German Guideline Program in Oncology (GGPO)

Evidence-based Guideline on Prevention of Skin Cancer

Version 1.1 – April 2014

AWMF registration number: 032/052GGPO

Guideline (Short Version)

DKG Krebsgesellschaft · Deutsche Krebshilfe Helfen. Forschen. Informieren. · AWMF

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1. Information about this guideline

1.1. Editors

German Guideline Program in Oncology of the Association of the Medical Scientific Societies (AWMF), the German Cancer Society (DKG) and German Cancer Aid (DKH).

1.2. Leading professional society

Association of Dermatological Prevention (ADP)

ARBEITSGEMEINSCHAFT DERMATOLOGISCHE PRÄVENTION

on behalf of the German Dermatological Society (DDG) and the Dermatological Oncology Working Group (ADO)

c/o Prof. Dr. med. E.W. Breitbart
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1.3. Funding of the guideline

This guideline was funded by the German Cancer Aid as part of the German Guideline Program in Oncology.

1.4. Contact

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1.5. Citation

The German Guideline Program in Oncology (German Cancer Society, German Cancer Aid, AWMF): Evidence-based guideline on prevention of skin cancer, short version 1.1,

2014, AWMF registration number: 032/052GGPO, http://leitlinienprogramm-onkologie.de/Leitlinien.7.0.html (accessed on DD.MM.YYYY)

1.6. Former changes of version 1

April 2014 Version 1.1.: modifications of the chapters 'Editors' and the 'Leading professional society', minor corrections to background texts, removing level of evidence '1--' (not included in the original citation and not relevant for this guideline), specification of the SAB's role in the development process.

1.7. Special notice

Medicine is subject to a constant process of evolution, so that all information can only reflect the state of knowledge at the time the prevention guidelines are printed. The greatest possible care has been taken over the recommendations given for the primary and secondary prevention of skin cancer.

In the public interest, please notify the German Guideline Program in Oncology (GGPO) editors of any dubious discrepancies.

1.8. Objectives of the German Guideline Program in Oncology

With the German Guideline Program in Oncology (GGPO), the Association of Scientific Medical Societies (AWMF), the German Cancer Society and German Cancer Aid have set themselves the task of jointly promoting and supporting the development, revision and use of scientifically-based and practical guidelines in oncology. This programme is based on medical scientific findings of professional associations and the German Cancer Society, the consensus of medical experts, users and patients, the AWMF's regulations governing the production of guidelines and professional support and funding of the German Cancer Aid. In order to depict the current state of medical knowledge and to take account of medical progress, guidelines need to be regularly reviewed and revised. In this respect, the use of the AWMF regulations is intended to provide a basis for the development of high-quality oncological guidelines. As guidelines constitute an important quality assurance and quality management tool in oncology, they should be specifically and consistently incorporated into everyday care. Active implementation measures as well as assessment programmes therefore play an important role in promoting the German Guideline Program in Oncology. The objective of the programme is to establish professional and medium-term financially secure preconditions for the development and production of high-quality guidelines. This is because these high-quality guidelines not only serve for the structured transfer of knowledge, but can also play a part in formulating health system structures. Examples that may be mentioned here are those of evidence-based guidelines as a basis for

compiling and updating Disease Management Programmes or the use of quality indicators derived from guidelines for certifying organ tumour centres.

1.9. Other documents relating to this guideline

This document is the long version of the evidence-based guideline on prevention of skin cancer. In addition to the long version, the following documents are supplementing this guideline:

- Summary of the guideline
- Patient guideline
- Guideline report on the process of compiling the guideline
- Evidence tables

This guideline and all the supplementary documents can be accessed via the following websites. (Please note that all these websites other than that of the Guidelines International Network are in German. Parts of the German Guideline Program and German Cancer Aid websites have an English translation.)

- German Guideline Program in Oncology (http://www.leitlinienprogramm-onkologie.de/OL/leitlinien.html)
- AWMF (www.leitlinien.net)
- Home pages of the professional societies involved, e.g. Association of Dermatological Prevention (www.unserehaut.de, www.hautkrebs-screening.de)
- German Cancer Society (http://www.krebsgesellschaft.de/wub_llevidenzbasiert,120884.html)
- German Cancer Aid (http://www.krebshilfe.de/)
- Guidelines International Network (www.g-i-n.net)

There is a specific evidence-based guideline on diagnosis, therapy and follow-up of melanoma within the German Guideline Program in Oncology [1] that can also be accessed via the websites of the German Guideline Program in Oncology and its sponsors.

1.10. Responsibilities

Co-ordination

Prof. Dr. med. E.W. Breitbart

Project team (in alphabetical order):

Markus Anders (January 2013 – October 2013)
Marcus Capellaro (March 2010 – February 2011)
Dr. Kohelia Choudhury (May 2013 – October 2013)
Friederike Erdmann (March 2010 – November 2011)

Felix Greiner (March 2010 – March 2011)
Dr. Rüdiger Greinert (March 2010 – October 2013)
Anna-Clara Mannheimer (January 2012 – October 2013)
Dr. Cathleen Muche-Borowski (March 2010 – March 2011)
Dr. Sandra Nolte (March 2010 – December 2010; June 2012 – December 2012)
Sonia Petrarca (March 2011 – December 2012)
Dr. Beate Volkmer (March 2010 – October 2013)

Professional societies and organisations involved

Table 1 lists the professional medical associations and other organisations, together with their appointed representatives, involved in producing the guideline.

Table 1: Overview of the associations, professional societies, organisations and patient representative groups involved and their appointed representatives

Professional societies and organisations involved	Representative
Association to Promote Dialogue in the Health System	Dr. Carsten Schwarz
Buxtehude Skin Cancer Self-Help Group	Annegret Meyer, Martina Kiehl
Centre for Media and Health Communication	Dr. Bettina Fromm (retired)
Dermatological Histology Working Group (ADH)	Prof. Dr. Christian Sander
Dermatological Oncology Working Group (ADO)	Prof. Dr. Axel Hauschild (retired), Prof. Dr. Carola Berking
European Society for Skin Cancer Prevention (EURO*SKIN*)	Dr. Rüdiger Greinert
Federal Association of German Pathologists (BDP)	Prof. Dr. Erhard Bierhoff*
Federal Office for Radiation Protection (BfS)	Dr. Monika Asmuß
German Association of Occupational Physicians (VDBW)	Dr. Uwe Gerecke
German Association of Psychosocial Oncology (DAPO)	Annkatrin Rogge
German Society of General Practice and Family Medicine (DEGAM)	Prof. Dr. Jean-François Chenot, Dr. Günther Egidi
German Dermatological Society (DDG)	PD Dr. Thomas Eigentler
German Dermatological Society (DDG) – Primary Prevention / Vitamin D	Prof. Dr. Jörg Reichrath
German Association for General Practitioners / Institute for CME and CPD in General Practice (IhF)	Dr. Diethard Sturm, Dr. Manfred Diensberg (representative)

