Study protocol

AtopicHealth²

Health care characteristics and quality of care for atopic dermatitis in Germany

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Study coordination:

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1 Synopsis

Study title	„AtopicHealth2" - Health care characteristics and quality of care for atopic dermatitis in Germany
Condition	Atopic dermatitis
Objective	Generating routine data on quality of care, treatments needs, and guideline-compliant care for atopic dermatitis from the patient's and the physician's perspective
Design	Non-interventional, multi-center, cross-sectional health care study in patients with atopic dermatitis under medical care
Estimated number of participants	N = 1,500 adult patients with atopic dermatitis in medical care
Inclusion criteria	• Diagnosed atopic dermatitis • Patient understands the survey and is expected to be able to complete the questionnaire • Patient gives written consent on participation • Patient has signed the data protection declaration
Exclusion criteria	Lack of mental, physical or linguistic ability to participate in a questionnaire survey
Main Outcomes	1. Severity levels 2. Health care situation and quality of care 3. Patient benefit of the ongoing therapy and compliance 4. Health economic outcomes
Study duration	Appr. 100 weeks
Observation period	One visit (cross-sectional study)
Work packages	The following study periods are planned (some periods may be overlapping): Study preparation (incl. obtainment of ethics vote): 10 to 16 weeks Center recruitments: 8 weeks First patient inclusion: tbd Last patient inclusion: tbd Overall recruitment period: 52 weeks Final data management period: 4-12 weeks after last patient out Determination of assessed cost parameters: 4-8 weeks Data analysis: 4-8 weeks Final report: 4 weeks
Statistical analysis	All data will be analysed with descriptive statistics and specified in terms of statistical standard values. Further statistical analyses will be performed according to the study questions.
Quality assurance	The study will be performed in accordance with the criteria of Good Epidemiological Practice and with the SOPs of CVderm on the basis of DIN ISO 9001:2008.
Ethics	Councelling of the national ethical committees will be obtained.

Principal investigator	Prof. Dr. med. Matthias Augustin	date
Medical advisor	Nora Kressel	date
Biometrics / statistical analyses	Dipl.-Psych. Anna Langenbruch	date
Study coordination	Nicole Zander, M.Sc.	date
Health Economics	Mandy Gutknecht, M.A.	date

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3 Abbreviations

AD	Atopic dermatitis
BVDD	Professional association of German dermatologists
CVderm	German Center for Health Services Research in Dermatology
DDG	German dermatological society
DLQI	Dermatology Life Quality Index
EKK	Questionnaire on costs of illness
EQ VAS	Visual analogue scale from Quality of Life questionnaire, designed by EuroQol Group
HOME	Harmonising Outcome Measures for Eczema
IVDP	Institute for Health Services Research in Dermatology and Nursing
PBI	Patient Benefit Index
PsoHealth	Study series on the health care situation of psoriasis patients, conducted by CVderm
SCORAD	Scoring Atopic Dermatitis
UKE	University Medical Center Hamburg-Eppendorf
VAS	Visual analogue scale
WPAI	Work Productivity and Activity Impairment

4 Responsibilities and addresses

4.1 Coordinating center

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4.2 Cooperation

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5 Introduction

Atopic dermatitis is one of the most common chronic diseases in Germany. Within the last three decades, the prevalence has doubled or even tripled in industrial countries (Ring et al. 2010). Reported prevalence rates range between 5 to 20 % among children (Carroll et al. 2005) and 1.13 to 4% among adults (Schaefer et al. 2008; Schmitt; Radtke et al. 2016). In the mid of the years 2000, clinicians often experienced that despite the comparably wide therapeutic spectrum of available topical agents, systemic drugs and physical procedures, patients expressed dissatisfaction concerning the treatment of their illness. Patients lamented the lack of sustainable effectiveness of the therapies, the difficulty concerning treatment, myriad side effects as well as the insufficient response regarding the treatment of patients severely affected. Due to poorly developed health services research in Germany, there were only few scientific analyses concerning these findings. These findings induced the first national study on AD in Germany called “AtopicHealth1” (Langenbruch et al. 2014). Data from this first large-scale study conducted in 2010 in dermatological practices, indicates that 13.3 % of the patients ranked the health care of the last years as “poor” or even “deficient”. At the same time, 82.1 % were “very content” or “content” with their previous treatments. Measured with the patient benefit index, 88.4 % of patients received a relevant benefit from their therapy. One third of the study population displayed a high impact of their atopic dermatitis on the perception of their global health state and the quality of life. The high disease-related daily burden was mostly caused by sleeplessness due to itching, what indicates insufficient treatment regimes in this case. A high percentage of patients used topical steroids and emollients. That indicates that many patients did not receive the necessary modern therapeutics for the treatment of their atopic dermatitis. At the same time, the necessary measures according to clinical guideline (Werfel et al. 2016) and scientific evidence are not implemented sufficiently. (Steinke et al. 2014; Langenbruch et al. 2014) First results from the German Atopic Eczema Registry TREATgermany showed that Ciclosporin is the most commonly used therapeutic agent among patients with severe atopic dermatitis – not least because it is the only agent explicitly approved for the treatment of severe atopic dermatitis (Schmitt et al. 2016).

