicators to prevent otherwise misleading judgements about the elements of care under examination (12).

The main purpose of contact clinic work is to differentiate allergic contact dermatitis from other kinds of dermatoses and to identify the responsible allergens. Patch testing, the mainstay of contact clinic work, is considered an essential investigation in eczematous skin diseases, where contact allergy

is suspected as a causative or contributing factor, and detection of relevant allergens is crucial for appropriate prevention and treatment (13). It has been shown that, by helping to diagnose the aetiology of allergic contact dermatitis, patch testing reduces the cost of therapy, reduces absences from work, and considerably improves patients' quality of life (14–17).

As the ability to identify contact allergens can directly influence the clinical outcome of patients with allergic contact dermatitis, a simple outcome indicator of the clinical performance of contact allergy services could be the ratio of patch-tested patients resolved/improved because of identification of relevant allergens. However, a number of important variables must be taken into account.

First, not all patients referred for patch testing actually suffer from allergic contact dermatitis. Indeed, many have irritant or endogenous eczema, the two principal differential diagnoses where patch testing is indicated (18), but also, as in this study, a wide range of other unrelated diseases. Apart from atopic dermatitis, which is included in the MOAHLFA index (19), the prevalence of indications other than contact allergy in patch test populations has never been previously evaluated. However, their impact on patch test outcomes can be partly inferred from the different frequencies of positive reactions reported by centres participating in contact allergy surveillance studies (20).

It has been observed that standard screening series can spot up to 70% of relevant allergens (21) and despite variations in time and from country to country, the baseline series appears to be a rather stable and valid screening tool (20, 22). The sensitivity of patch testing is increased by problem-based testing with additional potential sensitizers (23).

In a number of cases patch test results can be falsely negative due to inadequacy of test methodology. The precise proportion of these patients is, in practice, unpredictable and can only be assumed based on clinical and historical data. This requires an effort, on behalf of contact clinic professionals, to identify possible errors. On the other hand, patch test results can also be falsely positive. Some allergens tend to give irritant reactions sometimes difficult to differentiate from allergic ones, particularly by inexperienced observers (24).

Another bias is represented by positive reactions not relevant to the patient's present complaint. This is a crucial and very difficult point to define: the clinical relevance of positive reactions is often at risk of being both over- and under-evaluated, and inter-observer scoring variability is likely to occur (25, 26). In some cases substantial improvement after allergen/s avoidance can confirm the otherwise dubious current relevance of positive reactions.