Professional societies and organisations involved	Representative
German Ophthalmological Society (DOG)	Prof. Dr. Rudolf F. Guthoff
German Psoriasis Association	Hans-Detlev Kunz, Christiane Rose (retired)
German Society for Dermatosurgery (DGDC)	Dr. Christoph Löser
German Society for Epidemiology (DGEpi)	Prof. Dr. Andreas Stang
German Society for Journalism and Communication Science (DGPuK)	Dr. Eva Baumann
German Society for Occupational and Environmental Medicine (DGAUM)	Prof. Dr. Hans Drexler
German Society for Oral and Maxillofacial Surgery (DGMKG)	Prof. Dr. Dr. Bernhard Frerich, Dr. Dr. Heidrun Schaaf (representative)
German Society for Social Medicine and Prevention (DGSMP)	Prof. Dr. Alexander Katalinic, Dr. Annika Waldmann (representative)
German Society of Obstetrics and Gynaecology (DGGG)	Dr. Grit Mehlhorn
German Society of Oto-Rhino-Laryngology, Head and Neck Surgery (HNO)	Prof. Dr. Friedrich Bootz (retired), PD Dr. Andreas Gerstner
German Society of Pathology (DGP)	PD Dr. Christian Rose*
German Society of Paediatric and Adolescent Medicine (DGKJ)	Prof. Dr. Peter Höger
German Society of Urology (DGU)	Prof. Dr. Jürgen Gschwend
German Working Party for the Assistance of Persons with Disabilities and Chronic Diseases and their Relatives (BAG Selbsthilfe)	Christiane Regensburger
Otorhinolaryngology, Oral and Maxillofacial Surgical Oncology Working Group (AHMO)	Prof. Dr. Jochen A. Werner (retired), PD Dr. Andreas Gerstner
Professional Association of German Ophthalmologists (BVA)	Prof. Dr. Holger Mietz
Professional Association of German Urologists (BDU)	Dr. Bernt Göckel-Beining
Professional Association of Gynaecologists (BVF)	Dr. Wolfgang Cremer
Professional Association of Paediatric and Adolescent Physicians (BVKJ)	Dr. Herbert Grundhewer

Professional societies and organisations involved	Representative
Psycho-Oncology Working Group of the German Cancer Society (PSO)	Prof. Dr. Susanne Singer
Society of Epidemiological Cancer Registries in Germany (GEKID)	Dr. Annika Waldmann
* = joint representative of the professional association and the professional society	

Patient involvement

The guideline was drawn up with the direct participation of several patient representatives. Annegret Meyer and Martina Kiehl from the Buxtehude Skin Cancer Self-Help Group and Hans-Detlev Kunz from the German Psoriasis Association were invited as patient representatives. Christiane Regensburger represented the German Working Party for the Assistance of Persons with Disabilities and Chronic Diseases and their Relatives (BAG). These representatives were included as voting members on the working groups compiling the guideline.

Methodological support

By the German Guideline Program in Oncology:

- Dr. med. Markus Follmann, MPH MSc, Office of the German Guideline Program in Oncology – German Cancer Society
- Prof. Hans-Konrad Selbmann, Association of Medical Scientific Societies (AWMF).
- Dipl.-Soz.Wiss Thomas Langer, Office of the German Guideline Program in Oncology – German Cancer Society

By external contractors:

- Dr. med. Michaela Eikermann, Monika Becker, Thomas Jaschinski, Christoph Mosch; Institute for Research in Operative Medicine (IFOM), University of Witten/Herdecke
- Dr. Barbara Buchberger, MPH, Dr. Romy Heymann, Chair of Medical Management, University of Duisburg-Essen.

Translation

The document was translated by mt-g medical translation GmbH & Co. KG, Ulm, reviewed by the Association of Dermatological Prevention (ADP).

1.11. General remarks on the terminology used

Gender

In the interest of greater legibility, the use of the masculine and feminine forms at the same time will be avoided. All references to persons will apply equally to members of both sexes.

Patient

Similarly, for reasons of greater legibility, the term patient will frequently be used, even though the target group of this guideline is the general population. As a rule, the members of this group are not ill (with skin cancer), so that strictly speaking they are not patients.

Skin cancer

The term *skin cancer* is often understood to mean malignant melanoma only. When reference is made to skin cancer in this guideline, all skin cancer entities are intended, in particular the three most common forms mentioned below:

- Malignant melanoma (MM),
- Basal cell carcinoma (BCC),
- Squamous cell carcinoma (SCC).

2. Introduction

2.1. Target audience

The recommendations of the evidence-based guideline prevention of skin cancer are directed at all doctors and members of professional groups involved in the prevention and early detection of skin cancer. These include resident physicians with a preventive role (dermatologists, general practitioners, medical practitioners, non-specialist physicians, internal specialists in primary care, gynaecologists, urologists, surgeons, paediatricians, ENT specialists, oral and maxillofacial surgeons, histopathologists, dentists) as well as nursing staff and health assistants. Further audiences include medical scientific professional societies and professional associations, patient representatives and skin cancer self-help groups as well as quality assurance bodies and Federal and State Institutions, such as the Federal Office for Radiation Prevention (BfS), the Central Institute for Outpatient Care Provision in Germany (ZI), the Joint Federal Committee (G-BA) and the Society of Epidemiological Cancer Registries in Germany (GEKID).

Lastly, the guideline is directed at the population. A separate evidence-based patient guideline / lay version has been produced to provide a direct approach to the population.

2.2. Interface with the evidence-based guideline on diagnosis, therapy and follow-up of melanoma

(AWMF No 032/024GGPO)

The original plan was for a “skin cancer” guideline that was intended to cover the areas from prevention to palliative care. However, for pragmatic reasons such as scope and feasibility, it was instead decided in the preparatory and harmonisation phase to produce two guidelines linked via an interface group.

