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## Dermatology and medical law: the effect of legal issues on the treatment of patients in dermatological practices in southern Germany

**Background:** Usage of modern therapies in the treatment of chronic dermatological diseases has proven to be effective but associated with high costs. High therapy costs might raise legal issues and even lead to recourse claims. **Objectives:** To evaluate dermatologists' interests and knowledge in medical law and the occurrence of recourse claims, and to assess the impact of medical law on clinical practice. **Materials & Methods:** Dermatologists of the "Psoriasis-Praxisnetz Süd-West e.V." participated in a web-based questionnaire study investigating the relationship between medical law and usage of modern therapies. The questionnaire was separated in two sub-polls carried out from 11/2016 to 12/2016 and 02/2017 to 03/2017, respectively. The first addressed general topics of medical law and the second specific legal topics, particularly recourse claims. **Results:** Overall, 76 dermatologists participated in the first and 66 in the second sub-poll. In the first sub-poll, 27.6% of participants attended a seminar on medical law within the last 12 months. Furthermore, 28.8% of the participants of the second sub-poll already experienced a previous recourse claim, and 26.3% of those stated feeling confident or rather confident on legal topics. This proportion was lower among those who had not experienced a recourse claim (17.0%). Overall, 73.7% of those who had a previous recourse claim changed their prescription behaviour as a direct consequence thereof. **Conclusion:** The study demonstrates a close relationship between medical law issues and the prescription behaviour of dermatologists working in private practices in southern Germany. Regular legal education would thus be beneficial for patient-centred care

**Key words:** dermatology, recourse claim, medical law, clinical practice, prescription behaviour, southern Germany

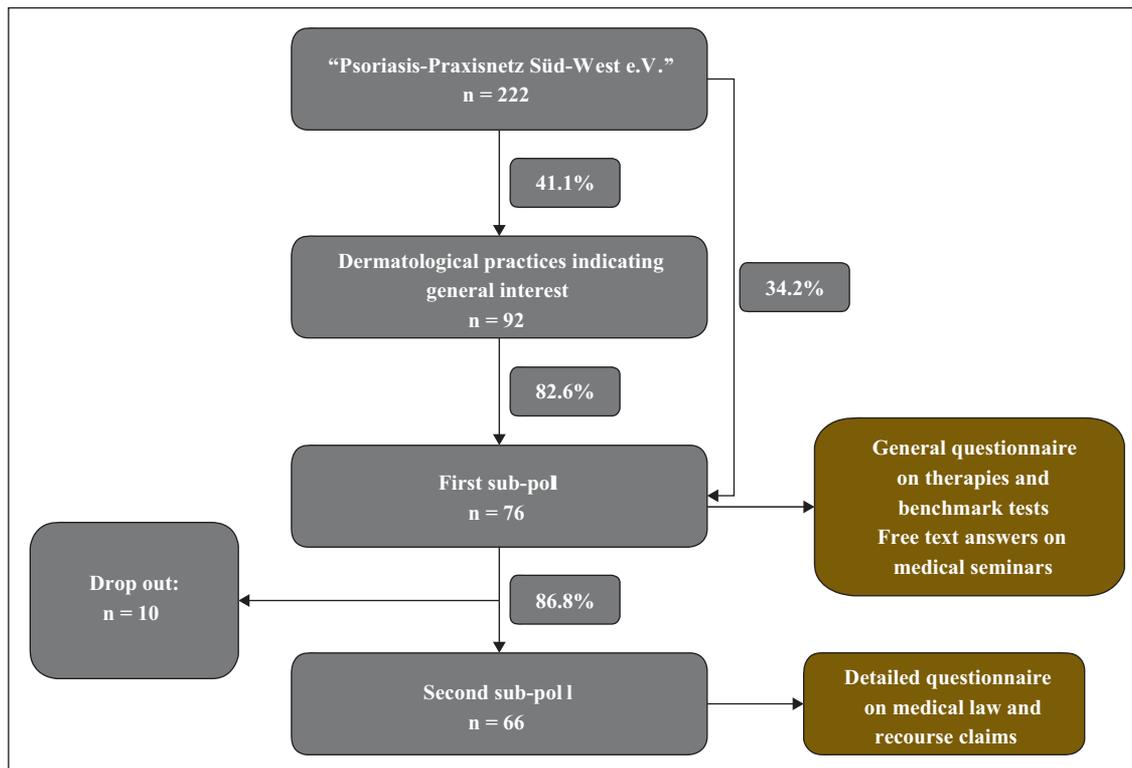
**P**soriasis, atopic dermatitis, and urticaria are chronic inflammatory skin diseases affecting many individuals [1-4]. The combined burden of symptoms and comorbidities [5-10] has a high socio-economic impact, resulting in substantial direct and indirect costs for health-care systems and society as a whole [11-13]. For moderate to severe forms of these diseases, modern therapies, including biologicals, are recommended by current guidelines and are therefore covered by patients' health insurances [14-20]. Several studies showed a cost-effectiveness advantage of biologicals in this regard [21-23].