All in all the data at hand partially speaks for a shortage of care for patients with atopic dermatitis. In this case the hesitant, partially due to unawareness and uncertainty, prescription of medical treatment by pediatricians and some dermatologists may contribute.

A further barrier concerning the implementation of innovative medication in atopic dermatitis care derives from unclear definition of “high need” in routine care. Furthermore there are practically no data in Germany concerning the matter of patient-compliance with therapeutics. This compliance however poses a crucial economic factor in therapy (Lewis und Finlay 2004). In this respect, for the benefit of an appropriate care for severely affected patients with atopic dermatitis, measures that enforce a rapid access to these drugs must be initiated. These measures require an assurance via sound data, especially knowledge of health care from the patient’s perspective.

Important key aspects of the patient’s perspective are a) the subjective burden of disease, b) the need for humane medical care, c) the experienced quality of care, d) the assessment of the benefit of the appropriated medical performances from the patient’s perspective, e) the compliance and “empowerment” of the patient.

5.1 Preliminary Research

The national care evaluation study AtopicHealth1 has provided pioneering methodological and content-related prior knowledge, which will be fully appointed in the study at hand. Resulting from the research, the following scientific papers were published:

> Langenbruch A, Radtke M, Franzke N, Ring J, Foelster-Holst R, Augustin M: Quality of Health Care of Atopic Eczema in Germany: Results of the National Health Care Study AtopicHealth. J Eur Acad Dermatol Venereol 2014; 28 (6): 719–726.
>
> Steinke S, Langenbruch A, Ständer S, Franzke N, Augustin M: Therapeutic Benefits in Atopic Dermatitis Care from the Patients' Perspective: Results of the German National Health Care Study 'Atopic Health'. Dermatology 2014; 1 (4): 358–364.

The scientific findings will be used for planning the Study “AtopicHealth2”, the initial data will be used as a reference for the further assessment of care for 2017. Other preliminary studies on atopic dermatitis at the German Center for Health Services Research in Dermatology (CVderm) and the University Hospital of Dresden are also taken into account; subsequent an extract summary:

Table 1: Previous studies on health care for atopic dermatitis in Germany at the CVderm in Hamburg (*) and at the University of Dresden (**)

Study	Year	Target group	Study type	Data source	Number of cases (n)
AtopicReal * (Beikert et al. 2014)	2008-09	pat. in self-help groups	survey	self-help	384
AtopicHealth 1* (Langenbruch et al. 2014; Steinke et al. 2014)	2010	pat. in derm. care	survey + examination	practices & clinics	1,678
AtopicCare ad * (Radtke et al. 2016)	2009	insured ≥ 18 years	secondary data analysis	Barmer GEK	48,140/ 1.64 Mio.
AtopicCare juv * (Augustin et al. 2015)	2009	insured < 18 years	secondary data analysis	Barmer GEK	30,354/ 293,181
AtopicWork *	2001-2015	working population	survey + examination	companies in Germany (>400)	2,064/ 147,117
AtopicPub * (Augustin et al. 2013)	2012	general population	public poll	FORSA	46/1,004
Atopic Eczema Registry “TREATgermany” ** (Schmitt et al. 2016)	since 2011	severe AD	register	dermatological centers	78 (December 2015)

5.2 Goal and benefit of the study

The aim of the present planned study “AtopicHealth2” is the generation of up-to-date scientific data concerning the quality of care for atopic dermatitis in Germany. A particular focus lies upon the description of ongoing therapies, quality of life and individual treatment needs and benefits from the patient’s perspective. Adult patients with all levels of severity and age groups are included. The Study is methodologically and contend-relatedly tied to the first national health care evaluation study AtopicHealth1. With these data, concerns about care from the patient-side as well as supply gaps can be characterized further and measures can be reached on different levels.