The interface group consisted of Prof. Dr. Breitbart (evidence-based guideline on prevention of skin cancer, co-ordinator) and Prof. Dr. Garbe and Prof. Dr. Schadendorf (evidence-based guideline on diagnosis, therapy and follow-up of melanoma, co-ordinators). The respective representatives of the other interface group or their deputies were always present in the harmonisation processes of the two guidelines.

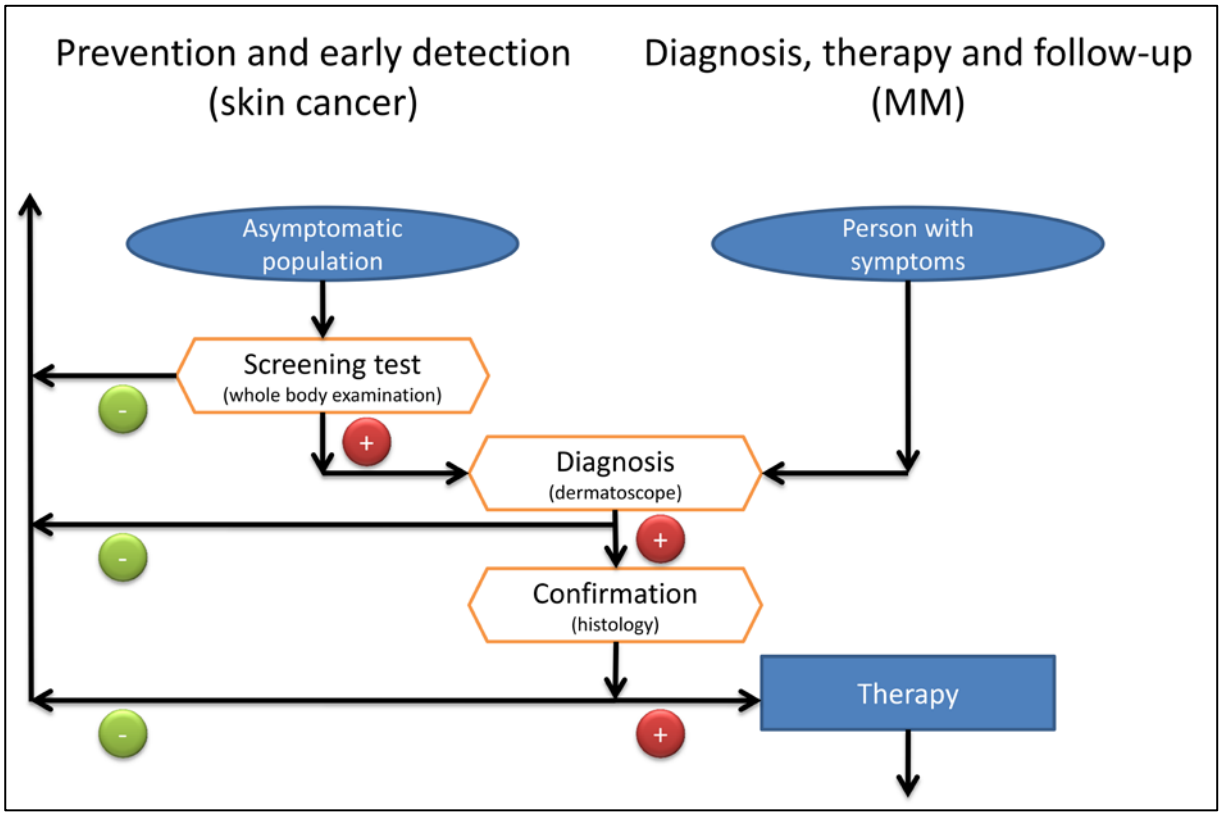

Figure 1: Overview of the interface with the evidence-based guideline on malignant melanoma

2.3. Period of validity and update process

The estimated period of validity of the guideline on the prevention of skin cancer is 5 years.

To be able to convey the latest state of knowledge in the field of skin cancer prevention, updates of the guideline will be necessary. A revision will be undertaken five years after completion of the follow-up research, i.e. June 2017.

Comments and advice on the update process are expressly requested and should be addressed to the guideline office:

c/o Prof. Dr. med. E.W. Breitbart
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2.4. Methodology

A detailed description of the methodological process can be found in the guideline report (www.leitlinienprogramm-onkologie.de/OL/leitlinien.html)

2.4.1. Modified SIGN evidence grading system

In order to classify the risk of bias of the studies identified, a modified system (seeTable 2) has been used in this guideline based on that of the Scottish Intercollegiate Guidelines Network (SIGN, see http://www.sign.ac.uk/pdf/sign50.pdf). In the system presented here, cross-sectional studies on diagnostic questions and pre-post comparisons have been included in level 2, as these have not previously been explicitly listed there.

Table 2: Modified SIGN classification of evidence table

Evidence class	Description (modifications in italics)
1++	High-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of systematic errors (bias)
1+	Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of systematic errors (bias)
1-	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of systematic errors (bias)
2++	High-quality systematic reviews of case-control or cohort studies (*including pre-post comparisons*) or High-quality case-control or cohort studies (*including pre-post comparisons*) with a very low risk of systemic distortions (confounding, bias or chance) and a high probability that the relationship is causal or *High-quality studies with a cross-sectional design to investigate diagnostic quality with a very low risk of systematic bias.*
2+	Well conducted case-control or cohort studies (*including pre-post comparisons*) with a low risk of systemic distortions (confounding, bias or chance) and a moderate probability that the relationship is causal or *Studies with a cross-sectional design to investigate diagnostic quality with a moderate risk of systematic bias.*
2-	Case-control or cohort studies (*including pre-post comparisons*) with a high risk of systematic distortions (confounding, bias, chance) and a significant risk that the relationship is not causal or *Studies with a cross-sectional design to investigate diagnostic quality with a high risk of systematic bias.*
3	Non-analytic studies, e.g. case reports, case series, *studies with a cross-sectional design without investigations for diagnostic quality.*
4	Expert opinion.

2.4.2. System of grading recommendations

The methodology of the German Guideline Program in Oncology (GGPO) allows for grades of recommendation to be allocated by the guideline authors as part of a formal consensus procedure. Accordingly, a multi-step, nominal group process moderated by the Association of Scientific Medical Societies (AWMF) was undertaken.

In the guideline, all evidence-based statements (see 0) and recommendations are assigned the level of evidence (see 2.4.1) of the studies on which they are based, while recommendations are also assigned a degree of strengths a strength (grade of recommendation). In terms of the strength of recommendation, three grades of recommendation are distinguished in this guideline (see Table 3), each of which is also reflected in the way in which the recommendations are worded.

