Comparison of patient pathways in the early detection of skin cancer – a claims data analysis

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Introduction

In Germany, approximately a quarter of a million new skin cancer cases are registered every year [1]. This figure is probably an underestimation of incident cases, given that not all regional cancer registries record the occurrence of non-melanoma skin cancer (NMSC), there is no reimbursement for reporting NMSC cases, and, in the case of skin cancer in general, neither recurrences nor secondary tumors are documented [2]. Despite modern and targeted therapies, prognosis in advanced stages is still poor, especially for cutaneous melanoma (CM) [3, 4]. Early detection of skin cancer is therefore important.

For early detection of skin cancer, with the additional benefit of reducing both patient distress and treatment costs, a pilot project for routine skin cancer screening (rSCS) was conducted in Schleswig-Holstein between 2004 and 2005 [5–7]. In 2008, rSCS was implemented as a structured prevention program throughout Germany [8]. Since then, it is part of the service catalog of the statutory health insurance (SHI), and insured individuals aged 35 or older can make use of this service every two years. After certification in the field of skin cancer screening, dermatologists and physicians from other disciplines may offer rSCS to their patients. Since introduction of rSCS, the participation rate has remained relatively constant at approximately 30% within the two-year

Summary

Background: Regarding skin cancer screening, patients in Germany have the choice between a direct screening by dermatologists or an initial screening by general practitioners followed by dermatological screening if further examination is required. The aim of this study is to evaluate whether screening by general practitioners is associated with risk selection in subsequent dermatological screenings.

Patients and Methods: We conducted a retrospective observational study based on claims data from a German health insurance company (Barmer GEK). Patient pathways in skin cancer screenings between 2008 and 2016 were analyzed, and differences between the two groups were tested at 95% confidence intervals.

Results: A total of 495,000 initial and 111,000 secondary examinations by dermatologists were analyzed. The proportion of subsequent excisions was lower in initial screenings by dermatologists. To diagnose one person with non-melanoma skin cancer or melanoma, five or 23 to 42 excisions were necessary, depending on the type of excision considered. The number of examinations to identify one patient ranged from 25 to 53 for non-melanoma skin cancer and 42 to 165 for melanoma. For melanoma, the number of excisions and screenings to diagnose skin cancer was lower in secondary examinations.

Conclusions: The results indicate a risk selection through initial examinations by general practitioners. However, there are other aspects that should be taken into account when comparing the two pathways.
period [9, 10]. Hence, 7.6 million patients participate in rSCS each year. The high number of cases indicates that an evaluation of this program is needed [11].

Regarding skin cancer screening, patients in Germany have the choice between direct screening by dermatologists (rSCS_{derm}) and initial screening by a general practitioner (rSCS_{gp}) followed by secondary screening by a dermatologist, if further examination is required.

There is, however, an ongoing discussion about the benefit of the initial rSCS_{gp} [12]. Therefore, the aim of the present study is to compare the patient pathways of initial rSCS_{gp} with those of initial rSCS_{derm}. The focus of the analysis is the quantification of risk selection resulting from a preceding rSCS_{gp}.

Certain aspects of this question have already been addressed in previous publications. The proportion of rSCS_{gp} and rSCS_{derm} with subsequent excision and diagnosis, respectively, has been presented for the year 2012 in the Barmer GEK physician’s report [13]. The reports of the BQS, the Institute for Quality and Patient Safety (Institut für Qualität und Patientensicherheit) illustrate the proportion of initial and secondary rSCS_{derm} with subsequent excision based on the claims data of the Central Institute of the National Association of Statutory Health Insurance Physicians (Zentraleinstitut der Kassenärztlichen Bundesvereinigung) [14, 15]. In addition, the BQS utilizes documentation data from skin cancer screening to illustrate the pathways between initial or secondary rSCS_{derm} and diagnosis.

Methods

Study design and data source

A retrospective observational study was conducted based on the claims data of one of the largest health insurance companies in Germany (Barmer GEK) with 9.2 million insured persons in 2018 (16.4 % of all SHI-insured people) [16–18]. For evaluation, claims data of the period from 2008 to 2016 containing information about diagnoses and invoiced services from both in-patient and out-patient care sectors were provided in pseudonymized form. The legal basis for the present evaluation is provided by article 75 of the German Social Security Code X (SGV X) on the transmission of social data for research and planning. Evaluation and reporting are based on the recommendations for Standardized reporting Routine for Secondary data Analyses (STROSA) [19].

