

POSITION STATEMENT

Patch test informed consent form: position statement by European Academy of Dermatology and Venereology Task Force on Contact Dermatitis

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Abstract

Background To our knowledge, an international consensus is lacking regarding the development of an adequate informed consent form for a patch test (PT) and the information that should be included in such document.

Objectives The aim of the study was to reach a consensus on the specific points that need to be addressed in a PT consent form.

Methods A Delphi survey, comprising 2 rounds and 1 final discussion, was used to gather and analyse data, which was conducted over the Internet. Each statement that reached a consensus with the respondents (9 expert dermatologists from Europe) was defined as a median consensus score (MED) of ≥ 7 and agreement among panelists as an interquartile range (IQR) of ≤ 3 . All study participants were members of the EADV task force on contact dermatitis.

Results The expert panel addressed several topics that should be included in an informed consent form for a PT: introduction, preparation for PT, testing procedure, allowed activities, adverse events and additional authorizations.

Conclusions Our results assess recommendations regarding points to be contained in an informed consent form for a PR. Future actions towards standardization and harmonization of this specific consent form are needed.

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Conflicts of interest

None to declare.

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Introduction

A skin patch test (PT) is an essential *in vivo* test procedure to confirm sensitization in subjects with suspected allergic contact dermatitis. It is a non-invasive rather straight forward method, but the allergen selection, the proper allergen concentration and the interpretation of the results require expertise. It can be reproducible when carried out by trained health professionals.^{1–3} Several guidelines have been developed through the years aimed at establishing the indication for PT and its execution in patients with contact dermatitis and other forms of delayed-type hypersensitivity.^{4–6}

As assessed in the guidelines developed by expert consensus coordinated by Uter, ‘Prior to testing, every patient must be informed – preferably in writing – about the purpose, the actual procedure and possible risks and adverse events associated with the PT as well as relevant legal privacy issues’.⁵ A strong recommendation was associated with this issue with 100% consensus reached, but the group did not explore the specific points that need to be addressed in the informed consent.^{5,6} In an international survey on skin PT procedures, attitudes and interpretation involving specialists (allergologists and dermatologists) from 47 countries, again the issue of informed consent was not explored into details. Their conclusions are that there is a clear need of updating PT procedures and attitudes.⁷ As a consequence if actions are required to standardize the PT, it is fundamental to include in such actions also indications for harmonization of an informed consent form. The aim of the present study was to reach a consensus on the specific points that need to be addressed in the PT consent form.

Materials and methods

Study design

This study was carried out gathering and analysing the opinion of experts using the collaborative Delphi method.⁸ Because of the nature of the study, ethical approval was not considered necessary.

Delphi methodology

The Delphi method involves the use of surveys and a final meeting to establish a consensus. Briefly, this process requires the formation of a steering committee responsible for identifying the issues/opinions surrounding a complex problem, the development of relevant survey questions and the recruitment of an expert panel to participate anonymously in the survey. Through repeated rounds of a self-administered questionnaire, as well as subsequent analysis and re-evaluation/modification of the answers, it is possible to gather quantitative information and establish a consensus.

Study participants

A steering committee (SC) was appointed, comprising 2 expert dermatologists (Anna Balato and Ana Giménez-Arnau) and 1

support methodologist (Emanuele Scala). The SC developed the questions, structured questionnaire, set up the online questionnaire, undertook statistical analysis of the data, produced interim documents and oversaw the process general management, but they did not participate in the survey.

The expert panel members, selected by the SC, included 9 expert dermatologists (Fabio Ayala, Andrea Bauer, Marie-Noëlle Crépy, Margarida Gonçalo, Jeanne Duus Johansen, Swen Malte John, Thomas Rustemeyer, Nicola Wagner and Mark Wilkinson) who were invited to participate in the consensus process through a modified Internet-based Delphi survey made up of 2 rounds and 1 final online meeting. The panelists were located in different European countries and were sent an email inviting them to take part in the study, as well as a link to access the online questionnaire. All study participants were members of the EADV task force on contact dermatitis.