Table 3: Grades of recommendation used

Grade of recommendation	Description	Wording
A	Strongly recommended	must
B	Recommended	should
0	Neither recommended nor not recommended	can

2.4.3. Statements

Apart from the recommendations, the guideline also contains evidence- or consensus-based statements. Statements are defined as expositions or explanations of specific facts or issues with no direct need for action. They are approved in a similar procedure to that used for recommendations in a formal consensus process. Evidence-based statements are also graded in accordance with the previously mentioned modified SIGN evidence grading (see 2.4.1).

2.4.4. Expert Consensus (EC)

Recommendations decided upon on the basis of a consensus of experts, and not on the basis of a systematic search or an adaptation of the guidelines, are identified as such by the grade "**EC**". Symbols representing the strength of recommendation are not given for ECs. The strength of recommendation is implicit in the wording of the sentence (must/should/can), in accordance with the grading inTable 3.

2.4.5. Independence and disclosure of possible conflicts of interest

German Cancer Aid provided financial resources through the German Guideline Program in Oncology (GGPO). These resources were used for staffing costs, office materials, literature procurement and consensus conferences (room hire, technology, catering, moderator's fees, travelling expenses of participants). The compilation of the guideline was editorially independent of the funding organisation. All members provided a written disclosure of possible conflicts of interest during the guideline process. The conflicts of interest disclosed are included in the guideline report to this guideline (http://leitlinienprogramm-onkologie.de/Leitlinien.7.0.html). The disclosures

of conflicts of interest were inspected and assessed by the co-ordinator. Following review by the guideline co-ordinator, none of the reported conflicts of interested was classed as sufficiently critical to have an impact on the remits.

As the Association of Dermatological Prevention (ADP) and with it in particular the guideline co-ordinator Prof Dr Breitbart has been active since the 1980s in the area of both primary and secondary prevention of skin cancer and in particular has designed, implemented and analysed the SCREEN project (SCREEN: Skin Cancer Research to Provide Evidence for Effectiveness of Screening in Northern Germany) [2], which was the basis for the introduction of national skin cancer screening in Germany, a potential conflict of interests was envisaged by the GGPO. In order to address this point the promotion of the guideline project was subjected to a neutral appraisal of the guideline by international experts.

Thus, it was intended to ensure that the evidence on secondary prevention was assessed independently. In order to meet this precondition already in the creation process, international experts in the field of skin cancer prevention have been included in the development of the guideline's chapter on the early detection of skin cancer. These experts are members of the Scientific Advisory Board (SAB) for the Prevention of Skin Cancer (see guideline report) that was founded in 2009 [3]. Furthermore the neutrality of the assessment regarding scientific evidence was ensured through the commission of external institutions (see chapter 5.2. in the guideline report).

2.5. Abbreviations used

Abbreviation	Explanation
ADP	Association of Dermatological Prevention
AJCC	American Joint Committee on Cancer
AK	Actinic keratosis
ALM	Acral-lentiginous melanoma
ArbSchG	Law on the Implementation of Protective Measures to Improve the Safety and Health of Employees at Work
AUVA	Austrian General Accident Insurance Institute
AWMF	Association of Medical Scientific Societies
BCC	Basal cell carcinoma
BER	Base-excision repair
BfS	Federal Office for Radiation Protection
BG ETEM	Professional Association of the Energy Textile Electrical and Media Products Sector
BKK	Company health insurance funds
CG	Control group
CI	Confidence interval
CLSM	Confocal laser scanning microscopy
CMN	Congenital melanocytic naevi
CPD	cis-syn-cyclobutane-pyrimidine dimers
CRBC	CPD-retaining basal cells
CT	Computer-assisted tomography
DBD	DNA-binding domain
DDG	German Dermatological Society
DKG	German Cancer Society
DKH	German Cancer Aid
DRG (G-DRG)	Diagnosis-Related Groups (German Diagnosis-Related Groups)
EASR	European age-standardised rate
EC	Expert consensus
EDC	Early detection of cancer
EIS	Electrical impedance spectroscopy
ENT	Ear, nose and throat
EORTC	European Organisation for Research and Treatment of Cancer

Abbreviation	Explanation
G-BA	Federal Joint Committee
GEKID	Society of Epidemiological Cancer Registries in Germany
GGPO	German Guideline Program in Oncology
GL	Guideline
GoR	Grade of Recommendation
HA	Health Assistant
HCA	Human capital approach
HPV	Human papillomavirus
IARC	International Agency for Research on Cancer
ICD	International Classification of Diseases
ICNIRP	International Commission on Non-Ionizing Radiation Protection
IG	Intervention group
IQWiG	Institute for Quality and Efficiency in Health Care
IW	Incapacity for work
KBV	National Association of Statutory Health Insurance Physicians
KDIGO	Kidney Disease: Improving Global Outcomes
LDH	Lactate dehydrogenase
LMM	Lentigo malignant melanoma
LOH	Loss of heterozygosity
MFS	Medical fee schedule (fee schedule outside the German statutory health insurance)
MM	Malignant melanoma
MPT	Multiphoton laser tomography
NBCC	Naevoid basal-cell carcinoma syndrome
NCCP	National Cancer Control Plan
NCN	Naevus cell naevus
NER	Nucleotide excision repair
NiSG	Act on Protection against Non-Ionising Radiation
NM	Nodular melanoma
NMSC	Non-melanocytic skin cancer
NNE	Number needed to excise
OCT	Optical coherence tomography

Abbreviation	Explanation
OR	Odds ratio
OStrV	Ordinance on the Protection of Employees against Hazards caused by Artificial Optical Radiation
PPV	Positive predictive value
QI	Quality indicators
QLQ	Quality of Life Questionnaire
QOL	Quality of life
RCT	Randomised controlled trial
ROS	Reactive oxygen species
RR	Relative risk
SAB	Scientific Advisory Board
SCC	Squamous cell carcinoma
SCREEN	Skin Cancer Research to Provide Evidence for Effectiveness of Screening in Northern Germany
SCS	Skin cancer screening
SHH-Gen	Sonic hedgehog
SHI	Statutory health insurance
SIGN	Scottish Intercollegiate Guidelines Network
SMO	Smoothened protein
SPF	Sun protection factor
SSE	Skin self-examination
SSK	Radiation Protection Commission
SSM	Superficial spreading melanoma
TNM classification	Staging of malignant tumours (tumour, lymph nodes (nodes), metastases)
UICC	International Union Against Cancer
UNEP	United Nations Environment Programme
UPF	Ultraviolet protection factor
URS	Uniform rating standard (fee schedule in the German statutory health insurance regarding outpatient care)
UV radiation	Ultraviolet radiation
UVI	UV index
UVSV	Ordinance on the Protection from Adverse Effects of Artificial Ultraviolet Radiation