Despite the benefits of biologicals, their prescription rates are still low [24, 25] and differ not only throughout Europe [26] but even within Germany [27]. These variations may be caused by patients' reluctance in consulting dermatologic practices [28] and by differing regulatory conditions in individual countries and provincial states within European countries [26, 27].

German national health regulations limit the prescription of costly medicaments such as biologicals. In case these regulations are not followed, physicians are subject to

benchmark testing, which is an audit carried out by a health insurance panel. In case of negative test outcomes, they are confronted with recourse claims. In Germany, regulatory issues such as fear of possible recourse claims, are a frequent concern. Additionally, high therapy costs and low reimbursements for patient management are stated as prevalent barriers [24, 26].

Research on recourse claim frequency and its impact on prescription of biologicals is rare. One potential way to prevent insecurities about legal issues among health care professionals and the related fear of a possible recourse claim is by strengthening knowledge regarding medical law [29]. However, before implementing targeted education on this complex context [30], it has to be determined whether dermatologists are concerned with legal issues and interested in further information on this topic. According to our knowledge, the link between legal issues and patient treatment has not been addressed in the existing literature. The aims of this study were to: (1) identify topics of medical law that are of interest to dermatologists; (2) evaluate the occurrence of recourse claims in dermatological



**Figure 1.** Schematic depiction of the study design.

practices; and (3) assess a potential association between medical law and the usage of modern therapies in south-western Germany.

## Methods

### Study design

Dermatologists from the “Psoriasis-Praxisnetz Süd-West e.V.”, a union of 222 members in practices located in the south-western federal states of Germany including Bavaria, Baden-Wuerttemberg, Rhineland-Palatinate and Hesse, were asked whether they had a general interest to participate in a web-based cross-sectional study including topics of medical law. A questionnaire was developed by an expert panel consisting of two dermatologists, two psychiatrists, and a lawyer specialized in medical law. Subsequently, an electronic questionnaire, separated into two sub-polls Q1 and Q2, was programmed. While Q1 enquired about general medical law topics and was carried out from 11/2016 to 12/2016, Q2 covered specific legal topics, particularly in the context of recourse claims, and was carried out from 02/2017 to 03/2017 (figure 1).

### Questionnaire

The first sub-poll Q1 of the study focused on the perception of medical law, the utilization of medical law seminars, and self-stated interests and needs for future seminars. The survey contained open questions such as: “Which medical

law seminars did you attend within the last 12 months?”, “Which topics regarding law did you engage with within the last 12 months?”, and “Do you have unanswered questions on medical law?”. Physicians were asked to state up to three answers for each question. If more than three answers were listed, all were taken into account. Furthermore, information on the size of their private practices (number of physicians and number of nurses), the number of patients per quarter (“How many patients do you supervise per quarter?”), and the number of patients treated with biologicals (“How many patients treated with biologicals do you supervise at the moment?”) was assessed. The initial analyses of Q1 were used for the development of the second sub-poll Q2, in which physicians were asked to declare whether they had experienced a prior recourse claim. No questions were asked on causes of the recourse claim. They were also asked whether they felt confident regarding medical law topics (yes/no or 5-point Likert-scale), how often fear of a possible recourse claim affected their prescription behaviour (often/never, 4-point Likert-scale), and whether they changed their prescription behaviour due to a recourse claim (yes/no). Participant numbers differed between Q1 and Q2, as not all dermatologists participating in Q1 also participated in Q2.

### Statistics

General characteristics were analysed using descriptive statistics and stratified by physicians’ experience with prior recourse claims. Groups were compared using the unpaired t-test, Chi square test, and Fisher’s exact test, when applicable. The *p* value set for significance was <0.05. To