The planned study represents an outstanding occurrence in German health services research, as it is a continuation of the study AtopicHealth1, conducted in 2010, capturing the standard of care for atopic dermatitis from the patient’s perspective with representative data, allowing comparisons over a period of more than 6 years. The results of the study intend to serve the scientific analysis of the current supply of care with topical therapy and systemic drugs and are applicable in the argumentation towards prescribers, users, cost bearers and decision-makers in health care policy (“health economic positioning”). Furthermore, the data serves acquiring knowledge regarding the preferences and application behavior of patients with atopic dermatitis. Multiple usage of the generated data is strived at.

Thus the study shows several significant benefits for the patients and supplying physicians:

1. The nationwide survey concerning the subjective burden of disease allows assessment of patient ”distress” and the need for care concerning atopic dermatitis.
2. As an inventory control of the current care, the study enables an acquisition of the existing supply gap with solid data.
3. Due to profiling of the “poorly cared-for patient” and his or her needs, the study facilitates future care provision planning.
4. The recorded predictors of “poor care” are requirements for the targeted dismantling of “care barriers” – to date, a not yet introduced strategy in Germany.
5. Due to the acquisition of quality indicators and benefit assessment from the patient’s perspective, the study allows a profound analysis of the benefit as perceived by the patient of the hitherto appointed types of therapy.
6. Acquisition of statements from the patient-side regarding compliance enables the articulation of patient-side predictors of non-compliance – aiming at an efficient patient supervision.
7. In analogy to the care evaluation study for psoriasis, the study at hand also identifies regional differences in care and further makes this a subject of discussion.
8. With the knowledge gained, a profound health-policy-related argumentation is enabled.

6 Study protocol

6.1 Study design

Open, multicenter cross-sectional observational study with at least n=1500 patients with atopic dermatitis of all types and all levels of severity.

6.2 Objectives

Concerning the current study, the following questions will be clarified:

1. How high is the subjective burden of disease of patients with atopic dermatitis in 2016/2017 in Germany?
2. What are the patient-specific needs in the course of medical care?
3. How is the quality of care for different levels of severity and therapeutic groups of the disease?
4. What kind of quality does the care measured via guideline compliant quality indicators and single items demonstrate compared to 2010?
5. How is the benefit of the medical services assessed from the patient's perspective?
6. To what extent are restrictions of compliance perceived from the patient's perspective and how are these explained?
7. To what extent is there an undersupply, particularly regarding treatment with systemic drugs?
8. Which predictors can be found for a proficient/poor care for atopic dermatitis patients?
9. How high are the costs-of-illness caused by atopic dermatitis and which predictors can be found?
10. Which impact does atopic dermatitis have on workability?

6.3 Patients

6.3.1 Number of patients

The study will include 1,500 up to 2,000 adult patients, to be recruited by about 100 active sites. Approximately 50 sites are required to include patients with all levels of severity. The remaining sites should only include patients with severe atopic dermatitis.

6.3.2 Inclusion criteria

Inclusion criteria are:

- Age 18 or older
- Diagnosed atopic dermatitis
- Patient understands the survey and is expected to be able to complete the questionnaire
- Patient gives written consent on participation
- Patient has signed the data protection declaration

6.3.3 Exclusion criteria

Exclusion criteria are:

- lack of mental, physical or linguistic ability to participate in a questionnaire survey

6.4 Sites

Recruitment will take place at 100 dermatological practices and ambulant clinics that are a) partially selected at random and b) accordant with the centers of AtopicHealth1. Due to the experience in AtopicHealth1 an active participation rate of 15% can be expected. Therefore, 700 practices need to be contacted.