Abbreviation	Explanation
WHO	World Health Organization
ZI	Central Institute for Outpatient Care Provision in Germany

3. Status quo of skin cancer

3.1. The aetiology of skin cancer

No.	Recommendations/Statements	GoR	LoE	Ressources
3.1.	On the basis of current knowledge, ultraviolet (UV) radiation is considered to be the most significant risk factor in the aetiology of skin cancer, even if not all details of the induction, promotion and progression of skin cancer in humans have been elucidated.	EC		

Full details of the clinical course, histopathological classification and TNM classification of basal cell carcinoma (BCC), squamous cell carcinoma (PEK) and malignant melanoma (MM) can be found in the long version of this guideline.

3.2. Incidence and prevalence of skin cancer

Table 4: Current key indicators for MM in Germany

Key indicators	Men	Women
Incidence 2009*		
New cases of disease	9,250	8,725
Age-standardised rate (European standard) per 100,000	17.4	16.0
Mortality 2010**		
Deaths	1,568	1,143
Age-standardised rate (European standard) per 100,000	2.8	1.6
Relative 5-year survival***		
Total	83.1%	91.7%
pT1	99.7	100.0
pT2	83.7	97.7
pT3	67.8	86.1
pT4	47.8	67.7
Prevalence****		
Absolute frequency 2004	24,300	34,200
Absolute frequency 2010 (predicted)	27,600	37,900
Data sources: * [4] ** [5] *** [6] **** [7]		

Table 5: Current key indicators for non-melanocytic skin tumours in Germany

Key indicators	Men	Women
Incidence 2009*		
New cases	63,543	55,655
Age-standardised rate (European standard) per 100,000	108.2	77.8
Mortality 2010**		
Deaths	346	275
Age-standardised rate (European standard) per 100,000	0.6	0.3

Data sources:
* [4]
** [5]

3.3. The individual, social and economic burden of skin cancer

The long version of this guideline includes a detailed presentation on the direct and indirect costs of skin cancer and the impact on quality of life.

3.4. Risk factors of skin cancer

No.	Recommendations/Statements	GoR	LoE	Ressources
3.2.	Constitutional risk factors: **Non-melanocytic skin cancer (NMSC)** An important constitutional risk factor for NMSC (basal cell carcinoma and squamous cell carcinoma) is • **skin type.** All other risk factors can be acquired during the course of life.		EC	
3.3.	Constitutional risk factors: **Malignant melanoma (MM)** The class of constitutional risk factors for MM includes **a) skin type and** **b) (large) congenital naevus.** All other risk factors can be acquired during the course of life.		EC	
3.4.	Acquired risk factors: **Non-melanocytic skin cancer (NMSC)** The main acquired risk factors for NMSC (basal cell carcinoma and squamous cell carcinoma) are: **a) actinic keratosis,** **b) previous history of NMSC,** **c) immunosuppression,** d) **chronic radiation keratoses.**		EC	

3.5.	Acquired risk factors: **Malignant melanoma (MM)** The main acquired risk factors for MM are: **a) previous history of melanoma,** **b) family history of melanoma,** **c) number of acquired naevi,** d) **clinically atypical moles.**	EC
3.6.	The probability of developing a **squamous cell carcinoma** is correlated with the UV dose to which a person is exposed during their life (cumulative dose). For **basal cell carcinoma,** the cumulative UV exposure appears to be of secondary importance. Intermittent UV exposure and sunburn are important in the case of BCC. For **malignant melanoma,** intermittent UV exposure and sunburn (at any age) are of major importance.	EC
3.7.	Other risk factors that are described for non-melanocytic skin cancer are exposure to arsenic or tar, particularly in the work environment. HPV infections are discussed both as a risk factor for skin cancer in their own right and as a cofactor in combination with ultraviolet (UV) radiation.	EC

In the following statements on the absolute and relative risks, the figures from the previous sections on constitutional risk factors, the risk from different UV exposure patterns and the risk from using solariums are summarised by way of conclusion and examples listed.

<table>
<tr><th>No.</th><th>Recommendations/Statements</th><th>GoR</th><th>LoE</th><th>Ressources</th></tr>
<tr><td>3.8.</td><td>Values for relative risks (RR) or lifetime risks are given in the literature in various studies for the constitutional risk factors described. Examples of such values are listed below for non-melanocytic skin cancer:

<table>
<tr><th>Risk factor</th><th>RR (95% CI)</th></tr>
<tr><td>Skin type I vs. IV (BCC)</td><td>5.1 (1.4-11.3)</td></tr>
<tr><td>Skin type II vs. IV (BCC)</td><td>5.3 (1.7-10.6)</td></tr>
<tr><td>Skin type I vs. IV (SCC)</td><td>1.4 (0.5-3.0)</td></tr>
<tr><td>Skin type II vs. IV (SCC)</td><td>2.2 (0.7-3.8)</td></tr>
<tr><td colspan="2">Sources: [8, 9]</td></tr>
</table>

The presence of multiple actinic keratoses over a 10-year period is reported as being associated with a lifetime risk for the development of a squamous cell carcinoma (SCC) in the region of 6-10%.

With a personal history of SCC, the risk of developing another SCC within 5 years is 30% and of developing a basal cell carcinoma (BCC) about 40%.

