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POSITION PAPER

# Drug allergy passport and other documentation for patients with drug hypersensitivity – An ENDA/EAACI Drug Allergy Interest Group Position Paper

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## Abstract

The strongest and best-documented risk factor for drug hypersensitivity (DH) is the history of a previous reaction. Accidental exposures to drugs may lead to severe or even fatal reactions in sensitized patients. Preventable prescription errors are common. They are often due to inadequate medical history or poor risk assessment of recurrence of drug reaction. Proper documentation is essential information for the doctor to make sound therapeutic decision. The European Network on Drug Allergy and Drug Allergy Interest Group of the European Academy of Allergy and Clinical Immunology have formed a task force and

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developed a drug allergy passport as well as general guidelines of drug allergy documentation. A drug allergy passport, a drug allergy alert card, a certificate, and a discharge letter after medical evaluation are adequate means to document DH in a patient. They are to be handed to the patient who is advised to carry the documentation at all times especially when away from home. A drug allergy passport should at least contain information on the culprit drug(s) including international nonproprietary name, clinical manifestations including severity, diagnostic measures, potential cross-reactivity, alternative drugs to prescribe, and where more detailed information can be obtained from the issuer. It should be given to patients only after full allergy workup. In the future, electronic prescription systems with alert functions will become more common and should include the same information as in paper-based documentation.

Adverse drug reactions lead to approximately 2–6% of all hospital admissions and occur in 10% of hospitalized patients (1). About 10–20% of adverse drug reactions are drug hypersensitivity reactions (DHR), which are unpredictable and typically resemble other allergic reactions (1). DHR may be severe, life-threatening, and even fatal. They are the most frequent cause of fatal anaphylaxis (2). Similarly, severe cutaneous adverse reactions (SCARs) are also associated with considerable mortality (3, 4). Re-administration of a drug to which the patient is hypersensitive to is the most important risk factor for recurrence and causes in some cases more severe and life-threatening reactions (5–9). It is not possible to predict whether a previous mild DHR predisposes to subsequent life-threatening reactions. Drug hypersensitivity (DH) is believed to persist and can be lifelong in many patients (1).

As only 10–20% of DHR can be confirmed by allergy tests including drug provocation tests (DPT) (10–12), the European Network on Drug Allergy (ENDA) and EAACI Interest Group on Drug Allergy have published guidelines and position papers on procedures and the management of specific DH (13–18). If avoidance of suspected drug is difficult either because of anamnestic DH reactions to several drugs or difficulties in selecting an alternative tolerated drug, a proper allergy investigation is strongly recommended (i) to confirm the tolerance to alternative drugs. In addition, the diagnosis of DH (ii) to identify the culprit drug and it's cross-reactivity is advised (1).

If the DHR can be confirmed, the patient must be never exposed to the culprit drug again in the future except for some rare occasions, for example, where desensitization treatment may be necessary. Unfortunately, reliable drug avoidance is not achieved in all patients (19). A frequent cause of re-exposure is that physicians are not aware of their patients' history of DHR. In the majority of cases, re-exposure could have been avoided by providing adequate documentation to and education of patients, doctors, and pharmacists (7–9, 20, 21). Inappropriate prescribing/prescription most often results from a wrong medical decision, lack of knowledge, or inadequate training (22, 23). Thus, it is crucial to properly communicate conclusions regarding 'forbidden' and allowed medication based on the history and allergy test results to the patient and care providers, attending doctors and other healthcare professionals, in particular pharmacists, involved in prescription and administration of drugs.

In practice, allergy centers within Europe have different methods of documenting drug allergies and the information provided is not standardized (Fig. 1). No other countries follow extensive national guidelines as those prepared by the British National Institute for Health and Care Excellence (NICE) (24). The aim of this position paper by ENDA and DAIG was to analyze the situation within Europe, to facilitate proper documentation of DH, and to construct and propose a common standardized drug allergy passport for the best care of drug-hypersensitive patients. The contents of the passport can also be transferred to computerized prescription systems. It is hoped that this position paper could inspire national allergological societies and authorities to speed up the process of a better documentation of drug allergy in the individual patients.

## Methods

### Present situation in Europe regarding drug hypersensitivity documentation

A questionnaire concerning documentation of drug allergy in the respective countries was sent to ENDA and DAIG members in leading drug allergy centers. They were asked to report the situation in their countries regarding existence of a common drug allergy passport or means of documentation of DH.