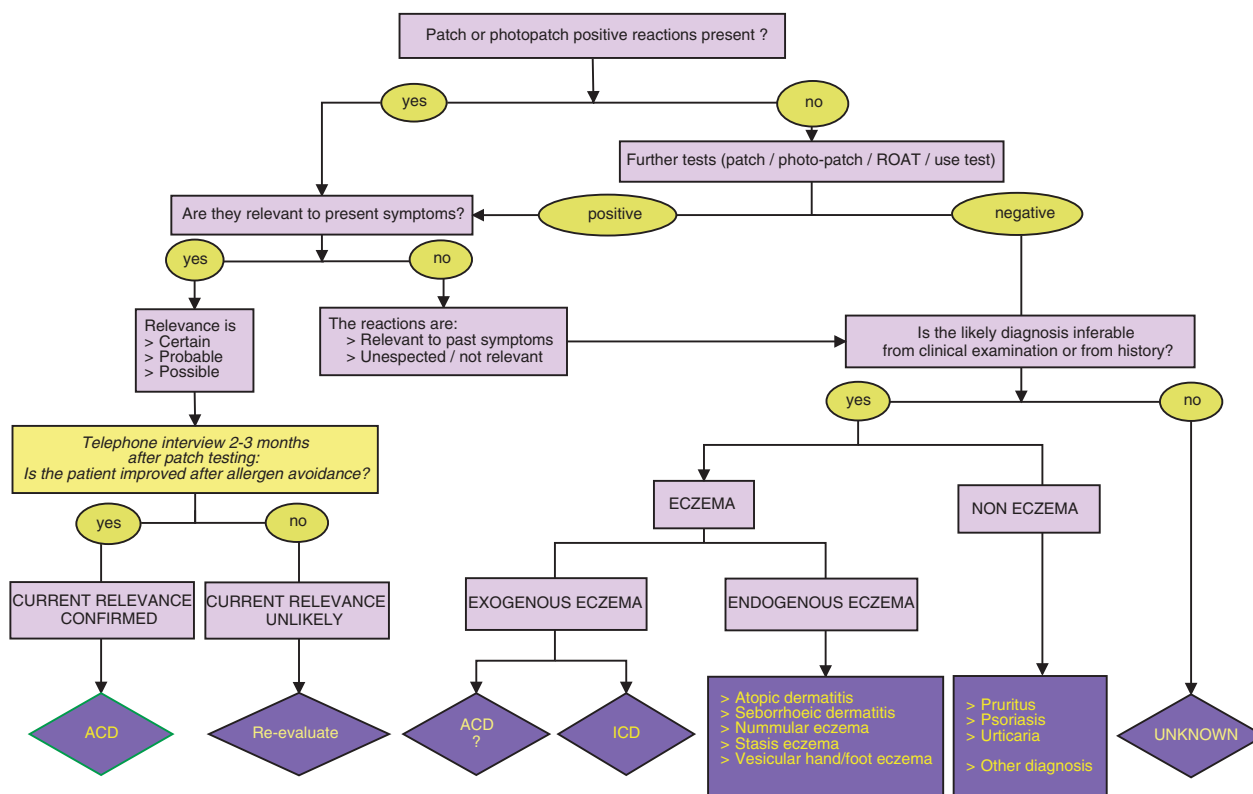


Fig. 1. Diagram illustrating the method followed to infer the likely differential diagnosis of patients referred for patch/photo-patch testing. ACD: allergic contact dermatitis (or photo-allergic contact dermatitis). ACD?: probable ACD (or photo-ACD) to unidentified allergen. ICD: irritant contact dermatitis. Other diagnosis include: lichen simplex chronicus, rosacea, mycosis, polymorphic light eruption, folliculitis, intertrigo, perioral dermatitis, burning mouth syndrome, parapsoriasis, xerosis, lichen planus, macular drug eruptions, multiple chemical sensitivity syndrome, impetiginized HSV infections, Duhring disease, Grover's disease, pemphigus vulgaris and oral pemphigoid.

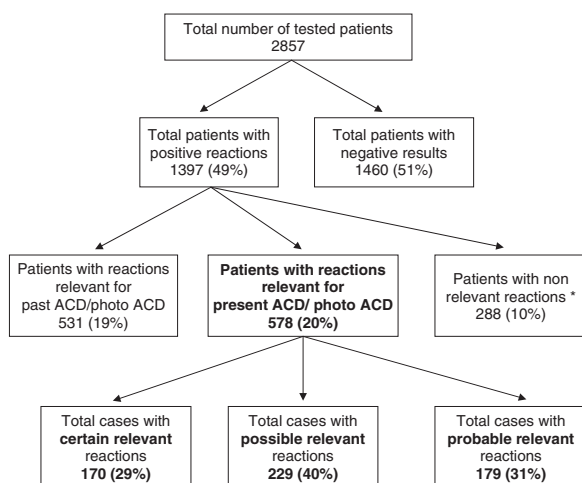


Fig. 2. Flow chart showing the overall patch/photo-patch tests result.

*Weak reactions with no apparent relevance to present or past dermatitis. ACD—allergic contact dermatitis

As, after patch testing, many patients return to their referring doctors, contact clinic professionals often lack information about their clinical outcome. The number of patients whose dermatitis

has resolved/improved after elimination of alleged relevant allergens can be verified by interviewing patients after a period of time sufficient to allow improvement of allergic contact dermatitis if contact with the offending allergen is avoided. Two to three months after patch testing seems a reasonable time, though in a few cases a longer time might be necessary. Studies on quality of life in patch-tested patients report follow-up evaluations performed at 6–12 months (13, 16). Patients can be interviewed by telephone and it is important to ask them questions designed so as to identify difficulties they might have had in understanding the explanations/instructions received at the end of patch testing and in identifying allergen sources or avoiding allergen exposure in everyday life. Patients who report persistent symptoms in spite of allergen avoidance should be submitted to clinical examination to verify possible coexistence of other skin diseases.

By interviewing patients after patch testing, contact clinic professionals can not only verify their clinical outcome, but also obtain useful feedback about their own accuracy in evaluating relevance, a skill universally recognized as difficult

Table 1. Clinical diagnosis of 2279 patients (80% of all patch-tested patients) with negative or non-relevant patch/photo-patch test/ROAT results

Clinical diagnosis		Number of patients	% of total patients
Exogenous eczema	Possible ACD from unidentified allergens	105	4
	ICD	285	10
Endogenous eczema	Atopic dermatitis	331	22
	Vesicular hand/foot eczema	108	
	Nummular eczema	67	
	Seborrhoeic dermatitis	89	
	Stasis eczema	29	
Non-eczema	Pruritus/prurigo	173	39
	Psoriasis	149	
	Urticaria ^a	148	
	Other ^b	654	
Unknown	No dermatitis present, nature of past problem not inferable from history	141	5
Total		2279	80

^aInclude seven cases of allergic contact urticaria from natural rubber latex (prick-test-positive).

^bInclude lichen simplex chronicus, rosacea, mycosis, polymorphic light eruption, folliculitis, intertrigo, perioral dermatitis, burning mouth syndrome, parapsoriasis, xerosis, lichen planus, macular drug eruptions, multiple chemical sensitivity, impetiginized HSV infections, Dühring disease, Grover's disease, pemphigus vulgaris and oral pemphigoid.

to acquire without long training (27, 28). Incidentally, we have found that post-patch-test interviews can be of educational value for training doctors. By highlighting the patient's perspective, an important point seldom considered (29, 30), they can lead to increased awareness of the negative effects of misleading advice derived from vaguely defined relevance. These effects range from unnecessary lifestyle change to anxious behaviour engendered by the fear of coming into contact with potentially ubiquitous substances generically understood as harmful. Two of our patch-tested patients suffered from severe multiple chemical sensitivity syndrome with a clear psychogenic component (31). Both of them

were obsessed by the idea of toxic traces of parabens in the environment. This belief had been started by the dubious results of previous tests reinforced by misleading information found on the internet. One patient turned out to be completely patch-test-negative, the other showed a weak 1+ reaction to paraben mix that, considering his absence of skin lesions and continuing gastrointestinal complaints in spite of a strict paraben-free diet, was considered as non-relevant.