With a personal history of BCC, the risk of developing another BCC within 3 years is 44% and of developing an SCC about 6%.
SCC occurs up to 65 times more frequently in immunosuppressed transplant patients than in controls. Immunosuppressed transplant patients develop more SCC than BCC (4:1).</td><td></td><td>EC</td><td></td></tr>
</table>

<table>
<tr><th>No.</th><th>Recommendations/Statements</th><th>GoR</th><th>LoE</th><th>Ressources</th></tr>
<tr><td>3.9.</td><td>Values for relative risks (RR) or lifetime risks are given in the literature in various studies for the constitutional risk factors described. Examples of such values are listed below for malignant melanoma:

<table><tr><th>Risk factor</th><th>RR (95%</th></tr><tr><td>Number of acquired naevi (100-120 vs. < 15)</td><td>6.89 (4.</td></tr><tr><td>Skin type (I vs. IV)</td><td>2.09 (1.</td></tr><tr><td>Family history of melanoma (yes vs. no)</td><td>1.74 (1.</td></tr><tr><td>Number of atypical naevi (5 vs. 0)</td><td>6.36 (3.</td></tr><tr><td>Personal history of melanoma (yes vs. no)</td><td>8.5 (5.8</td></tr></table>Sources: [10-12]

Congenital naevi with a diameter of > 10 to 20 cm are known as “large congenital naevi”. They are associated with a risk of approximately 2-10% of developing a melanoma during the course of life.</td><td></td><td></td><td>EC</td></tr>
<tr><td>3.10.</td><td>The relative risks (RR) for the development of different skin cancer entities (basal cell carcinoma (BCC), squamous cell carcinoma (SCC) and malignant melanoma (MM)) depend on the UV exposure pattern. BCC does not depend on the cumulative UV dose (RR = 0.98, 95% CI 0.68-1.41), whereas SCC is more strongly dependent on the cumulative dose (RR = 1.53, 95% CI 1.02-2.23). MM is intermediate between the two in relation to the cumulative dose (RR = 1.2, 95% CI 1.00-1.44). For MM, however, there is an increased risk from intermittent UV exposure (RR = 1.71, 95% CI 1.54-1.90) or from sunburn at any age (RR = 1.91, 95% CI 1.69-2.17) [13].</td><td></td><td></td><td>EC</td></tr>
<tr><td>3.11.</td><td>The relative life risk (RR) for a malignant melanoma is RR = 1.75 (95% CI: 1.35-2.26) if solariums are used regularly (at least once a month) before the age of 35 [14].</td><td></td><td></td><td>EC</td></tr>
</table>

4. Primary prevention

The effect of UV radiation on the skin is the main cause of skin cancer. The aim of primary prevention is therefore to prevent excessive UV exposure of the skin. This applies first and foremost to UV exposure from the while being outdors. Various measures are suitable, but the individual sensitivity of the skin to UV radiation needs to be borne in mind.

4.1. Individual behaviours

No.	Recommendations/Statements	GoR	LoE	Ressources
4.1.	Protective measures against solar ultraviolet radiation must be applied in the following order: • avoidance of exposure to strong solar radiation, • wearing suitable clothing, • using sunscreens.	EC		
4.2.	The following measures must be taken to avoid exposure to strong solar radiation in the relevant weather conditions: • remain outside as little as possible, • avoid staying outside in the middle of the day, • the length of time in the sun should not exceed the individual intrinsic protection time of the skin, • seek shade, • undertake outdoor activities in the morning and evening hours, • accustom the skin slowly to the sun (e.g. in spring / on holiday), • avoid sunburn at all events.	EC		
4.3.	When staying outside in the sun, suitable clothing, headwear and sunglasses should be worn for protection.	EC		
4.4.	Suitable sunglasses must be worn in strong sunlight. Never look directly at the sun in the sky. This applies even when wearing sunglasses.	EC		
4.5.	Where possible, physical measures (avoidance of exposure, textiles) must be used in the first place for protection from sunlight. Sunscreens must be used for areas of the skin that cannot otherwise be protected. The use of sunscreens must not result in staying out longer in the sun.	A	1+	[15-20]

No.	Recommendations/Statements	GoR	LoE	Ressources
4.6.	Sunscreens should be applied carefully to free areas of skin that are not covered by clothing (head, face, hands, arms, legs) and the following should be observed: • use an appropriate sun protection factor, • apply as thick a layer as possible (2 mg/cm²), • apply evenly to all uncovered areas of skin, • apply before exposure to the sun, repeat the application after 2 hours and after bathing (the protective time is not prolonged as a result).	EC		
4.7.	There are contradictory data as to whether the risk of melanoma is reduced by using sunscreen.	ST	1++	[18-22]
4.8.	In accordance with international and national recommendations (WHO, ICNIRP, EUROSKIN, SSK, DKH and ADP), the use of sun studios must be avoided to reduce the risk of development of skin cancer.	EC		
4.9.	Food supplementation with selenium, vitamin A and beta-carotene must not be recommended as a measure for skin cancer prevention.	A	1++	[21, 23, 24]
4.10.	Intensive solar / ultraviolet (UV) radiation represents a risk for skin cancer to all certain groups and must be avoided.	EC		
4.11.	Children must not be allowed to develop sunburn.	EC		
4.12.	Babies must not be exposed to direct sunlight.	EC		
4.13.	Children must be required to wear skin-covering clothing in strong sunlight.	EC		
4.14.	Children with a light skin colour in particular must use sunscreens as well as avoid strong ultraviolet (UV) radiation exposure and additionally wear sun-protective textiles.	A	1++	[25]
4.15.	Children's eyes must be protected by suitable children's sunglasses that meet the previously mentioned requirements (see Recommendation 4.4.).	EC		
4.16.	Immunosuppressed transplant recipients must use sunscreens to protect themselves from skin cancer as part of a consistent, comprehensive ultraviolet (UV) radiation protection strategy.	A	2+	[26]
4.17.	Immunosuppressed people must ensure they have a consistent, comprehensive untraviolet (UV) radiation protection strategy.	EC		

No.	Recommendations/Statements	GoR	LoE	Ressources
4.18.	In people at high risk for skin cancer (e.g.: transplant recipients, immunosuppressed patients) who practice consistent, extensive sun protection, vitamin D levels should be checked and vitamin D supplements given where necessary.	EC		
4.19.	Moderate exposure to ultraviolet (UV) radiation and high vitamin D levels possibly have a protective effect against the occurrence and development of various types of cancer, including malignant melanoma. However, the existing evidence for a relationship between the risk of cancer and vitamin D intake is insufficient.	ST	2+	[27-30]
4.20.	The Guideline Group is currently unable to answer the question as to the optimal (reasonable) ultraviolet (UV) radiation exposure to ensure sufficient endogenous vitamin D production without incurring an increased risk of skin cancer.	EC		

No.	Dessenting opinion of DEGAM on section 4.1.
4.21.	The German Society of General Practice and Family Medicine (DEGAM) generally does not pass on recommendations with the strength of recommendation “must” to the general population. On the one hand, the data relating to a possible vitamin D deficiency and the need to spend time outdoorsdoes not suffice to issue a general recommendation to avoid sunlight. Secondly, it is not DEGAM’s policy to give- well-intentioned-generalised recommendations for behaviour in terms of cancer prevention to the population, which fail to take into account the particular aspects and preferences of the individual subjects.