6.5 Project development

The project consists of the following steps:

1. Conception
    a. Information to the boards of the German dermatology societies DDG and BVDD
    b. Cooperation agreements
    c. Obtainment of ethics vote
2. Planning
    a. Systematic literature research on national and international standards on diagnosis and treatment of atopic dermatitis following Cochrane criteria
    b. Refinement of definitions for core concepts of outcomes, e.g. quality of care, status of “high need” and status of “underprovision of health”.
    c. Application of quality of care indicators that were developed based on “AtopicHealth1” by an expert committee consisting of 10 members:
        i. Process indicators (derived from expert consensus based on guideline)
        ii. Outcomes indicators (derived from expert consensus process)
    d. Biometric planning
    e. Adaptation and final versions of study forms and questionnaires
3. Study conductance
    a. Recruitment of centres
    b. Data collection in the centres
    c. Data entry and -management
    d. Determination of assessed cost parameters
4. Data analysis and statistical evaluation
5. Final report
6. Publications

6.6 Outcomes

If obtainable from patient details, the outcome-parameters are selected, if possible, in a large consensus with the international standards as well as the preliminary publications of the HOME-Initiative (Schmitt J et al. and Augustin M et al). The following target parameters are intended:

1) Description of the level of severity

- Clinical: SCORAD (Darsow et al. 2005), Body Surface Area (grid for recording) (Wallace 1951); optionally EASI (to be discussed with sponsor)
- Dermatology Quality of Life: DLQI (Finlay und Khan 1994), EQ VAS (generic health questionnaire); (EuroQol--a new facility for the measurement of health-related quality of life 1990; Schulenburg vd et al. 1998)

2) Description of the health care situation and quality of care

- Process: quality: "Health care-index" from 12 indicators of process quality (see below, 6.6.1)
- Outcomes: quality: based on a selected number of single outcomes, e.g. DLQI, PBI, SCORAD
- Data regarding the present supply chain

3) Presentation of patient benefit of the ongoing therapy and compliance

- Patient benefit Index - PBI (Augustin et al. 2009; Blome et al. 2009)
- Compliance Scales (adapted from AtopicHealth1)

4.) Health economic outcomes

- Direct costs (treatment costs, out-of-pocket costs): EKK (adapted from "PsoHealth3")
- Indirect costs incl. workability: EKK (adapted from PsoHealth3)
- Presenteism and absenteeism: Work Productivity and Activity Impairment (WPAI) (Reilly et al. 1993)

6.6.1 Development of quality of care indicators for AD

Firstly, an extensive, systematic literature review, including national and international guidelines on atopic dermatitis, was performed in order to identify potential quality indicators. This systematic literature review resulted in 74 indicators.

In the second stage, an expert committee consisting of 10 members was formed. All members of the expert committee had previously been involved in the development of the S2 guideline on the treatment of AD. The members of this expert committee extracted the final quality indicators in a modified Delphi consensus process. The expert condensed the 74 indicators of quality of care indicators identified in stage 1 to a set of 24 quantifiable non-redundant key indicators of clinical relevance.

A second Delphi survey resulted in 15 key indicators. Moreover, the results were discussed in a smaller expert group including physicians, statisticians, methodologists and patients. In the final round, the 10 members of the expert committee agreed on the 12 proposed quality indicators (table 2):

Table 2: Process quality indicators derived from expert consensus based on guideline

Area	Indicator	Condition
History	AD provocation factors	The patient has been asked for provocation factors
	Patient´s personal history of atopy	The patient has been asked about factors associated with atopy, e.g. allergic rhinitis, allergic asthma, family history
Diagnostics	Hanifin and Rajka criteria	The criteria were assessed
	RAST (=Phadiatop) test	RAST testing was performed
Treatment	Regular performed skin care	Regular skin care was applied
	Corticocosteroids and/or topical immunomodulators	Topical steroids or topical immunomodulators were used
	Antiseptics for impetiginisation	In case of impetiginisation antiseptics were used
Prevention	Avoidance of provocation factors	Provocation factors were avoided
	Decontamination of house dust if sensitized to dust mites	Measures against house dust mites were taken
	Avoidance of smoking at home	Smoking was avoided at home
	Individual counselling on prevention	The patient has participated in individual counselling on prevention factors
	Taking part in patient education classes	The patient has taken part in at least on patient education program

Seven (eight only if patients sensitized to dust mites were analyzed) applicable key process indicators were evaluated in AtopicHealth1 on n = 1,678 patients in 2010.