Study population

Utilization of screening

Utilization of rSCS was analyzed for those individuals aged 35 or older who were insured for at least four quarterly periods before and two quarterly periods after the initial skin examination. Participation in screening between the third quarter of 2008 and the first quarter of 2016 was identified based on the corresponding settlement items (Table S1, Online-Supplement). Skin cancer screening services that were billed privately or under selective contracts could not be included due to lack of data.

To ensure the required insurance time, a new cohort was formed for each quarterly screening period. The four quarterly periods prior to rSCS were used as wash-out phase: patients with skin cancer diagnosis within this period were excluded from the analysis. This approach reduced the risk that patients already treated for skin cancer at the time of rSCS were erroneously identified as patients whose skin cancer was diagnosed by the rSCS. On the other hand, the comparatively short wash-out phase allowed inclusion of patients with recurrent tumors. To determine the diagnoses, we considered diagnoses that had additional labeling of the diagnostic confidence as “assured” for the out-patient sector and main diagnoses for the in-patient sector [20]. All evaluations were performed for cutaneous melanoma (CM, ICD-10 C43), non-melanoma skin cancer (NMSC, ICD C44), and skin cancer in total, including CM in situ (ICD D03) and NMSC in situ (ICD D04). To ensure follow-up of patients after rSCS, only patients who were still insured at the Barmer GEK two quarterly periods after their rSCS_{derm} were included.

Patient pathways from screening to diagnosis

In Germany, every SHI-insured person aged 35 or older is entitled to participation in population-related rSCS. All insured individuals can choose between direct screening by a dermatologist or initial screening by a general practitioner. According to the guideline for early cancer detection of the Joint Federal Committee (Gemeinsamer Bundesausschuss, GBA), different patient pathways exist [21] as described below (Figure 1).

If a patient participates in initial rSCS_{gp} and a suspected skin cancer diagnosis is made, he or she is referred to a dermatologist for further examination. Given that the used claims data do not contain any information on referrals, assumptions were made regarding the reconstruction of rSCS patient pathways. In this context, a connection between both screening examinations was assumed, if they were performed within two quarterly periods corresponding to a maximum observation period of six months and a minimum observation period of three months. Thus, on the one hand, the majority of the secondary rSCS_{derm} is taken into consideration, while on the other hand, a connection between primary and secondary screening can reasonably be assumed within this period.
– If an rSCS\textsubscript{derm} was performed in the same or the following quarterly period as the rSCS\textsubscript{gp}, the rSCS\textsubscript{derm} was traced back to the rSCS\textsubscript{gp}.
– If an excision was performed in the same or the following quarterly period as the rSCS\textsubscript{derm}, it was assumed that the excision was the consequence of the rSCS\textsubscript{derm}.
– Finally, it was assumed that a diagnosis of skin cancer made in the same quarterly period as the excision or in the following quarter was the result of the excision and the rSCS\textsubscript{derm}.

The decision of the insured individual for a direct rSCS\textsubscript{derm} resulted in the following patient pathway:
– If a dermatologist makes the diagnosis of suspected skin cancer during initial rSCS\textsubscript{derm}, this suspicion is also verified by excision. In this case, it is assumed that excisions performed in the same or the following quarterly period as the rSCS\textsubscript{derm} are a consequence of the rSCS\textsubscript{derm}.
– If the skin cancer diagnosis was made in the same or the following quarterly period as the excision, the excision was traced back to the rSCS\textsubscript{derm}.

Based on the assumptions mentioned above, the following parameters were calculated for both patient pathways:
– proportion of patients with rSCS\textsubscript{derm} after rSCS\textsubscript{gp},
– proportion of patients with excision after rSCS\textsubscript{derm},
– proportion of patients with excisions to diagnose skin cancer in a patient (number of excisions to diagnose; NED),
– proportion of patients with rSCS\textsubscript{derm} to diagnose skin cancer in a patient (number of screenings to diagnose; NSD).

The relevant services were identified by means of the fee schedule positions (Gebührenordnungspositionen, GOPs) (Table S1, Online-Supplement). In GOPs, general and skin cancer-specific excisions are differentiated. In this context, skin cancer-specific excisions are used for both verification of suspected diagnoses and their treatment. In contrast, general skin excisions may be used for any intervention involving the skin, independent of the underlying disease. To evaluate the impact of the coding behavior of physicians on the results, the analysis was performed using both all (general and specific) GOPs and exclusively skin cancer-specific GOPs. In another approach, the NSD was evaluated under the assumption that no excision was required for diagnosis, meaning that a confirmed skin cancer diagnosis was made within three quarterly periods of rSCS\textsubscript{derm} independent of an excision.