4.2. Primary prevention measures for the population

No.	Recommendations/Statements	GoR	LoE	Ressources
4.22.	Knowledge about the effects of ultraviolet (UV) radiation and sun protection measures must be passed on constantly.	A	1+	[31-36]
4.23.	To improve sun protection behaviour, interventions about ultraviolet (UV) radiation protection should be conducted in schools and playschools or day care centres, with particular regard to the target group of younger children.	B	1+	[33, 37-39]
4.24.	Interventions that target a sustained effect on behaviour should involve several components and should be implemented intensively and repeatedly.	B	2+	[33, 40-44]

No.	Recommendations/Statements	GoR	LoE	Ressources
4.25.	Doctor-patient communication (e.g. in connection also with skin cancer screening) should be used for primary preventive measures. (see also section 0 Doctor-patient communication)	B	1++	[45-48]
4.26.	The following recommendations must be given in the doctor-patient discussion on cancer prevention: **Content** • Information about the risks of ultraviolet (UV) radiation • Motivation to change behaviour • Avoid exposure to strong solar radiation o Avoid the midday sun o Stay out in the sun for as little as possible o Seek shade o Avoid sunburn o Be aware of the ultraviolet (UV) radiation index • Accustom the skin slowly to the sun • Wear protective clothing • Use sunscreens without prolonging exposure time o Be aware of individual skin sensitivity o Give information about the different skin types • Advice on individual protective measures according to th patient's skin type • Pay attention to possible side effects of medicines in the • Protect children in particular • Avoid sun studios (refer to NiSG) • Wear sunglasses	EC		
4.27.	The ultraviolet (UV) radiation index should be more intensively publicised, firmly anchored in the media and used as an aid in UV protection campaigns. At the same time, the limits of its value should be observed.	EC		
4.28.	Parents of babies and young children must be informed about appropriate sun protection for their children. (see also Recommendation 4.3.)	A	1++	[49]
4.29.	Schoolchildren and adolescents must be intensively informed about skin cancer risks, instructed in the practical use of protective measures and receive appropriate support from teachers.	A	1++	[41]

No.	Recommendations/Statements	GoR	LoE	Ressources
4.30.	The tendency to acquire risk factors for skin cancer (e.g. naevi) must be reduced by interventions at school age with a long-term and repetitive approach.	A	2+	[37, 39, 44, 50, 51]
4.31.	Sufficient shaded areas must be established in day-care centres, kindergartens and schools.	A	1++	[52]
4.32.	Technical and organisational measures to minimise ultraviolet (UV) radiation exposure, particularly during the midday hours (e.g. provision of shaded areas, structuring of the timetable, consideration of UV radiation protection in the timetabling of sports events), should be an essential part of primary prevention.	B	2+	[33, 42, 53, 54]
4.33.	For outdoor workers, suitable technical and organisational ultraviolet (UV) radiation protection measures (shaded areas, work organisation, rules governing breaks) should be promoted and take precedence over personal protective measures.	EC		
4.34.	Outdoor workers must be informed of the ultraviolet (UV) radiation risks and UV radiation protection measures by means of training measures.	A	1+	[55-59]
4.35.	Outdoor workers must be protected by detailed legal regulations as they are at particular risk from intensive ultraviolet (UV) radiation.	EC		

5. Secondary prevention

5.1. Early detection of skin cancer

Where reference is made in this chapter to “skin cancer screening”, the term “skin cancer” is intended here, as in the whole of the guideline, to mean the three most common malignant skin cancer entities: malignant melanoma (MM), basal cell carcinoma (BCC) and squamous cell carcinoma (SCC).

No.	Recommendations/Statements	GoR	LoE	Ressources
5.1.	Population-based screening with the target diseases of malignant melanoma, basal cell carcinoma and squamous cell carcinoma, in which a standardised examination of the skin over the whole body is performed by trained physicians, has been shown to result in an increase in the detection rate of tumours at an early stage.	ST	2++	[60, 61]
5.2.	Skin cancer screening of the general adult population results in an initial increase in the incidence of skin cancer (prevalence phase of screening) and an increase in the detection rate of skin cancer at an early stage. This result could impact on the morbidity of malignant melanoma, basal cell carcinoma and squamous cell carcinoma.	ST	2++	[60, 61]
5.3.	A single study indicates that population-based skin cancer screening could reduce mortality from melanoma.	ST	2+	[60]
5.4.	Skin cancer screening should be offered as part of the prevention of skin cancer.	B	2+	[60]

No.	Dessenting opinion of DEGAM
5.5.	The German Society of General Practice and Family Medicine (DEGAM) regards the evidence for the benefit of a general skin cancer screening programme as insufficient. In individual cases, early detection of skin cancer can be performed following balanced information about the pros and cons.

No.	Recommendations/Statements	GoR	LoE	Ressources
5.6.	The standardised whole-body skin examination to screen for malignant skin tumours must be performed by physicians. The precondition for this is participation in special advanced education courses on the early detection of skin cancer.	A	2++	[60, 61]

No.	Recommendations/Statements	GoR	LoE	Ressources
5.7.	On the basis of the current evidence, it is not possible to make any statement about examination intervals for people not at increased risk.	EC		
5.8.	In the context of skin cancer screening, the time to presentation for further confirmation of the findings following the suspicion of a malignant melanoma, basal cell carcinoma or squamous cell carcinoma should not exceed ten working days.	EC		

No.	Dessenting opinion of DEGAM
5.9.	In the context of skin cancer screening, people with a suspected malignant melanoma must be given the opportunity to attend for further, where necessary surgical, investigations within ten working days.