Survey questionnaire

The questionnaire was administered in English, and a selection of 31 statements was developed (Table S1). In particular, each participant answered questions in 6 main topic areas in order to reach a unique informed consent form for patients who undergo the PT (Table 1). The panelists scored each statement using a Likert scale from strongly disagree (1) to strongly agree (10), and free text space was also provided to encourage comments. A numerical identification system was used to ensure that the participants remained anonymous.

Consensus definition and data analysis

The median response (MED) and interquartile range (IQR) were calculated for each statement, as previously described.⁸ The level of agreement required for consensus among the panel members was decided prior to commencing the study.

Each statement that reached a consensus with the respondents was defined as a median consensus score (MED) ≥ 7 , and agreement among panelists as an IQR of ≤ 3 , whereas a MED score of ≤ 3 was considered to represent a consensus to reject the statement.

An IQR of ≥ 4 required a review of the criteria by SC (via discussion). The statements in question were then either revised and included in the second questionnaire or rejected based on additional comments received from panel members.

Table 1 Delphi Questionnaire topics

Topic 1: Introduction
Topic 2: Preparation for patch testing
Topic 3: Testing procedure
Topic 4: Allowed activities during patch testing
Topic 5: Adverse events
Topic 6: Additional authorizations

The questionnaire used in the second round contained the previous median and IQR of the ratings obtained in the first round for each retested statement, as well as some comments to clarify the wording. Respondents were asked to re-rate each item, using the information from the previous round as feedback, and to comment upon their rating. After the second round, the revised MED and IQR values were calculated. In Fig. 1, the flowchart of the study is summarized.

Results

The participants were made up of 9 expert dermatologists. In the first round, all experts responded obtaining 100% compliance rate (9/9) (Fig. 1). Of the 9 questionnaires received, 8 were complete, one had 2 missing items (#8 and #31 SM1). As shown in Fig. 1, all respondents who took part in the first round also responded to the second one. No missing answers were registered in the second round.

Topic 1: Introduction

The panelists strongly agreed that a 'brief explanation of what PT is' (MED = 10, IQR = 0.5) is needed in the introduction section of patients' informed consent form for the PT (Table 2). This statement reached the agreement for the consensus in the first round.

Topic 2: Preparation for PT

After the first round, only 5 out of 11 statements (45%) reached an agreement for the consensus: 'No sunbeds for 2 weeks before testing' (MED = 10, IQR = 2), 'No topical corticosteroids on the back for 1 week before the test' (MED = 10, IQR = 2), 'No moderate or high dose of systemic corticosteroids' (MED = 9,

IQR = 1), 'Warn to bring own contact materials suspected to cause the reaction' (MED = 10, IQR = 0.5) and 'Warn to bring the health and safety data sheets of work chemical suspected to cause the reaction' (MED = 10, IQR = 1.5; Table 2). The remaining 55% of the items (6/11) failed to reach an agreement (IQR > 3) in the first round, but for some of them, an acceptable MED was reported (MED > 7; data not shown). In view of this, the items were reviewed and rephrased by the SC. Qualitative comments made by the experts improved the section of patients' pharmacological anamnesis. Indeed, the item 'Make sure that the patients bring the list of all drugs that are taking' (IQR = 4), was changed, in the second round, to 'Pharmacological anamnesis, especially regarding immunosuppressant drugs, has to be performed prior to PT' which enhanced the agreement levels (IQR = 0). Similarly, the statement 'No antihistamines for 3 days before the test' (IQR = 6.5) was changed to 'Regarding antihistamine use: if prick tests are undertaken concomitantly, no antihistamines for 3–10 days before the test (depending on the half-life of the drug used)', which improved the agreement score (IQR = 0.75).

Concerning patients' procedure before the PT, the item 'Warn of the possibility of shaving if hairy back is present' (IQR = 3.5) was slightly changed to 'If hairy back is present, it might be helpful to perform a shaving 2 days before PT to avoid barrier disruption by shaving immediately before PT', which reached an adequate agreement score (IQR = 2).