Statistical evaluation
Descriptive analysis was performed at the level of year and person, meaning that each person was included once per year. If there was more than one initial rSCS within a calendar year, the first screening was included. Differences between the two patient pathways were tested at 95 % confidence intervals for binomially distributed data. In accordance with epidemiological standards, NED and NSD were rounded up and expressed as whole numbers [22, 23]. All analyses were performed with the SAS Enterprise Guide, Version 7.1 (SAS Institute Inc., Cary, NC).

Results
During the observation period, a total of 495,000 initial rSCS\textsubscript{derm}, 1.9 million initial rSCS\textsubscript{gp}, and 111,000 secondary screenings were observed. Accordingly, the proportion of
secondary rSCS<sub>derm</sub> in patients with initial rSCS<sub>gp</sub> was 5.9 %. Age and gender distribution of participants in initial and secondary rSCS<sub>derm</sub> were comparable. 37.7 % (n = 186,712) of initial and 37.6 % (n = 41,630) of secondary rSCS<sub>derm</sub> participants were male. The mean age for participation in initial and secondary rSCS<sub>derm</sub> was 61.4 (median 62) and 61.5 years (median 63), respectively.

The proportion of patients undergoing excision as a consequence of rSCS<sub>derm</sub> was dependent on the type of screening and excision (Figure 2). Compared to secondary rSCS<sub>derm</sub>, the proportion of screenings with subsequent excision was significantly lower after initial rSCS<sub>derm</sub> (for both all and skin cancer-specific excisions). Within the entire observation period, a total of 494,728 initial rSCS<sub>derm</sub> with 45,870 (9.3 %) skin cancer-specific and 96,697 (19.5 %) total excisions were claimed, while 13,677 (12.4 %) skin cancer-specific and 26,140 (23.6 %) total excisions were documented after 110,591 secondary rSCS<sub>derm</sub>.

Following the patient pathway from screening to diagnosis, the NED is the next parameter to be analyzed. With respect to skin cancer-specific excisions, a higher NED was observed for CM after initial rSCS<sub>derm</sub> compared to secondary rSCS<sub>derm</sub> (42 vs. 34) (Table 1). No significant differences were found for NMSC and all skin cancer diagnoses including their precursor forms.

Compared to exclusive consideration of skin cancer-specific excisions, the NED was lower when all excisions performed to establish the diagnosis were taken into account (Table 2). Skin cancer diagnoses including precursor forms after initial rSCS<sub>derm</sub> represented an exception.

Compared to initial rSCS<sub>derm</sub>, the number of excisions to identify a CM patient were lower for secondary rSCS<sub>derm</sub> (23 vs. 32), while no significant differences were found for NMSC and all skin cancer diagnoses including precursor forms. However, the NED for NMSC and all skin cancer diagnoses decreased within the observation period for both skin cancer-specific excisions and all excisions.

Of 110,591 patients with rSCS<sub>gp</sub> and subsequent rSCS<sub>derm</sub>, a total of 13,677 patients underwent skin cancer-specific excision and 26,140 patients underwent (general or specific) excision. Accordingly, the agreement between general practitioners and dermatologists with respect to suspected

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**Figure 2** Rate of skin cancer screenings by dermatologists with consecutive skin cancer-specific and general excisions (2008–2016).

*Abbr.:* rSCS, routine skin cancer screening.

*Numerator:* person with skin cancer-specific excisions or all excisions subsequent to an initial or a secondary skin cancer screening by dermatologists; *denominator:* person with an initial or a secondary skin cancer screening by dermatologists; specific excisions: used for verification of suspected diagnoses and treatment of skin cancer patients; all excisions: specific excisions + general excisions.
Table 1  Number of excisions* (skin cancer-specific*) to diagnose one patient with skin cancer after routine skin cancer screening (NED).  