Another example is represented by nickel, still a very frequent sensitizer in Italy (20) and the leading allergen in our patch test population, with 23% patients sensitized to it. In our experience, the great majority of these positive reactions (85%) are related only to past and transient episodes of contact dermatitis from cheap jewellery, rivet buttons, or similar items. However, the number of patients unreasonably concerned about the presence of nickel in their diet, or in cosmetic products, is high. In our country, the nickel obsession favours a prosperous market of 'nickel-tested' cosmetics.

We think that negative or non-relevant patch test results can be as useful to the long-term outcome as clearly positive and relevant ones, and, in general, we prefer not to recommend patients to avoid allergens when we cannot reasonably explain, in the first instance to ourselves, why and how they should do so. This is possibly the reason why we had a high ratio of improved patients but a relatively low ratio of positive reactions relevant to present symptoms (20% of all patch-tested patients) as compared with those relevant only to past symptoms (19%) or non-relevant (10%).

Our results show a strong association between the degree of relevance and the clinical outcome ($\chi^2 = 55.2$; $P = 0.0001$) with a relatively high proportion of unimproved patients among those with reactions scored as only possibly relevant (Table 2). This could partly reflect our own failure to give patients appropriate information (16). Interestingly enough, most of the sensitizers involved were potentially ubiquitous or ill-defined substances [nickel, methylchloroisothiazolinone (and) methylisothiazolinone, *Myroxylon pereirae*], and

Table 2. Clinical outcome of 578 patients (390 F, 188 M) with positive reactions considered currently relevant to their present symptoms

Relevance	Outcome				Total
	Resolved	Improved	Unimproved	Lost to follow-up	
Certain	104 (61.2%)	47 (27.6%)	10 (5.9%)	9 (5.3%)	170 (100.0%)
Probable	66 (39.3%)	63 (35.2%)	23 (12.8%)	27 (15.1%)	179 (100.0%)
Possible	61 (26.6%)	90 (39.3%)	42 (18.3%)	36 (15.7%)	229 (100.0%)
Total	231 (40.0%)	200 (34.6%)	75 (13.0%)	72 (12.5%)	578 (100.0%)

The results show a strong association between the degree of relevance and the clinical outcome ($\chi^2 = 55.2$; $P = 0.0001$) with a high proportion of resolved eczema among those scored as certainly relevant and a high proportion of unimproved patients in the group scored as only possibly relevant.

the uncertainty in judging their relevance paralleled the difficulty patients had in avoiding them.

As for the relatively low number of occupational allergic contact dermatitis (13%) in our population, it is probably due to the presence in our catchment area of another contact clinic with a long-established tradition in occupational allergies.

The high number (80%) of negative/non-relevant tests made us carefully reconsider our own possible failure to diagnose allergic contact dermatitis in a number of patients but this is balanced with the patients' differential diagnosis and the possibly inappropriate referrals. In fact, it could be argued that this very high proportion is an indicator of poor overall performance and of inadequate patient screening.

We are unable to vet patients referred for patch testing. Though inadequate understanding of the clinical picture as well as of the correct indication for patch testing is evident in some cases, the most common reason for referral actually is the search for possible, even if unlikely, allergic aggravating factors in a variety of chronic and/or pruritic conditions recalcitrant to conventional therapies.

Referrals are sometimes prompted by the patients' suspicion of being allergic and by their insistent requests for specific investigations. We think that most of these referrals are nonetheless legitimate. First of all, patch testing has been reported to be relevantly positive in a wide range of eczematous and non-eczematous disorders (32). Secondly, patch tests, as well as other standardized allergy tests, give patients the feeling of being properly investigated and may prevent adverse outcomes due to increasingly popular, potentially insidious, unproven diagnostic complementary techniques (33).

To follow-up patients we employed semi-structured telephone interviews rather than questionnaire-based ones, because we felt they would be more sensitive and reliable. However, as they are quite time consuming, we did not follow up patients with non-relevant positive patch tests; therefore, we had no control group. This is, perhaps, the main limit of our study. Further studies should include in their follow-up at least a random sample of patients with non-relevant positive reactions.

In conclusion, the outcome of patch testing depends on difficult-to-standardize variables. One of them, the actual relevance of positive reactions, depends, in turn, on other variables, including the patient's clinical outcome after allergen(s) avoidance. We consider that the proportion of relevantly patch-test-positive patients resolved/improved after allergen avoidance is an appropriate and useful patch-testing outcome indicator. It is not one that can be used by external agencies to evaluate and compare the performance of contact clinics, but it is

an instrument that can give specialized professionals valuable information about the results of their work, helping them to improve the accuracy of patch test relevance determination.

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