The statement 'Inform that the breakfast is allowed on the day of the test' failed to reach a consensus during the first round (MED = 5, IQR = 6), indicating disagreement. However, qualitative comments from experts reflected the concept that skipping breakfast before the PT is not necessary. In the second round, this point was indicated as 'No fasting is required before PT', which obtained a strong agreement from panel members (MED = 10, IQR = 0).

Regarding pregnancy and breastfeeding section, there was no agreement for the statements 'No pregnancy' (MED = 9, IQR = 4) and 'No breastfeeding' (MED = 7, IQR = 6). In the second round, both items were changed to 'PT should be avoided during pregnancy, but they might be performed according to the precautionary principle', and 'PT should be avoided during breastfeeding, but they might be performed according to the precautionary principle', which reached an even lower agreement respect to first round (IQR = 5 and IQR = 7, respectively). Qualitative comments from panel members suggested that PT is not harmful during pregnancy or breastfeeding. During the online meeting, SC and panelists decided to rephrase both items as follows: 'There is no evidence that PT is harmful during pregnancy. It can be performed during pregnancy according to the general precautionary principles' (IQR = 2) and 'There is no evidence that PT is harmful during breastfeeding. It can be performed during pregnancy according to the general precautionary principles', which reach IQR = 0.

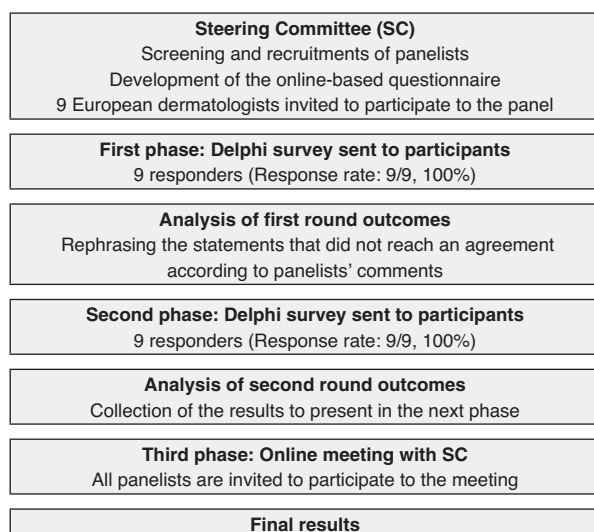


Figure 1 Flowchart of the study.

Table 2 Expert consensus in Delphi study

Statements	MED	IQR
Introduction		
1. Brief explanation of what patch testing is	10	0.5
Preparation for patch testing		
2. No sunbeds for 2 weeks before testing	10	2
3. No topical corticosteroids on the back for 1 week before the test	10	2
4. No moderate or high dose of systemic corticosteroids	9	1
5. Warn to bring own contact materials suspected to cause the reaction	10	0.5
6. Warn to bring the health and safety data sheets of work chemical suspected to cause the reaction	10	1.5
7. Pharmacological anamnesis, especially regarding immunosuppressant drugs, has to be performed prior to patch testing	10	0
8. Regarding antihistamine use: if prick tests are undertaken concomitantly, no antihistamines for 3–10 days before the test (depending on the half-life of the drug used)	9	0.75
9. If hairy back is present, it might be helpful to perform a shaving 2 days before patch testing to avoid barrier disruption by shaving immediately prior to patch testing	10	2
10. No fasting is required before patch testing	10	0
11. There is no evidence that patch testing is harmful during pregnancy. It can be performed during pregnancy according to the general precautionary principles	10	2
12. There is no evidence that patch testing is harmful during breastfeeding. It can be performed during pregnancy according to the general precautionary principles	10	0
Testing procedure		
Day 1		
13. Inform on the application of standard series, eventual supplementary series and/or own contact materials	10	1.5
14. Warn on the possibility to apply contact materials for investigative purpose	10	2.5
15. In some cases (lesions aggravated by sun exposure or lesions on photo-exposed areas) it might be necessary to perform irradiation of the areas of patch test with ultraviolet (solar) light on day 1 or 2	10	2
Day 3		
16. Inform to wear old clothes for the possibility of staining	9	2.5
17. Describe possible manifestations and symptoms of possible reactions	10	1.5
Day 4 or 5		
18. Inform that there will be a discussion of results	9	2.5
19. Inform on the possibility to come back the following week or if a reaction will develop up to 3 weeks	10	1.5
Allowed activities during patch testing		
20. Warn that a very limited shower is allowed	9	1
21. Inform that sporting activities are not allowed	10	0.5
22. Inform that it is possible to use extra tape at home to better fix the patches	10	2.5
23. Warn that no antihistamines and/or corticosteroids (unless previously agreed) are allowed	10	2.5