| Year | Skin cancer-specific* excisions* per CM diagnosis | Skin cancer-specific* excisions* per NMSC diagnosis | Skin cancer-specific* excisions* per skin cancer diagnosis |
|------|--------------------------------------------------|---------------------------------------------------|----------------------------------------------------------|
|      | Initial rSCS<sub>derm</sub> | Secondary rSCS<sub>derm</sub> | Initial rSCS<sub>derm</sub> | Secondary rSCS<sub>derm</sub> | Initial rSCS<sub>derm</sub> | Secondary rSCS<sub>derm</sub> |
|      | n | 95 % CI | n | 95 % CI | n | 95 % CI | n | 95 % CI | n | 95 % CI | n | 95 % CI |
| 2008 | 49 | 42–62 | 34 | 27–49 | 7 | 7–8 | 7 | 6–8 | 5 | 5–5 | 5 | 4–5 |
| 2009 | 37 | 33–43 | 42 | 34–54 | 7 | 6–7 | 7 | 6–7 | 5 | 5–5 | 5 | 4–5 |
| 2010 | 39 | 35–45 | 35 | 29–45 | 6 | 6–6 | 6 | 6–7 | 4 | 4–4 | 4 | 4–5 |
| 2011 | 40 | 35–45 | 38 | 31–50 | 6 | 6–6 | 6 | 6–7 | 4 | 4–4 | 4 | 4–5 |
| 2012 | 40 | 35–45 | 39 | 32–52 | 6 | 6–6 | 6 | 6–7 | 4 | 4–4 | 4 | 4–5 |
| 2013 | 48 | 42–56 | 25 | 21–31 | 6 | 6–6 | 5 | 5–6 | 4 | 4–4 | 4 | 4–4 |
| 2014 | 43 | 38–49 | 35 | 28–45 | 5 | 5–5 | 5 | 5–6 | 4 | 4–4 | 4 | 4–4 |
| 2015 | 46 | 40–53 | 30 | 24–39 | 5 | 5–5 | 5 | 5–6 | 4 | 4–4 | 4 | 4–4 |
| 2016 | 44 | 38–53 | 29 | 21–45 | 5 | 5–5 | 5 | 4–5 | 4 | 4–4 | 4 | 3–4 |
| Total | 42 | 40–44 | 34 | 32–37 | 6 | 6–6 | 6 | 6–6 | 4 | 4–4 | 4 | 4–4 |

Abbr.: CM, cutaneous melanoma; NMSC, non-melanoma skin cancer; rSCS<sub>derm</sub>, routine skin cancer screening by a dermatologist; n, number of patients; CI, confidence interval.

*Skin cancer-specific excisions: used for verification of suspected diagnoses and treatment of skin cancer patients.

*number of excisions to diagnose one patient with skin cancer = number of excisions in patients after undergoing rSCS
number of excisions in patients with skin cancer diagnosis after rSCS

Table 2  Number of excisions* (all*) to diagnose one patient with skin cancer after routine skin cancer screening (NED).  

| Year | Excisions* (all*) per CM diagnosis | Excisions* (all*) per NMSC diagnosis | Excisions* (all*) per skin cancer diagnosis |
|------|----------------------------------|----------------------------------|------------------------------------------|
|      | Initial rSCS<sub>derm</sub> | Secondary rSCS<sub>derm</sub> | Initial rSCS<sub>derm</sub> | Secondary rSCS<sub>derm</sub> | Initial rSCS<sub>derm</sub> | Secondary rSCS<sub>derm</sub> |
|      | n | 95 % CI | n | 95 % CI | n | 95 % CI | n | 95 % CI | n | 95 % CI |
| 2008 | 38 | 34–44 | 24 | 21–30 | 6 | 6–6 | 5 | 5–6 | 5 | 5–5 | 4 | 4–4 |
| 2009 | 32 | 29–35 | 25 | 22–28 | 6 | 6–6 | 6 | 5–6 | 4 | 4–5 | 4 | 4–4 |
| 2010 | 30 | 28–33 | 23 | 20–26 | 5 | 5–5 | 5 | 5–6 | 4 | 4–4 | 4 | 4–4 |
| 2011 | 32 | 30–35 | 25 | 22–29 | 5 | 5–5 | 5 | 5–6 | 4 | 4–4 | 4 | 4–4 |
| 2012 | 30 | 28–33 | 26 | 23–30 | 5 | 5–5 | 5 | 5–6 | 4 | 4–4 | 4 | 4–4 |
| 2013 | 33 | 31–36 | 21 | 19–24 | 5 | 5–5 | 5 | 4–5 | 4 | 4–4 | 4 | 3–4 |
| 2014 | 34 | 31–37 | 23 | 20–27 | 5 | 5–5 | 5 | 4–5 | 4 | 4–4 | 4 | 3–4 |
| 2015 | 35 | 33–39 | 23 | 20–27 | 5 | 5–5 | 5 | 5–5 | 4 | 4–4 | 4 | 4–4 |
| 2016 | 33 | 30–38 | 21 | 17–27 | 5 | 4–5 | 4 | 4–5 | 4 | 4–4 | 3 | 3–4 |
| Total | 33 | 32–34 | 24 | 23–25 | 5 | 5–5 | 5 | 5–5 | 4 | 4–4 | 4 | 4–4 |