**Table 1.** Drop-out analysis for the first and second sub-poll.

	Q1 <sup>1</sup> [n = 76]	Q2 <sup>2</sup> [n = 66]	p value <sup>3</sup>
In which federal state is your practice?			
Bavaria	17 (22.4%)	15 (22.7%)	
Baden-Wuerttemberg	28 (36.8%)	25 (37.9%)	0.447
Hesse	11 (14.5%)	10 (15.2%)	
Rhineland-Palatinate	18 (23.7%)	15 (22.7%)	
Other	2 (2.6%)	1 (1.5%)	
How long have you been working as a dermatologist?			
Less than 10 years	13 (17.1%)	12 (18.2%)	1.000 <sup>3</sup>
More than 10 years	63 (82.9%)	54 (81.8%)	
How many physicians are working in your office?			
1 physician	22 (28.9%)	20 (30.3%)	0.415
2-3 physicians	31 (40.8%)	25 (37.9%)	
4 or more physicians	23 (30.3%)	21 (31.8%)	
How many nurses are working in your office?			
Less than 5 nurses	23 (30.3%)	21 (31.8%)	0.714 <sup>3</sup>
5 or more nurses	53 (69.7%)	45 (68.2%)	
How many patients do you treat within three months?			
Less than 1,000 patients	2 (2.6%)	2 (3.0%)	
1,001-2,000 patients	19 (25.0%)	17 (25.8%)	0.447
2,001-3,000 patients	22 (28.9%)	17 (25.8%)	
More than 3,000 patients	33 (43.4%)	30 (45.5%)	
Do questions about medical law influence your daily routine as a physician?			
Constantly	14 (18.4%)	11 (16.7%)	
Frequently	34 (44.7%)	29 (43.9%)	0.154
Rarely	26 (34.2%)	25 (37.9%)	
Never	2 (2.6%)	1 (1.5%)	

<sup>1</sup>Q1 = first sub-poll. <sup>2</sup>Q2 = second sub-poll. <sup>3</sup>P value calculated by Fisher's exact test between Q1 and Q2.

minimize bias due to dropouts between the two sub-polls, a drop-out analysis was performed. Word clouds were prepared for visualization of seminars attended in the past 12 months, topics medical law dermatologists faced during the last 12 months, and open questions on topics regarding medical law. Free text answers were categorized using an inductive approach. The size of the respective key word was proportional (square-rooted proportion) to the extent it was mentioned. IBM SPSS Statistics (Version 25, IBM Corporation, Armonk, USA) was used for all analyses and alpha error was set at 0.05.

## Results

### Participating physicians

Overall, 76 of the 222 contacted dermatologists (34.2%) participated in the first open sub-poll Q1, and 66 (29.7%) in the second sub-poll Q2 (figure 1). The drop-out analysis showed that there were no significant differences between the study populations of Q1 and Q2 ( $p > 0.05$ ). Most of the practices of the participating physicians were in Baden-Wuerttemberg (Q1: 36.8%, Q2: 37.9%;  $p = 0.447$ ) and most participants had more than 10 years of work experience (Q1:

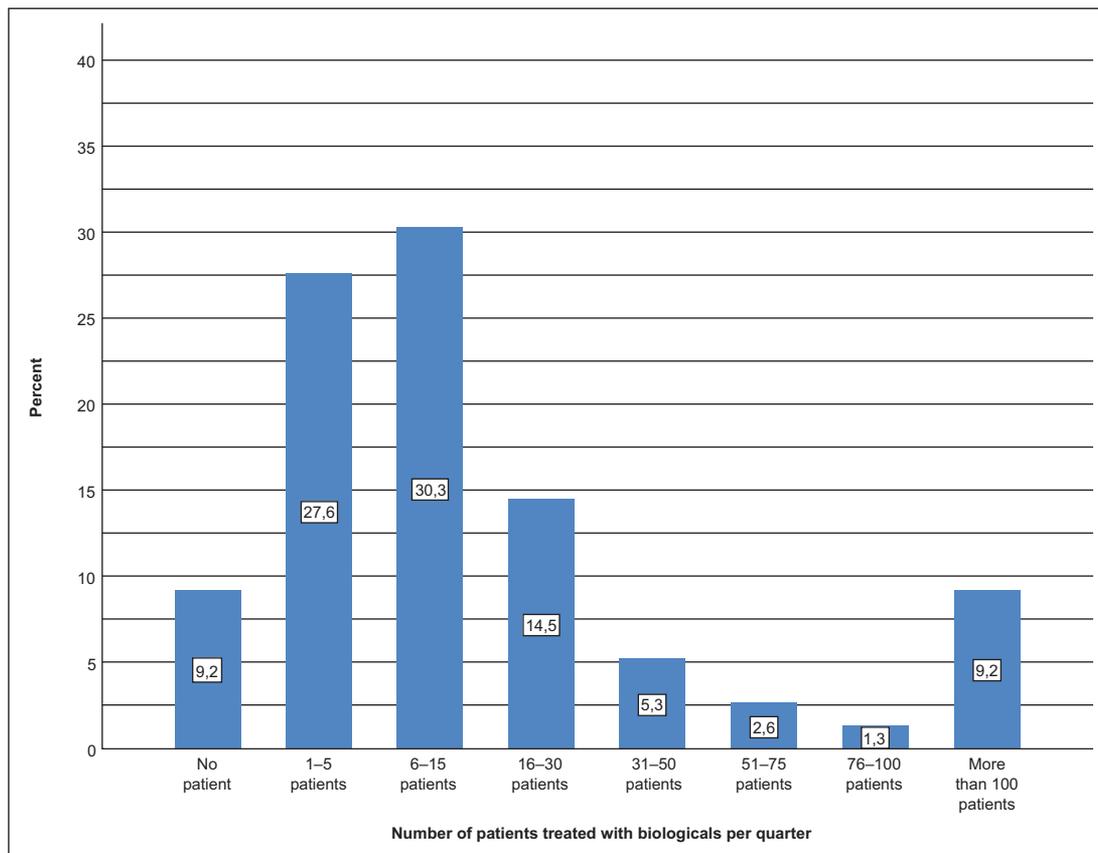
82.9%, Q2: 81.8%;  $p = 1.000$ ) (table 1). The size of the practices ranged from single-physician offices (Q1:28.9%, Q2: 30.3%) to those with four or more physicians (Q1: 30.3%, Q2: 31.8%;  $p = 0.415$ ) (table 1). Furthermore, nearly half of the dermatologists (Q1: 43.4%, Q2: 45.5%) reported treating more than 3,000 patients per quarter ( $p = 0.447$ ) (table 1).