Table 2 Continued

Statements	MED	IQR
Adverse events		
24. Persistent positive reactions up to 1 month	8	3
25. Pigmentary positive reactions	9	2.5
26. Eczema flares	9	2
27. Active sensitization is very rare although it should be taken into account	10	2
28. Scars might develop exceptionally, but they are linked to itch and scratch and not to patch test itself	9	1
Additional authorizations		
29. The possibility to take a biopsy and/or blood sampling as well as the possibility to take pictures should be mentioned in the consent form but the permission must be asked in a separate form	9.5	2

MED, median; IQR, interquartile range.

Topic 3: Testing procedure

This topic was divided in 3 sections: (a) Day 1, (b) Day 3, (c) Day 4 or 5. In the first section, 67% (2/3) of items reached the agreement at first round: 'Inform on the application of standard series, eventual supplementary series and/or own contact materials' (MED = 10, IQR = 1.5) and 'Warn on the possibility to apply contact materials for investigative purpose' (MED = 10, IQR = 2.5). Conversely, 33% (1/3) of items were reviewed. In particular, the statement 'Warn on the possibility to irradiate PT with UV lamp' did not reach the agreement during the first round (MED = 9, IQR = 4), so it was changed into 'In some cases (lesions aggravated by sun exposure or lesions on photo-exposed areas), it might be necessary to perform irradiation of the areas of the PT with UV (solar) light on day 1 or 2' in the second round, which improved the agreement (IQR = 2).

Regarding section 2 (Day 3) and 3 (Day 4 or 5), a high level of consensus and acceptable agreement levels was obtained in regard to almost all of the statements. Particularly, the items 'Inform to wear old clothes for the possibility of staining' (MED = 9, IQR = 2.5) and 'Describe possible manifestations and symptoms of possible reactions' (MED = 10, IQR = 1.5) for the section 2, and 'Inform that there will be a discussion of results' (MED = 9, IQR = 2.5) and 'Inform on the possibility to come back the following week or if a reaction will develop up to 3 weeks' (MED = 10, IQR = 1.5) for section 3.

Topic 4: Allowed activities during PT

To better define the activities that are allowed for patients during the PT, the SC suggested 4 items. After the first round, all of the statements reached the consensus with regard to the experts' agreement. The panelists agreed that during PT 'a very limited shower is allowed' (MED = 9, IQR = 1), 'sporting activities are not allowed' (MED = 10, IQR = 0.5), 'it is possible to use extra tape at home to better fix the patches' (MED = 10, IQR = 2.5)

and 'no antihistamines and/or corticosteroids (unless previously agreed) are allowed' (MED = 10, IQR = 2.5).

Topic 5: Adverse events

When rating the adverse events related to the PT in the first round, the panelists reached acceptable consensus scores on 50% (3/6) of items, 16% (1/6) of statements were directly rejected and the remaining 34% (2/6) were reviewed by SC. The panelists agreed that adverse events that should be reported are 'Persistent positive reactions up to 1 month' (MED = 8, IQR = 3), 'Pigmentary positive reactions' (MED = 9, IQR = 2.5) and 'Eczema flares' (MED = 9, IQR = 2). Conversely, the item 'Local infections' was rejected according to the consensus definition (MED = 3, IQR = 5.5). The item 'Scars' did not obtain an agreement after the first round (MED = 7, IQR = 4), and it was changed to 'Scars might develop exceptionally, but they are linked to itch and scratch and not to PT itself, achieving a better consensus (MED = 9, IQR = 1) during the second round. On the other hand, the item 'Active sensitization' reached a quite high consensus score but a lower agreement among the experts (MED = 8, IQR = 4). In the second round, this item was changed into 'The phenomenon of active sensitization is very rare and if developed it can be correctly managed', which slightly improved the agreement but did not achieve yet an adequate score (IQR = 3.5). During the online meeting, the SC and experts strongly agreed that 'Active sensitization is very rare although it should be taken into account' (MED = 10, IQR = 2).