Abbr.: CM, cutaneous melanoma; NMSC, non-melanoma skin cancer; rSCS<sub>derm</sub>, routine skin cancer screening by a dermatologist; n, number of patients; CI, confidence interval.

*all excisions: general excisions on the skin: used for all procedures on the skin, regardless of the underlying disease + skin cancer-specific excisions.

*number of excisions to diagnose one patient with skin cancer = number of excisions in patients after undergoing rSCS
number of excisions in patients with skin cancer diagnosis after rSCS
The last question relates to the number of screenings required to identify a skin cancer patient (Table 3). For CM, the NSD of initial rSCS$_{derm}$ was between 166, if a specific or general excision was performed after screening, and 409 in case of a skin cancer-specific excision. For secondary rSCS$_{derm}$, the NSD was between 99 and 273 (specific and all excisions). Accordingly, initial rSCS$_{derm}$ resulted in a significantly higher number of dermatological screenings to diagnose a patient with CM. The NSD for diagnosing a patient with NMSC was significantly lower. For initial rSCS$_{derm}$ it was between 25 and 53, and for secondary rSCS$_{derm}$ between 20 and 45, depending on whether a general or a skin cancer-specific excision was performed after screening.

When considering all skin cancer diagnoses including their precursor forms, one of 19 patients after initial rSCS$_{derm}$ with subsequent excision (general or specific) received a diagnosis of skin cancer. When only skin cancer-specific excisions were considered, the NSD was 36. For secondary rSCS$_{derm}$, the NSD was between 15 and 30. When assuming that no excision was required for establishing the diagnosis, the NSD decreased by half for all three diagnosis groups.

### Discussion

The aim of this study was to compare the effects of the two screening pathways starting with initial rSCS$_{derm}$ vs. initial rSCS$_{gp}$. Based on the proportion of screenings with subsequent excision, it was assessed whether patients with initial examination by dermatologists were more likely to be suspected of having skin cancer than patients with secondary rSCS by dermatologists, due to differences in their risk profile and skin cancer prevalence. The finding that the proportion of patients with subsequent excision was higher after secondary screenings (irrespective of excision type) contradicts this hypothesis and may be considered as indicator for an effective preselection of patients by general practitioners. Based on analysis of routine data, it is not possible to evaluate to what extent the suspicion of skin cancer by general practitioners contributes to an increased need for forensic confirmation and thus to a higher excision rate after secondary rSCS$_{derm}$. When interpreting these results, it should be taken into account that in recent years the proportion of patients with subsequent excision among participants of initial rSCS$_{derm}$ and secondary rSCS$_{derm}$ has steadily converged.

With respect to the second parameter, the number of excisions to identify a skin cancer patient, a significantly lower number of required interventions after secondary rSCS$_{derm}$ vs. initial rSCS$_{derm}$ was found for CM, while no differences were observed for NMSC and all skin cancer types together. However, an ideal NED is difficult to define, as it results from the consideration of avoiding unnecessary excisions while not making false-negative diagnoses. Accordingly, the NED is affected by many factors that complicate its interpretation, such as experience and training of physicians, concern about false-negative diagnoses, and expectations of patients regarding a high sensitivity of the examination [18]. In this respect, the reduction of the proportion of excisions with negative finding by combination of rSCS$_{gp}$ and secondary rSCS$_{derm}$ compared...
to \( rSCS_{\text{derm}} \) alone cannot be interpreted unconditionally as an indicator for the efficacy of initial \( rSCS_{\text{gp}} \). Excisions immediately following \( rSCS_{\text{gp}} \) were not considered. However, given that only about 2 % of all excisions are performed without previous \( rSCS_{\text{derm}} \), it can be assumed that inclusion of these cases would have only minor effects [13].