### Therapeutic experience

More than 90% of the physicians of Q1 (69/76) reported treating patients with biologicals. Furthermore, 27.6% stated treating 1-5 patients, and 30.3% stated treating 6-15 patients with biologicals per quarter. Additionally, 9.2% stated treating more than 100 patients per quarter with biologicals (figure 2). Nearly all of the participants also had experience with alternative costly therapies, particularly with conventional anti-psoriatic systemic therapies (98.7%), specific hyposensitization (98.7%), and Toctino (94.7%) (supplementary figure 1).

### Relevant topics of medical law and seminars

Overall, 63.1% (48/76) of participants of Q1 and 60.6% (40/66) of participants of Q2 stated that questions related



**Figure 2.** Number of patients treated with biologicals by dermatologists participating in the first sub-poll per quarter.

to medical law constantly or frequently influenced their daily routine as physicians ( $p=0.154$ ). Only 2.6% (2/76) and 1.5% (1/66), respectively, did not report any influence related to medical law questions.

The most prevalent legal topics dermatologists reported being confronted with in the last 12 months were: topics on patient education, anti-corruption law, recourse and benchmark tests, and liability (figure 3A; supplementary table 1). The most open questions concerned the topics: patient education and recourse and benchmark tests (figure 3B). Among all participants of Q1, 27.6% (21/76) had attended a seminar on medical law within the last 12 months. Most of these physicians attended seminars on German anti-corruption law, hygiene regulations, and recourse claims (figure 3C).