Topic 6: Additional authorizations

After the first round, the item regarding the 'Permission to take pictures or video for investigative, academic purposes' failed to reach an agreement (MED = 8, IQR = 5.5) and the item 'Permission to take biopsy and or peripheral blood sampling' (MED = 6.5, IQR = 5) reached a negative consensus, indicating disagreement. On the basis of qualitative comments made by the experts, the SC joined both statements in a unique item for the second round. In this case, the experts totally agreed that 'The possibility to take a biopsy and/or blood sampling as well as to take pictures should be mentioned in the consent form but the permission must be asked in a separate form' (MED = 9.5, IQR = 2).

Discussion

In this multicentre study, we aimed to provide a shared patient informed consent document for the PT. To our knowledge, an international consensus is lacking regarding the development of an adequate informed consent form and the information that should be included in such document.

We inspected the informed consent documents for PT distributed in different countries (Denmark, France, Germany, Italy, Portugal, Spain, The Netherlands and the United Kingdom) and found variation in the contents. To build a consensus regarding the content of the informed consent document, the Delphi technique was used.

In the opinion of panelists, the informed consent form must contain a brief explanation about PT. In line with the current guidelines for the PT, every patient must be informed – preferably in writing – about the purpose, the actual procedure and possible risks and adverse events associated with PT as well as relevant legal privacy issues.⁵

The PT involves the controlled application of contact allergens under standardized conditions in order to investigate whether it is possible to trigger a specific delayed-type immune reaction against a given allergen. Any contact sensitization is demonstrated by a localized, immunologically triggered eczematous reaction.^{5,6}

Current or recent systemic immunosuppression, topical treatment with corticosteroids, UV exposure (recreational or therapeutic one) or antihistamines may be associated with false-negative test results.^{5,6} Therefore, pharmacological anamnesis is required prior to the PT. Panelists agreed that sunbeds, topical and systemic corticosteroids as well as antihistamines (depending on the half-life of the drug used) should be discontinued before testing. However, all of these treatments do not constitute an absolute contraindication for the PT.⁶ Positive testing reactions have been also observed in patients on immunosuppressive agents.^{9–11} Thus, if the medication cannot be discontinued PT is still possible.

The choice of allergens to be tested shall be based on history and therefore include all exposures elicited from the patient.^{12,13} However, exclusive testing of the suspected trigger is usually not sufficient, given that unexpected contact allergens are also frequently identified as relevant causative agents in patients with contact allergy.⁵ In addition to the standard series and supplementary test series, it may be necessary to test certain products or substances that the patient has used because they are not commercially available as test preparations.¹⁴ In this case, patients should provide to the professional the health and safety data sheets of suspected product.

Tests should be applied to the upper back because of the extensive area, facilitating the placement of various substances. Other areas that can be used are the upper arms and possibly the upper thighs.¹⁵ Hairy areas should be avoided due to low adhesion of patches. However, if necessary, hair may be removed using razor blades, although the use of chemical hair removal products is not allowed.^{15,16}

The experts also agreed that fasting is not required prior testing. Interestingly, prolonged fasting might reduce hypersensitivity reactions according to a Japanese study.¹⁷

Regarding specific patient groups such as pregnant and breastfeeding women, there is no evidence of any harmful effects of the PT during pregnancy or lactation. However, the testing is generally not recommended, unless there are urgent reasons for the immediate workup of a contact allergy.⁶ Here, the panel agreed that the PT can be performed during pregnancy and breastfeeding, taking into account the general precautionary principles.