### Construction of a drug allergy passport

Based on existing versions of a drug allergy passport in Germany and Switzerland and on a drug allergy alert card in Denmark, the group coordinator proposed standardized versions of a drug allergy letter/certification, a drug allergy alert

**Abbreviations**

DAIG, drug allergy interest group of the EAACI; DH, drug hypersensitivity; DHR, drug hypersensitivity reaction; EAACI, European academy of allergy and clinical immunology; ENDA, European network on drug allergy; INN, international nonproprietary name.

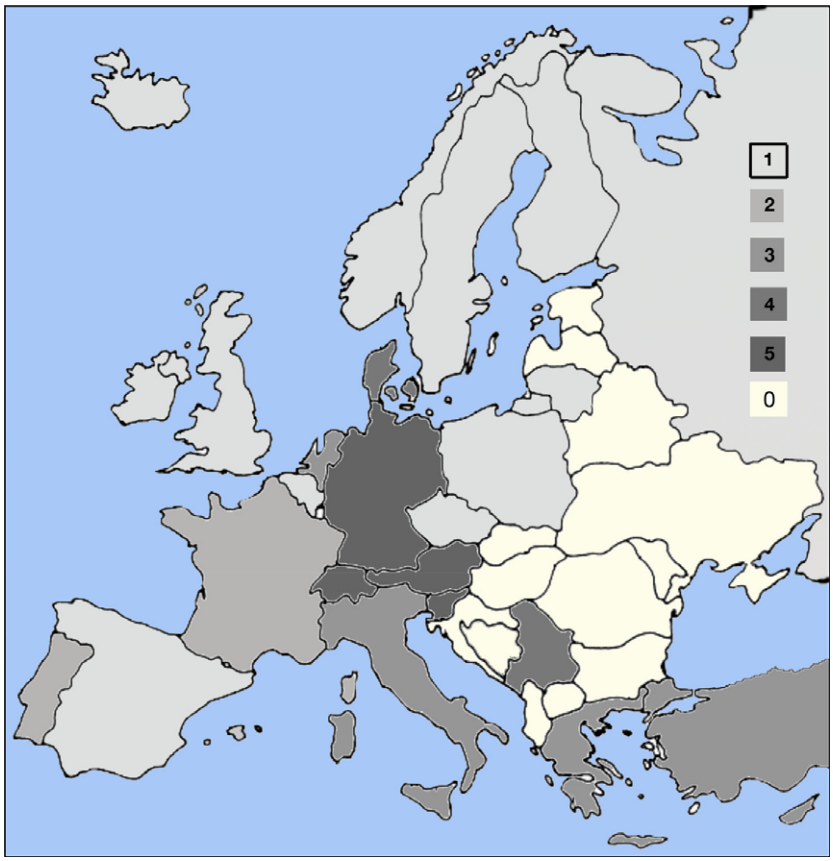


**Figure 1** Status of an allergy passport in Europe. Countries providing either a letter with the test results and/or a copy of the medical records (1; $n = 24$). Countries additionally providing standardized form without details (2; $n = 2$) or with more details (3; $n = 4$). Countries providing a drug allergy alert card or warning in the health card (4; $n = 2$) or a drug allergy passport (5; $n = 4$). No information was available to our task force from several Eastern European countries (0).

card, and a drug allergy passport, which were discussed and voted on by the task force.

### Consensus meetings and process

Meetings to discuss the purpose, principle means, and details of drug hypersensitivity documentation were held in Basel (September 2012), Milan (June 2013), and Malaga (September 2013). The assessment of the consensus levels for key statements and for the final versions of the drug letter/certification, drug allergy alert card, and the drug allergy passport was performed in Malaga (September 2013) and Copenhagen (June 2014) by voting and was recorded by giving the number of agreements and disagreements for each statement from the attending 20 participants. The agreement with the statements is given as the percentage of agreeing persons.

## Results

The response rate of the questionnaire was 24 of 25 (96%). Documentation of DH throughout Europe is very heterogeneous. All countries either provide a letter or certificate with the test results or a copy of the medical records. In twelve countries, these are the only means of documentation, and others provide certificates without/with test results ($n = 2$/$n = 4$), a drug allergy alert card/warning in the health card ($n = 2$, Denmark, Serbia) (Fig. 1), or an allergy passport ($n = 4$, Germany, Switzerland, Austria, Slovenia). Three countries (UK, Ireland, Iceland) additionally had a system with medic alert talismans to be always worn by the patients to indicate a DH.