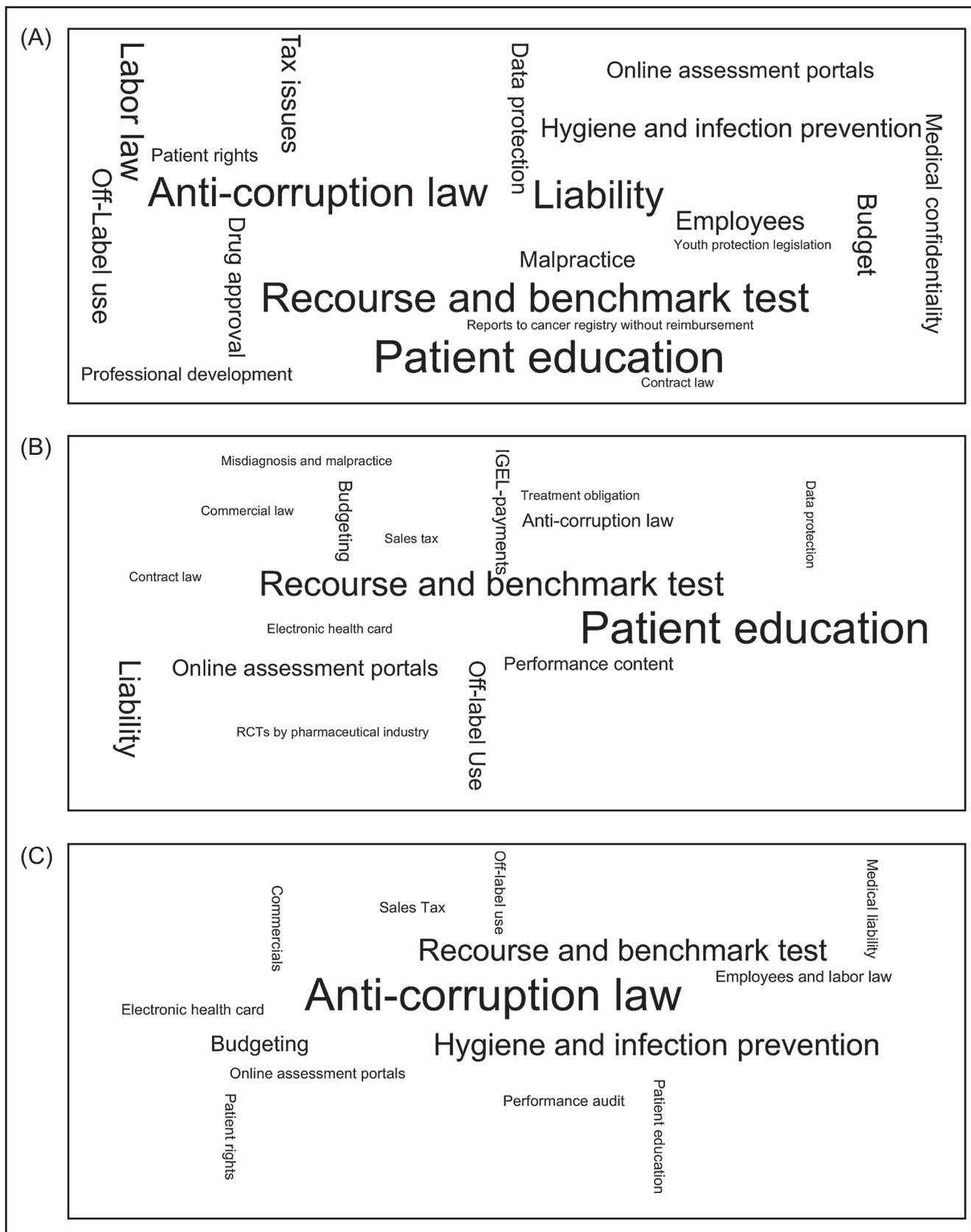
### Benchmark tests

Overall, 42.1% (32/76) of the participants of Q1 had experienced previous benchmark tests (figure 4A). The occurrence of benchmark tests, however, was not evenly distributed between federal states. In Bavaria, a relative majority (58.8%;  $n=10/17$ ) underwent benchmark testing. In Baden-Wuerttemberg, 46.4% ( $n=13/28$ ) and in Hesse, 45.5% ( $n=5/11$ ) were affected, whereas the proportion was lowest in Rhineland-Palatinate with only 22.2% ( $n=4/18$ ) (figure 4B). Thus, participating dermatologists in Bavaria were nearly three times more likely to report experiencing a benchmark test than dermatologists in Rhineland-Palatinate. Additionally, a majority of

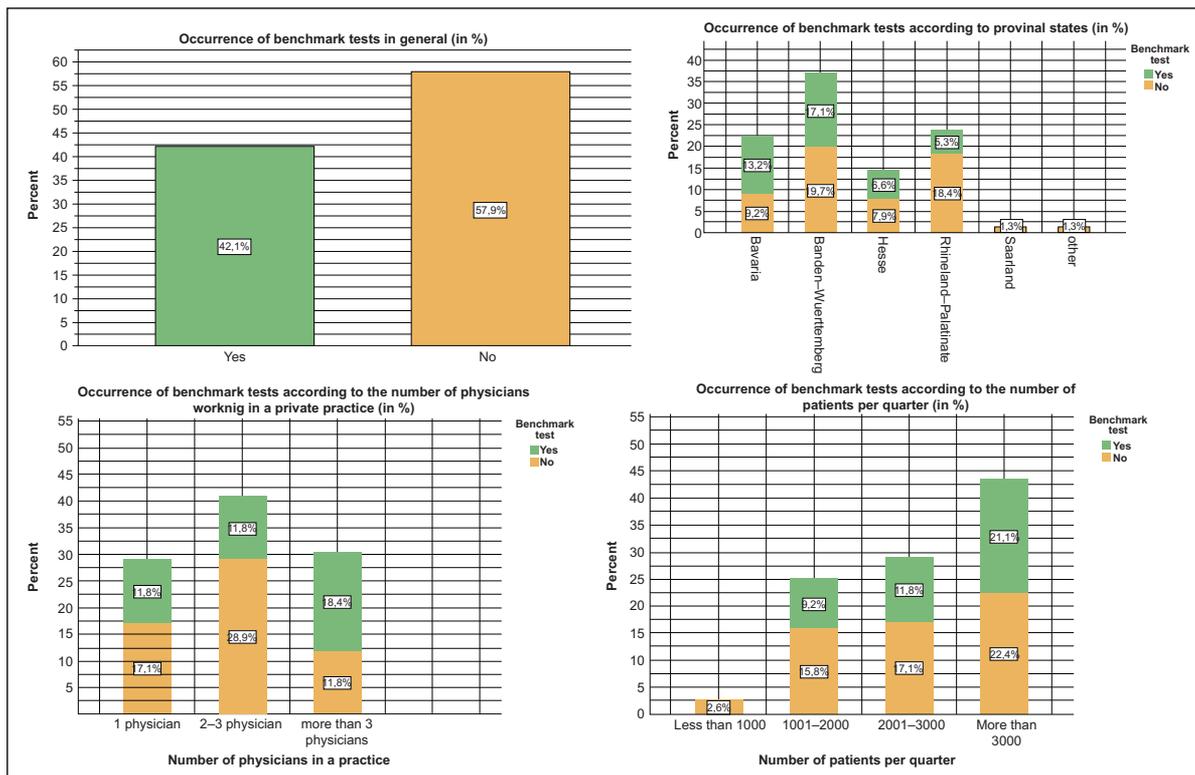
participants from practices with more than three physicians (60.9%,  $n=14/23$ ) experienced a benchmark test. Dermatologists from smaller practices reported less benchmark tests, namely 40.9% ( $n=9/22$ ) from single-physician practices and 29.0% ( $n=9/31$ ) of participants from practices with two to three physicians (figure 4C). Thus, dermatologists from larger practices with more than three physicians were substantially more likely to report experiencing benchmark tests than dermatologists in smaller practices. The occurrence of benchmark tests also correlated positively with the number of patients. Physicians who treated more than 3,000 patients with biologicals per quarter were more likely to report undergoing benchmark testing than physicians who treated less patients (figure 4D).