PT exposure time (occlusion) can be shorter (24 h) or longer (48 h).⁵ However, the short occlusion might result in false-negative test results, possibly due to insufficient allergen penetration.¹⁸

Based on clinical experience, in case of lesions aggravated by sun exposure or lesions on photo-exposed areas, it might be necessary to perform irradiation of the PT areas with UV (solar) light on day 1 or 2. During occlusion, patients should avoid practicing excessive physical activity in order to keep the back dry as patches may come off.¹⁶ Limited showers are allowed, and the use of extra tape at home to better fix the patches is permitted.

The first reading is usually performed at least 15 min after the PT has been removed. As assessed by the current guidelines on the PT, a second reading is mandatory on day 3 or 4, and another reading after 7–10 days can be recommended.⁵ Additionally, the panel agreed that professionals have to inform the patients about (a) wearing old clothes for possibility of staining, (b) manifestations and symptoms of possible reactions on day 3, (c) discussion of results on day 4 or 5 and (d) possibility to come back the following week or if a reaction will develop up to 3 weeks.

Local skin irritation caused by chemicals contained in PT substances is an unavoidable side effect. Extremely sensitive individuals may develop skin hypo- or hyperpigmentation (rare) or scars (very rare) at the test site.⁶ Scars might be linked to itch and scratch and not to the PT itself. Persistent PT reactions (≥ 14 days) were observed in 17.9% of positive PT reactions using standard series. Regarding systemic adverse effects, exacerbation of pre-existing dermatitis was observed in 35% of the study population by Jacob *et al.*¹⁹ Active sensitization is very rare, although it should be taken into account. In particular, PT reactions that occur after day 7 may be evidence of active sensitization, although there may also be other reasons for this phenomenon (individual patient reactivity and characteristics of certain contact allergens or cross-reactivity).^{6,20}

In conclusion, our results assess recommendations regarding points to be contained in an informed consent form for the PT, anyhow we strongly believe that future actions towards standardization and harmonization of this specific consent form are needed.

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Supporting information

Additional Supporting Information may be found in the online version of this article:

Table S1. Round 1 statements.

Supplementary Table 1. Round 1 statements

Statements

Introduction

1. Brief explanation of what patch testing is

Preparation for patch testing

2. No sunbeds for 2 weeks before testing
 3. No topical corticosteroids on the back for 1 week before the test
 4. No moderate or high dose of systemic corticosteroids
 5. Warn to bring own contact materials suspected to cause the reaction
 6. Warn to bring the health and safety data sheets of work chemical suspected to cause the reaction
 7. Make sure that the patients bring the list of all drugs that are taking
 8. No antihistamines for 3 days before the test
 9. Warn of the possibility of shaving if hairy back is present
 10. Inform that the breakfast is allowed on the day of the test
 11. No pregnancy
 12. No breastfeeding
-

Testing procedure

Day 1

13. Inform on the application of standard serie, eventual supplementary serie and/or own contact materials
14. Warn on the possibility to apply contact materials for investigative purpose
15. Warn on the possibility to irradiate PT with UV lamp

Day 3

16. Inform to wear old clothes for the possibility of staining
17. Describe possible manifestations and symptoms of possible reactions

Day 4 or 5

18. Inform that there will be a discussion of results
 19. Inform on the possibility to come back the following week or if a reaction will develop up to 3 weeks
-

Allowed activities during patch testing

20. Warn that a very limited shower is allowed
 21. Inform that sporting activities are not allowed
 22. Inform that it is possible to use extra tape at home to better fix the patches
 23. Warn that no antihistamines and/or corticosteroids (unless previously agreed) are allowed
-

Adverse events

24. Persistent positive reactions up to 1 month
 25. Pigmentary positive reactions
 26. Eczema flares
 27. Local infections
 28. Active sensitization
 29. Scars
-

Additional authorizations

30. Permission to take pictures or video for investigative, academic purposes
 31. Permission to take biopsy or peripheral blood sampling
-