With respect to the third parameter, a lower number of screenings to identify a skin cancer patient was found for secondary \( rSCS_{\text{derm}} \) compared to initial \( rSCS_{\text{derm}} \). These findings were observed for all diagnosis groups (CM, NMSC, all skin cancer types) and all assumptions made concerning excisions (specific excisions, all excisions, no excisions required) and can be interpreted as an indication for a selection of risk patients by \( rSCS_{\text{gp}} \).

Comparable figures with respect to the number of initial \( rSCS_{\text{derm}} \) with subsequent excision are provided by the physician report of the Barmer GEK: in 10.2 % (vs. 9.3 % in our evaluation) of the participants, skin cancer-specific excisions and in 20.1 % (vs. 19.6 %) general or skin cancer-specific excisions were performed [13].

Results on the NED in general are provided by evaluation of histopathological data acquired in the framework of rSCS in Germany. These yielded an NED of 12 for CM and 2 for NMSC, albeit without differentiation between initial and secondary \( rSCS_{\text{derm}} \) [14]. With respect to all skin cancer diagnoses, the NED amounted to four excisions after initial \( rSCS_{\text{derm}} \) and three excisions after secondary \( rSCS_{\text{derm}} \) [15]. However, information on excisions was missing in 20 % to 50 % of the histopathological data, and these were therefore excluded from the analysis. Additional insights are provided by the pilot project SCREEN. In participants aged 20 years or older, the NED was 27 for CM, 8 for basal cell carcinoma (BCC), and 41 for squamous cell carcinoma (SCC) [5, 7]. When only participants from the age of 35 were included, corresponding to the age group entitled to benefit from the rSCS program, the NED for CM was lower compared to all \( rSCS_{\text{derm}} \) participants (22 vs. 27) [24]. Although all studies described above were conducted in Germany, they resulted in a lower NED compared to our findings (NED 23–42 for CM and 5 for NMSC). The only identified international publications addressing effects of different patient pathways have been conducted in Australia and compare the NED of skin cancer screenings performed by mainstream general practitioners and general practitioners predominantly treating skin cancer patients [25, 26]. In this study, dermatological examinations were not evaluated.

The last rSCS parameter analyzed in this study is the NSD. Here, the results of the rSCS evaluation based on histopathological data are consistent with our results: compared to the initial \( rSCS_{\text{derm}} \), a secondary \( rSCS_{\text{derm}} \) after positive first screening by general practitioners is associated with a higher probability of receiving a diagnosis of skin cancer (NSD 41 vs. 23) [15]. The results of the physician report of the Barmer GEK on NSD in initial \( rSCS_{\text{derm}} \) are comparable to our results when using the case definition “without requirement of excision”. The NSD was 77 for CM (vs. 73 in our evaluation), 16 for NMSC (vs. 14), and 10 for any skin cancer diagnosis (including precursor forms) (vs. 9) [13]. In addition, some publications only report the number of screenings to diagnose a patient with skin cancer without showing whether the finding was based on an initial or a secondary \( rSCS_{\text{derm}} \). A study analyzing the claims data of the years from 2008 to 2012 yielded an NSD of 500 for CM and 56 for NMSC [10]. Similar results were obtained in an evaluation of histopathological data from 2013 that reported NSDs of 454 for CM and 41 for NMSC [15]. These values are comparable to the evaluation of the present study for the period from 2008 to 2012, if diagnoses based on skin cancer-specific excisions are considered (239–531 for CM and 45–74 for NMSC). Two further publications based on data about screenings by dermatologists from the SCREEN project yielded NSDs of 217 for CM, 65 for BCC, and 327 for SCC [5, 7]. Our results are also comparable to the international Euromelanoma Screening Campaign that provided skin cancer screening to approximately 60,000 people in thirty European countries in the period from 2009 to 2010. Here, the NSD for CM was 243 [27].

However, our study is also subject to limitations that should be considered when interpreting the results. While a randomized controlled study is the most suitable study type to evaluate an intervention such as the population-related rSCS program, retrospective observational studies are the only option to analyze the effects of the program, given that no accompanying studies were conducted during initiation of the rSCS program [28]. In this study, we used claims data of a health insurance company with 16.4 % of all SHI-insured individuals in Germany. Given the differences in gender, age, morbidity, and utilization of health care services between the collectives of insured persons of individual health insurance companies, the results of this study cannot be extrapolated unconditionally to the entire population of Germany [29].