### Recourse claims

In Q2, participants ( $n=66$ ) were stratified based on whether or not they experienced a recourse claim. Overall, 28.8% ( $n=19$ ) reported experiencing a recourse claim, while 71.2% ( $n=47$ ) did not. A further stratification according to federal state showed that reports of experiencing recourse claims were highest in Bavaria with 46.7% ( $n=7/15$ ), followed by Hesse with 40% ( $n=4/10$ ). In other federal states, the reports of recourse claims were substantially lower, with 24.0% ( $n=6/25$ ) in Baden-Wuerttemberg and 13.3% ( $n=2/15$ ) in Rhineland-Palatinate ( $p=0.250$ ). The frequency of recourse claims did not substantially change with professional experience ( $p=0.732$ ). Physicians with professional experience of up to 10 years stated a frequency



**Figure 3.** Free text answers of dermatologists regarding questions on medical law ( $n = 76$ ). For each question, zero to three answers could be given. Font size was proportional to frequency of entries on the topic (actual font size = square root of proportion  $\times$  largest font size). **A)** Legal topics dermatologists were confronted with during the last 12 months ( $n = 88$ ). **B)** Open questions on topics regarding medical law ( $n = 49$ ). **C)** Professional development courses within the last 12 months ( $n = 30$ ).



**Figure 4.** Occurrence of benchmark tests in the population of dermatologists participating in the first sub-poll ( $n = 76$ ); in general (A); according to provincial states (B); according to the number of physicians in a practice (C); and according to the number of patients per quarter (D).

of 33.3% ( $n = 4/12$ ), whereas physicians with professional experience of more than 10 years stated a frequency of 27.8% ( $n = 15/54$ ). For dermatologists working in larger practices with four or more physicians, the frequency was 42.9% ( $9/21$ ) and thus higher than for dermatologists working alone (20.0%,  $n = 4/20$ ) or in practices with two to three physicians (24.0%,  $n = 6/25$ ;  $p = 0.216$ ). In practices with less than five nurses, the frequency was 19.0% ( $4/21$ ), whereas in practices with five or more nurses, the frequency was higher with 33.3% ( $15/45$ ;  $p = 0.262$ ). For physicians treating more than 3,000 patients per quarter, the frequency was 40% ( $n = 12/30$ ;  $p = 0.272$ ) (table 2).

Overall, 26.3% ( $5/19$ ) of participants who already experienced a recourse claim and 17.0% ( $8/47$ ) of those who had not stated being confident or rather confident regarding medical law. In contrast, 36.8% ( $7/19$ ) of those who had already experienced a recourse claim and 42.6% ( $20/47$ ) of those who had not stated that they were not confident or rather not confident ( $p = 0.806$ ) (table 2).

Fear of a possible recourse claim had substantial influence on the prescription behaviour of the participants although the number of missing answers was rather high for this question, particularly in the group who had not yet experienced a recourse claim ( $23/47$ ; 48.9%). Notably, a lower percentage of responding dermatologists who had previously experienced a recourse claim ( $8/16$ ; 50.0%) reported a change in their prescription behaviour often or sometimes due to fear of a possible recourse claim, compared to those with no previous experience of a recourse claim ( $19/24$ ; 89.2%) (table 2).

Additionally, 73.7% ( $14/19$ ) of the dermatologists who previously experienced a recourse claim stated that fear of another recourse claim affects their prescription behaviour ( $p = 0.075$ ) (table 2). Of these, 12 claimed legal assistance which was successful in nine. Hence, 53% ( $10/19$ ) of the recourse claims were clearly not justified; further information in the other cases was unavailable.