Principally, in addition to a discharge letter by the doctor, who made the diagnosis, we recommend different forms of DH documentation, which are in part complementary (Table 1; 100% agreement). There are several purposes of the documentation: (i) to protect patients by informing them, their care providers, treating and prescribing doctors, dentists, and pharmacists about DH, (ii) to enable physicians to treat with possible alternative medication, (iii) to provide expert information on reliability (by specifying test methods), and (iv) to highlight previous life-threatening reactions (100% agreement). It is not the purpose of the documentation to give information on acute treatment of a DHR, with the possible exception of pretreatment regimen (in certain reactions to radiocontrast media or general anesthesia) (100% agreement).

**Table 1** Comparison of different drug hypersensitivity documentation formats

| Documentation | Importance | Patients with DH | Content | Issued by | When |
|---|---|---|---|---|---|
| Certification or letter | High, needed in all patients without allergy passport, universal | All | All relevant information | Doctor, charities, organizations | When discharged from hospital/clinic |
| Drug allergy alert card | Facultative | Severe reactions | Name (INN) and type of drug, issuer (bilingual) | Allergist | When discharged from hospital/clinic |
| Drug allergy passport | Strongly recommended | All | Name (INN) and type of drug, reaction, tests, alternative drug(s), issuer | Allergist | After full allergy workup |

Documentation may serve different primary purposes. In a discharge letter or (more formal) certificate, all allergies, and all available and potentially relevant information, have to be listed (Table 2). In contrast, a drug allergy passport provides only the major relevant information for the prescribing doctors. Finally, the data in a drug allergy alert card are restricted to the international nonproprietary name (INN) and type of the drug(s) to avoid and are usually issued after life-threatening reactions. The principal purposes of the drug allergy passport and drug allergy alert card are to record DH and allergens such as natural rubber latex, dyes, and disinfectants frequently used in the medical environment (100% agreement). All other allergies, such as food allergy, insect venom allergy, or allergy to aeroallergens, should be listed in a letter, medical record, or if applicable, in an anaphylaxis emergency action plan, which also contains information about self-treatment for the patient.

Drug allergy documentation should be easily readable, durable, and easy to issue and carry (100% agreement). The information given should be comprehensible to the patient, care provider, doctor, and pharmacist (100% agreement). The patient has to understand why he has to avoid certain drugs and that he always has to inform doctors and pharmacists about his DH, but more detailed information on risk and probability of DHR may be needed for doctors (and pharmacists). It is advisable that the information is comprehensible worldwide; thus, international versions (e.g., in English) should exist (100% agreement). As it is unknown whether DH in patients may ever disappear, lifelong avoidance is recommended in confirmed DH after complete allergy investigation.

The proposed drug allergy passport (Fig. 2) is a medical document ideally issued only by an allergist after proper allergy workup according to general guidelines (95% agreement). In comparison with a letter/certificate, it is smaller and printed on durable cardboard paper with standardized information about (i) the patient, (ii) the contact details of the allergist who issued the passport, (iii) drugs to be avoided, tests performed, and symptoms of reactions, and (iv) tolerated alternatives and further remarks (e.g., advice on premedication).

The drug allergy alert card (Fig. 3) is intended to give basic information on the drug(s) to be avoided (100% agreement). Similar allergy alerts can be used in electronic medical records. The small size allows it to fit in a purse to be carried at all times. However, it contains only limited information, that is, the name (INN) and type of drug(s) to be avoided, and contact details of the allergy center issuing the card. Information can be in national language on one side and in English on the other.

**Table 2** Content of drug hypersensitivity documentation

- Patient identification (including address, phone no., next of kin's phone no.)
- International nonproprietary name (INN) of drugs
- Name of drugs (trade names)
- Type of drug (i.e., antibiotic or analgesic)
- Dose and route of administration
- Manifestations and symptoms/severity
- Diagnostic and test results
- Date of diagnosis
- Dates of previous reactions
- Indication for the culprit drug use
- Treatment of the reaction ± response to treatment
- Duration of symptoms
- Kinetics of reaction
- Date of reaction(s)
- Possible cofactors and diseases
- Possible cross-reacting drugs
- Safe alternative drug(s)
- Documentation of tolerance of alternative drugs
- Doses of alternative drug tolerated
- Name, address, of issuer including phone number and e-mail address of issuer, where additional information can be readily obtained

The ideal allergy documentation for the treating doctor has to include data listed in Table 2, which, however, may be more useful in clinical studies. Minimum information is patient identification, DH drug, and reliability of hypersensitivity (Table 2). In principle, all essential data should be listed in the discharge letter or a more formal certificate. An example of a certificate issued before allergy workup has been completed is shown in Table 3 (100% agreement). To document the reliability of a DH diagnosis, specific descriptions, such as 'historic', 'suspicion of', and 'possible/probable