6.7 Sample size consideration

Due to the sample size of n=1,500 a high power up to 100% can be expected with regard to the relevant significance tests – in many analyses even for small effects. Hence it is essential to complement significance tests whenever possible with effect size measurements.

6.8 Data management

The arrival of each questionnaire will be documented by the study center. All the data will be copied from the original questionnaires and entered manually in Excel databases by trained and experienced data managers. To detect systematic errors of data entry the first 100 data sets will be entered twice in two different databases by independent managers. Afterwards, the two records of the same patients will be compared and in case of discrepancy an independent data manager will determine the correct entry using the original questionnaires. Furthermore, after importing the whole data set to SPSS it will be analyzed for plausibility by application of appropriate algorithms. Implausible data will be corrected or defined as missing values.

Free text entries about clinical characteristics and treatment will be checked and categorized by a physician. Data regarding health economic outcomes will be checked, categorized and translated into concrete costs by an expert in health economy prior to further analysis.

6.9 Statistical analysis

All data will be analysed with descriptive statistics and specified in terms of statistical standard values (absolute and percentage frequencies for categorical data; min, max, mean, standard deviation, median for continuous data). Further statistical analyses will be performed according to the study questions. In particular, the outcomes of different subgroups will be compared and predictors for specific outcomes will be determined by application of adequate significance tests. Data analyses will be conducted by means of IBM SPSS Statistics for Windows, Version 23 (IBM Corp., Armonk, NY, USA).

6.10 Quality assurance

The study will be conducted following the criteria for Good Epidemiological Practice. CVderm was certified in accordance with DIN ISO 9001 in 2008 and was re-certified in 2013. Furthermore, CVderm follows its own standard operating procedures.

6.11 Adverse Events

In the course of this scientific project, no specific data on the safety of medical products will be collected. However, the study participants will be reminded about their obligation to submit any important safety data in the usual German procedure (Nebenwirkungsmeldungen an das BfArM oder die Arzneimittelkommission der Deutschen Ärzteschaft).

6.12 Data protection and ethics

Before implementing this study, the protocol, the questionnaires, the proposed informed consent and the patient information gets reviewed by the Hamburg Physician Chamber Ethics Committee.

The study (including the participating dermatologists) follows the current legal requirements for data protection. Patients will only be included as study participants if they have given their informed consent in a written form to their dermatologists. For this purpose the CVderm provides written information to patients and a declaration of consent for the participating dermatological centers. For the study interviews in the dermatology centers the dermatologist is responsible solely. The questionnaires will be pseudonymised (encrypted with a numerical code so that only the staff of the recruiting site is able to allocate personal patient data by using a so called key list).

The participating centers make sure to save the original versions of the patient agreement as w ell as the corresponding key list for ten years beyond the end of the study. The pseudonymised questionnaires will be processed to the statistical analysis unit of CVderm. This way, it is not possible for the statistical analysers to identify an individual person. Pseudonymised questionnaires will be archived as paper

forms or on storage media at the University Medical Center Hamburg-Eppendorf for 10 years. If necessary inspection of the study documents can be granted to regional authorities.
All patients are entitled to ask for information on individual study related data in the respective dermatological center. The latter can receive this data from the study center by transferring the numerical code of this individual patient.

6.13 Publications

The data will be reported in an internal study report. This will contain study objectives, methods and results. Furthermore, results of the study will be published in international journals under the authorship of all significantly contributing scientists and will be presented at conferences as oral or poster presentations.

7 Timeline

Exact timelines depend on the starting time and will be provided after finalizing the study contract.
Some periods may be overlapping.

Study preparation, including obtainment of ethics vote	10 to 16 weeks
Centre recruitments	8 weeks
Overall recruitment period	52 weeks
First patient inclusion	tbd
Last patient inclusion	tbd
Interims report	18 weeks after first patient in
Final data management period (after last patient out)	4-12 weeks
Determination of assessed cost parameters	4-8 weeks
Data analysis	4-8 weeks
Final report	4 weeks
First publication	After submission of final report

This project will be supported by an unrestricted grant from Sanofi Aventis GmbH Deutschland. The supporting body does not have any responsibilities in the study. The study planning, operation and publication will be conducted independently from any third party support.

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