## Discussion

The aims of the study were to evaluate the interest of office-based dermatologists from southern Germany in medical law and to identify the influence of legal issues on dermatological practice. Important topics in this respect are benchmark tests and recourse claims, which were shown to be common in the study population. Our results show that the fear of recourse claims had a substantial influence on prescription behaviour and thus on the treatment of patients. Recourse claims in Germany are only made in relation to the treatment of patients with statutory health insurance, constituting about 90% of the overall population. Treatment costs are reimbursed according to an agreement between the physician and the health insurance company. Notably, off-label use of biologicals is not reimbursed according to the guidelines. In case the treatment costs are not considered justified, the health insurance company will perform a benchmark test and, based on its outcome, raise recourse claims. This, however, does not apply to private patients,

**Table 2.** General population and descriptive analysis of dermatologists participating in the second sub-poll Q2.

	Total [n = 66]	Previous experience of a recourse claim [n (%)]	No previous experience of a recourse claim [n (%)]	p value	Relative risk of recourse claim
	<b>66 (100%)</b>	<b>19 (28.8%)</b>	<b>47 (71.2%)</b>	-	-
In which federal state is your practice?					
Bavaria	15 (22.7%)	7 (36.8%)	8 (17.0%)	0.250	46.7%
Baden-Wurttemberg	25 (37.9%)	6 (31.6%)	19 (40.4%)		24.0%
Hesse	10 (15.2%)	4 (21.1%)	6 (12.8%)		40.0%
Rhineland-Palatinate	15 (22.7%)	2 (10.5%)	13 (27.7%)		13.3%
Other	1 (1.5%)	0 (0%)	1 (2.1%)		0%
How long have you been working as a dermatologist?					
Up to 10 years	12 (18.2%)	4 (21.1%)	8 (17.0%)	0.732 <sup>2</sup>	33.3%
More than 10 years	54 (81.8%)	15 (78.9%)	39 (83.0%)		27.8%
How many physicians are working in your office?					
1 physician	20 (30.3%)	4 (21.1%)	16 (34.0%)	0.216	20.0%
2-3 physicians	25 (37.9%)	6 (31.6%)	19 (40.4%)		24.0%
4 or more physicians	21 (31.8%)	9 (47.4%)	12 (25.5%)		42.9%
How many nurses are working in your office?					
Less than 5 nurses	21 (31.8%)	4 (21.1%)	17 (36.2%)	0.262 <sup>2</sup>	19.0%
5 or more nurses	45 (68.2%)	15 (78.9%)	30 (63.8%)		33.3%
How many patients do you treat within three months?					
Less than 1,000 patients	2 (3.0%)	0 (0%)	2 (4.3%)	0.272	0%
1,001-2,000 patients	17 (25.8%)	4 (21.1%)	13 (27.7%)		23.5%
2,001-3,000 patients	17 (25.8%)	3 (15.8%)	14 (29.8%)		17.6%
More than 3,000 patients	30 (45.5%)	12 (63.2%)	18 (38.3%)		40.0%
Do questions about medical law influence your daily routine as a physician?					
Constantly	11 (16.7%)	3 (15.8%)	8 (17.0%)	0.905	-
Frequently	29 (43.9%)	8 (42.1%)	21 (44.7%)		-
Rarely	25 (37.9%)	8 (42.1%)	17 (36.2%)		-
Never	1 (1.5%)	0 (0%)	1 (2.1%)		-
Do you feel confident regarding medical law topics?					
Yes	1 (1.5%)	0 (0%)	1 (2.1%)	0.806	-
Partially	12 (18.2%)	5 (26.3%)	7 (14.9%)		-
Ambivalent	26 (39.4%)	7 (36.8%)	19 (40.4%)		-
Not really	24 (36.4%)	6 (31.6%)	18 (38.3%)		-
No	3 (4.5%)	1 (5.3%)	2 (4.3%)		-
How often does the fear of a possible recourse claim affect your prescription behaviour? <sup>1</sup>					
Often	4 (10.0%)	0 (0%)	4 (16.7%)	0.075 <sup>1</sup>	-
Sometimes	23 (57.5%)	8 (50.0%)	15 (62.5%)		-
Rarely	11 (27.5%)	6 (37.5%)	5 (20.8%)		-
Never	2 (5.0%)	2 (12.5%)	0 (0%)		-
Missing data	26 (39.4%)	3 (15.8%)	23 (48.9%)		-
Did you change your prescription behaviour due to a recourse claim?					
Yes	N/A	14 (73.7%)	N/A	N/A	-
No	N/A	5 (26.3%)	N/A		-

<sup>1</sup> Percentages reported exclude missing values. <sup>2</sup> P value calculated by Fisher's exact test between Q1 and Q2.

constituting about 10% of the population. Here, the patients themselves are charged with the treatment costs and have to request reimbursement from their insurance company. In Switzerland, the situation is similar to that in Germany. Recourse claims against office-based physicians are possible in cases where economic anomalies are detected by a benchmark test. In contrast thereto, recourse claims can be actively avoided in Austria since reimbursement for a therapy with costly medication must be requested upfront by an office-based physician.