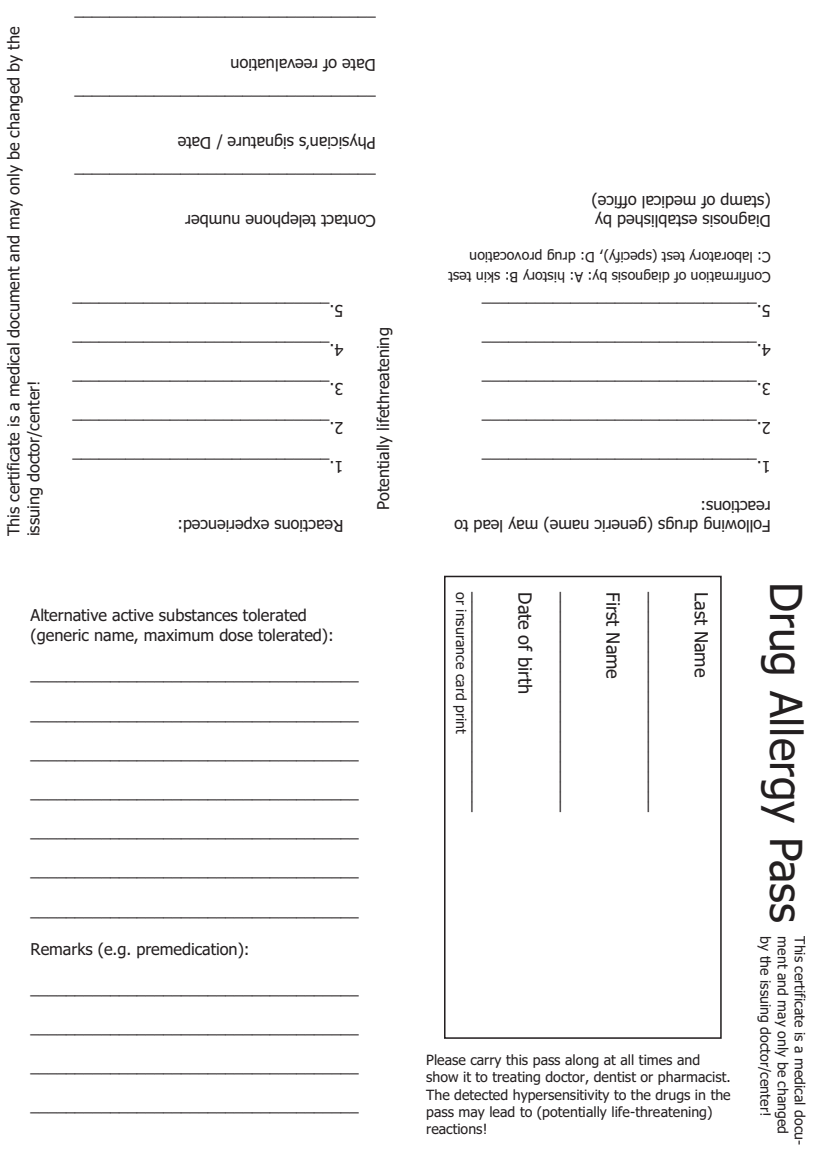


**Figure 2** Drug allergy passport. The upper half shows the outside, the lower one the inside text of the pass, the folding line indicated by the dotted line. For countries with numbers of social security or insurance, a version of the drug allergy passport with a listing of this information is available on the Drug Allergy Interest Group section of the EAACI website.

temporal relationship', may be used (100% agreement), although interpretation of the subtle differences may be difficult for nonallergists.

## Discussion

Comprehensive documentation of DH is important to prevent accidental re-exposure to culprit drugs (25, 26). A European drug allergy passport has been constructed and is strongly recommended by the task force for use after complete allergy workup. However, depending on the situation and opportunities of the issuing institution, other means of information, such as a drug allergy alert card/talisman, certificate, letter, or copy of the medical record, may be considered, as complementary documents, differing in the amount of information given and its general format.

Ignorance of a patient's drug allergy has been reported to account for 12% of prescription errors in a hospital (22). It is one of the most common factors leading to erroneous prescription of a drug, such as a beta-lactam in patients with penicillin allergy (7, 9, 20, 21). Prescription errors account for 70% of medication errors (23). Previous studies demonstrated that many of these prescription errors could be avoided and DHRs could be prevented (8, 20–22). Lack of proper DH documentation is the main reason for prescription errors (8, 25, 26). Therefore, it is necessary to empower the patients as well as medical staff with a more comprehensive DH information and documentation (26). As only 10–


**Figure 3** Example of a drug allergy alert card.

20% of suspected DH can be confirmed, less experienced doctors, the lack of awareness, and adopting a false sense of security may expose a DH patient to unnecessary risks (9). However, despite their low frequency, avoidable severe and even fatal drug reactions have been reported (9), and more precise and effective documentation has been called for (20, 26).