Moreover, the SHI data provide no information on several aspects, thus complicating the interpretation of the results. Because it can be assumed that the guideline for early cancer detection of the GBA is not always implemented in practice, patients will in some cases make use of \( rSCS_{\text{derm}} \) after initial \( rSCS_{\text{gp}} \) on their own initiative, that is, without referral of their general practitioner. At the same time, general practitioners may refer patients to dermatologists without definite suspicion (deviating from the guideline) against a background of forensic confirmation.

The claims data of the SHI also provide no information as to whether insured individuals decided to participate in screening on the basis of a skin lesion detected after
self-examination or without any such sign. This lack of information may result in a bias, if patients with skin lesions detected after self-examination have a higher probability of receiving a diagnosis of skin cancer. However, previously published studies have not provided any evidence for differences between rSCS participants with or without skin lesions detected after self-examination [30]. Another limitation is the determination of the actual number of excisions required to identify a patient with skin cancer. This value is difficult to determine. While consideration of only skin cancer-specific excisions will exclude excisions performed for other reasons than for confirmation of diagnosis, this will also prevent registration of excisions encoded as general excisions, thus resulting in underestimation of the NED. Consideration of all excisions, on the other hand, will indeed ensure that no excisions are excluded, but will also include minor surgical interventions not performed for diagnosis of skin cancer, thus resulting in overestimation of the NED. Moreover, the general limitations of routine data analyses apply: it is not possible to verify that claimed services have actually been provided.

Another parameter that would have been required for a more comprehensive evaluation of the screening program is the proportion of false-negative diagnoses. Given that reliable determination of this parameter for comparison of primary rSCS<sub>derm</sub> vs. secondary rSCS<sub>derm</sub> is not possible, we were not able to calculate the sensitivity and specificity of the rSCS program.

**Conclusions**

In conclusion, secondary skin cancer screening by dermatologists results in lower NED and NSD.

Compared to participants of the initial skin cancer screening, dermatologists perform more excisions in participants of the secondary skin cancer screening. These results indicate a preselection of patients with enhanced risk of skin cancer through examinations by general practitioners, although quantification of the impact of forensic confirmation is not possible.

However, there are other aspects that should be taken into account when comparing the two patient pathways. Combining the screenings performed by general practitioners and dermatologists has the potential to reach another target group than examination by dermatologists alone. Accordingly, general practitioners have an important role in distribution of information and early detection of skin cancer, in particular for patients who do not regularly consult a dermatologist or who are not informed about the rSCS program. Another relevant reason for the two-step screening procedure is the organizational aspect: In Germany, approximately 35,000 general practitioners and 3,900 dermatologists are registered with the Association of Statutory Health Insurance Physicians (Kassenärztliche Vereinigung) and are permitted to treat SHI-insured individuals [31]. In 2013, dermatologists performed a total of 3.1 million rSCS corresponding to 809 skin examinations per physician [15]. In addition, 4.5 million skin examinations were performed by general practitioners. If all patients had used the initial rSCS<sub>derm</sub>, the workload could not have been handled by the current number of dermatologists. To enable continued participation of all insured persons in rSCS as well as easing the workload for dermatologists, all insured persons should be encouraged to utilize the rSCS at their general practitioner. A decision for either initial rSCS<sub>derm</sub> or rSCS<sub>gp</sub> should also consider the possibility of false-negative diagnoses, which result in delayed diagnosis. To our knowledge, however, there are no publications addressing the proportion of false-negative diagnoses between the groups of specialists performing the initial examination. Similar approaches of collaborations, with the aim to reduce the workload of dermatologists, are already implemented in Great Britain and are currently being evaluated internationally in the field of telemedicine [12, 32].

In case of a suspected diagnosis by a general practitioner, however, the period between initial suspicion and further examination by dermatologists is associated with additional stress for the patient. To reduce this stress, dermatologists should prioritize the appointment for a secondary screening. Finally, additional costs for the health care system arising from a second rSCS should be taken into account.

There is still a great need for research concerning rSCS. There is, for example, an ongoing debate about the potential benefits and harms of the rSCS program in general [33–36]. Resolving this issue will require comprehensive evaluation of the effects of the program. For such an evaluation, study designs are needed that track screening participants over a longer period of time to enable statements about false-negative findings and mortality to be made.

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