Legal topics were reported to play a substantial role in dermatologists' daily practice but only about a quarter of them had attended a legal seminar in the past 12 months. The legal seminars attended were mostly related to the topic of anti-corruption law, which did not represent the most frequently reported topic of law the physicians were confronted with and left them with open questions. Thus, more courses of high quality covering selected legal topics of interest should be offered. Among these, the topic of recourse claims and benchmark tests appears to be particularly relevant. Improving knowledge of these topics could positively influence patient-centred care. Consequently, better communication and adaption could provide benefit. To our knowledge, no previous studies are available on the topic of legal seminars relating to benchmark tests and recourse claims.

About 40% of the participants of the first sub-poll had already experienced benchmark tests for possible non-compliance regarding the prescription of costly medication such as biologicals. The frequency of benchmark tests was not evenly distributed among the study participants. In Bavaria, the relative occurrence of benchmark tests was more than three times higher than in Rhineland-Palatinate, raising the question of whether cost regulations for dermatologists are handled differently in individual German federal states, however, we have not found scientific literature on this matter. Thus, further studies are recommended.

Notably, the frequency of benchmark tests was higher for dermatologists in larger practices and for dermatologists treating high numbers of patients. Cost management may become complex for these groups of dermatologists, leading to potential conflicts with cost regulations.

Most participants in the first sub-poll recognized that questions of medical law had at least some influence on their daily routine. This confirms that legal education is important for physicians as shown by a previous pilot study [31].

About 30% of the dermatologists participating in the second sub-poll had been confronted with recourse claims, illustrating the relevance of this topic for practicing dermatologists. As with benchmark tests, the occurrence of recourse claims was not evenly distributed among the study population and appears to be higher in Bavaria and Hesse than in Baden-Wuerttemberg and Rhineland-Palatinate. This is in accordance with previous findings showing that dermatologists in Bavaria reported high costs of therapy, low reimbursements, and fear of possible recourse as barriers for guideline-compliant prescription of biologicals for psoriasis and urticaria [24]. Increased legal training during medical education, as practiced in Australia and the United States [29], might reduce these barriers and contribute to a more adequate prescription of biologicals to patients suffering from severe forms of dermatological diseases. In addition, efforts need to be undertaken to increase the accep-

tance of biologicals by health insurance authorities, as they were found to be cost effective in the long term [21-24]. These efforts may be supported by the introduction of biosimilars which will lead to a decrease in therapy costs [32]. For Etanercept and Infliximab, for which biosimilars are already available, price reductions of 19% and 25% compared to the originator products have been reported [33].

### Study limitations and strength

Potential limitations of the study include self-selection bias, as only members of the network "Psoriasis-Praxisnetz Süd-West e.V." were invited to participate and a bias for participation of physicians previously confronted with legal topics cannot be excluded. Furthermore, the number of participants was relatively small considering the more than 1,000 dermatologists practising in Bavaria [34] and Baden-Wuerttemberg [35]. Thus, we cannot ascertain representability and believe that this might not have been achieved. However, as this study was based on preliminary experimental evaluation, significance and generalizability were not primary aims. Despite an initial response rate of only 41.1% ( $n = 92/222$ ), follow-up response rates were high both for the first sub-poll (82.6%,  $n = 76/92$ ) and the second sub-poll (86.8%,  $n = 66/76$ ). Additionally, there was a low drop-out rate between the first and second sub-polls with no significant difference between the participants in both sub-polls, allowing for a combined evaluation of both sub-polls. Furthermore, a broad spectrum of participants regarding practice size and professional experience was covered. Nevertheless, a non-response error due to a response rate of less than 50% cannot be excluded and may have led to a bias regarding the results [36].

### Conclusion

This study demonstrates a substantial influence of medical law on the prescription behaviour of dermatologists working in private practices in southern Germany. This may be due to being confronted with recourse claims after prescribing costly therapies, such as biologicals. Additionally, many of the participating dermatologists stated that they were not confident regarding medical law topics. Thus, there is a substantial need for further legal education, which can be beneficial for patient-centred care. Future efforts should also focus on increasing the frequency of systemic therapies, as recommended by national and international guidelines, for the treatment of moderate-to-severe dermatological diseases. ■

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## Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1684/ejd.2022.4265. Table S1 Free text answers from dermatologists regarding questions on medical law ( $n=76$ ). For each question, zero to three answers could be given. Figure S1 Experience of costly therapies in dermatologists participating in the first sub-poll.

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