Currently, in Europe an individual letter, copy of medical report, a standardized form with or without details, a drug allergy alert card in Denmark, and a drug allergy passport in Germany, Austria, Slovenia, and Switzerland have been available for documentation of DH in patients. Although copies of medical reports and individual letters may provide very detailed information related to DH, they might be too detailed and complicated for pharmacists and general practitioners. In addition, the language they are written in may restrict its use outside the native country. A drug allergy passport, which is a personal identification cardlike formal document, is aimed to contain selected relevant information for future drug therapy in individual patients. The content of such a document has been agreed upon within the group. It combines relevant information and recommendations given after full allergy workup in an easily readable and portable format and should be suitable for the majority of patients. The DH alert card is even smaller and easier to carry; it is bilingual and focuses on the recommendation to avoid specific drugs but without giving further information. A certificate may serve as temporary intermediate documentation before further allergy workup. Such a certificate, a letter, or a copy of medical records containing more detailed information may be needed for decision-making for a risk/benefit analysis in complex situations (e.g., in a patient with remote history of penicillin in whom this drug is important). In the three countries, where medic alert talismans (e.g., bracelets, necklaces) are common and regularly given to patients with DH, they may be of additional value, while in some other countries, where doctors are not familiar with such talismans they are less helpful. In some regions and hospitals, electronic prescription systems with alert functions have been successfully introduced (27–29). A similar alert system covering the whole country is presently developed in Scandinavian countries. Such systems will become more common in the future and will include the same minimum information as in paper-based documentation described in this article (30).

In conclusion, considering the fact that many DHRs are avoidable, ENDA and DAIG consider appropriate DH documentation a crucial measure for the prevention of repeat exposure to the culprit drug. Across Europe, the DH documentation provided to patients is not standardized yet and shows huge diversity in the level of detail and format provided. It should be mandatory that a detailed letter/

**Table 3** Example of an initial medical certification issued after a reaction before allergy workup has been performed (italic script indicates explanations or alternatives, bold script refers to the respective drug name, '±' indicates possible additions depending on probability or information available)

| |
|---|
| Patient surname, forename, date of birth suffers from a potentially life-threatening drug hypersensitivity and has reacted with: |
| • *Description, for example:* (±historic) (±suspicion of) anaphylaxis (*specify with symptoms, e.g.,* dyspnea, vomiting, unconsciousness) *or* maculopapular exanthema in (±possible) temporal relationship with oral *or* intravenous *or* intra-articular administration of **drug name** (international nonproprietary name, *in brackets commercial name, if potentially relevant also further ingredients*) ±, and (*other drugs*). |
| ± It might be relevant that the patient in association with the reaction had possible cofactors (*if present:* e.g., mononucleosis/sepsis/chronic urticaria/other potential cofactors/confounders) or previous reactions (*specify:* to the same *or* other drugs). |
| • ± *Elicitor, if possible, e.g.:* (± suspicion of) **name (INN)** hypersensitivity (± history only, confirmatory tests pending) |
| The above-listed medications and all **names (INN) of drug** (e.g. metamizole, acetaminophen, dipyrone) or **compounds** (e.g., beta-lactam antibiotics) (*specify from knowledge of cross-reactivity, clinical symptoms, etc.*) are to be avoided until the reaction has been fully investigated by allergy testing. |
| Stamp of medical office/name of doctor |
| Date of issue/signature of doctor |
| Format: hospital/clinic discharge letter, with official letterhead including telephone number and e-mail address. If possible, add patient's address, phone no., next of kin's phone no. |

certificate/copy of the medical records containing all relevant information is given to every DH patient. In addition, we strongly recommend using a standardized drug allergy passport and/or a drug allergy alert card to increase awareness of DH and minimize prescription errors. Finally, the importance of always having the information on DH available should be emphasized to the patient. It is also recommended that a copy of the allergy document is kept on file at the issuing medical institution.

## Conflict of interest

The corresponding author and coordinator declares no conflict of interest. There has not been any conflict of interest by any of the co-authors. All named authors were involved in consensus group meetings, retrieval of information of drug allergy documentation in different countries and in the discussion, and approval of the final manuscript.

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