No.	Recommendations/Statements	GoR	LoE	Ressources
5.10.	At-risk persons (see section 3.4) must be taught to carry out skin self-examination so as to be able to identify abnormal skin lesions. At-risk persons must be informed about their individual risk and be regularly examined (at intervals to be defined individually) by a trained physician by means of a whole-body skin examination.	EC		
5.11.	For people at increased risk for skin cancer, the physician, together with the person to be screened, should define an appropriate interval, based on an assessment of the individual risk profile.	EC		
5.12.	Negative consequences of skin cancer screening involve excisions with a benign histology (false-positive tests). The number-needed-to-excise described in studies ranges from 3.25 to 179, i.e. between 3.25 and 179 excisions are needed to confirm one malignant skin tumour histologically.	ST	2+	[60, 62-64]

No.	Recommendations/Statements	GoR	LoE	Ressources
5.13.	With the exception of false-positive tests, there is little evidence to date about potential risks and negative consequences of skin cancer screening. Possible negative consequences are overdiagnosis, overtreatment, negative psychological consequences and possible delays in diagnosis as a result of false-negative tests. These potential risks and negative consequences of skin cancer screening should be reduced as far as possible by appropriate physician training and teaching measures. Physicians should discuss potential risks and negative consequences with their patients before the screening.	EC		

5.2. Screening test / presumptive diagnostic procedures

5.2.1. Screening test

No.	Recommendations/Statements	GoR	LoE	Ressources
5.14.	A whole-body examination must be performed for skin cancer screening.	A	2++	[60, 65-67]
5.15.	For a whole-body examiantion, the examination room must be well-lit and the examiner must approach the person to be screened close enough to be able to detect skin changes with the naked eye.	EC		
5.16.	The diagnosis of non-melanocytic skin cancer by whole-body examination has a sensitivity of 56-90% and a specificity of 75-90%.	ST	1-	[65]
5.17.	In a cross-sectional study with Australian family physicians, sensitivity in the diagnosis of skin cancer types by whole-body examination was 100% for melanomas (n=1), 89% for basal cell carcinomas (n=62), 80% for dysplastic naevi (n=30), 58% for benign naevi (n=69), 42% for squamous cell carcinomas (n=18) and 10% for actinic keratoses (n=31), while specificity for these entities was 76-99%.	ST	2+	[66]
5.18.	In the diagnosis of melanoma by clinical examination, the sensitivity of non-dermatologically trained practitioners was 86-95% and the specificity 49-77%. Training in the diagnosis of melanoma did not produce any substantial increase in sensitivity and specificity in general practitioners.	ST	2-	[68, 69]

No.	Recommendations/Statements	GoR	LoE	Ressources
5.19.	According to a systematic review, the available study data are insufficient to draw conclusions about statistically significant differences between dermatologists and primary care physicians in terms of accuracy in classifying suspected melanoma lesions. In terms of diagnostic accuracy, the sensitivity of dermatologists was 0.81-1.0 and of primary care physicians 0.42-1.00. In terms of biopsy or referral accuracy, the sensitivity was 0.82-1.0 (dermatologists) and 0.70-0.88 (primary care physicians).	ST	2++	[70]
5.20.	The person to be screened must be asked about skin changes at the beginning of the screening / presumptive diagnostic procedures.	EC		
5.21.	The results of the self-examination of the person to be screened should be included at the beginning of the screening / presumptive diagnostic procedures to identify and differentiate between malignant and benign skin changes.	B	2-	[71]

5.2.2. Presumptive diagnostic procedures

No.	Recommendations/Statements	GoR	LoE	Ressources
5.22.	Dermatoscopy should be performed in the presumptive diagnostic procedure. It should be used to improve the clinical diagnosis of melanocytic lesions.	B	2++	[72, 73]
5.23.	Dermatoscopy must be performed only after appropriate practical training.	A	2++	[73]
5.24.	Dermatoscopy can be performed in people at increased risk undergoing an individualised check-up.	0	2++	[74]
5.25.	For all lesions of the skin and the adjacent mucosae in the facial, genital or anal region that would be insufficiently investigated by diagnostic procedures involving the use of dermatoscopy, the patient must have a consultation with further specialist diagnostic procedures.	EC		
5.26.	Algorithms for describing pigmented lesions and instant cameras for observing the disease course with the aim of reducing the proportion of excised benign lesions relative to melanomas should not be used.	B	1++	[75, 76]

No.	Recommendations/Statements	GoR	LoE	Ressources
5.27.	The value of whole-body photography in melanoma risk patients remains unproven.	ST	2-	[77, 78]
5.28.	Special image processing programmes for the detection of melanomas have been developed, but their value remains unproven.	ST	2-	[79]
5.29.	Teledermatology can be used to assess benign and malignant skin tumours.	0	2++	[80-82]
5.30.	Spectrophotometric analysis of pigmented lesions has shown no improvement in sensitivity and specificity in the diagnosis of melanoma.	ST	2-	[69, 83, 84]
5.31.	The value of near-infrared spectroscopy in distinguishing melanocytic and non-melanocytic skin changes from one another and from normal skin remains unproven.	ST	3	[85]
5.32.	Confocal laser scanning microscopy (CLSM) has a high resolution in assessing pigmented and non-pigmented skin lesions. Following suitable training, CLSM can improve the diagnostic accuracy of individual lesions.	ST	1-	[65, 86, 87]
5.33.	The value of multiphoton laser tomography in the diagnosis of melanoma remains unproven.	EC		
5.34.	The value of optical coherence tomography (OCT) in distinguishing melanocytic and non-melanocytic skin changes from one another and from normal skin remains unproven.	EC		
5.35.	The value of multifrequency electrical impedance spectroscopy (EIS) in distinguishing melanocytic and non-melanocytic skin changes from one another and from normal skin remains unproven.	EC		
5.36.	The value of high-resolution ultrasonography in distinguishing melanocytic and non-melanocytic skin changes from one another and from normal skin remains unproven.	EC		

5.3. Confirmatory diagnostic procedures

No.	Recommendations/Statements	GoR	LoE	Ressources
5.37.	The histopathological examination of a suitable tissue sample is the standard confirmatory diagnostic method. The histopathological diagnosis must be used to confirm a suspicious lesion.	EC		

No.	Recommendations/Statements	GoR	LoE	Ressources
5.38.	At the time of tissue sampling, consideration must be given to the relevant specific functional features in each case (e.g. in the facial and genital region) to prevent a functional disorder (e.g. ectropion, facial nerve paralysis) simply as a result of the tissue sampling.	EC		
5.39.	On clinical suspicion of a malignant melanoma, this lesion must first of all be completely excised with a small safety margin.	EC Based on the existing guidelines [1] and [88]		
5.40.	The optimal tissue sample for histopathological assessment of a skin lesion suspected of being malignant melanoma is the complete excision (excision biopsy) with a safety margin of 2 mm, including the removal of fatty tissue.	ST	2+	Guidline adoption [89]
5.41.	In the case of large, extensive tumours on the face or acral skin that are suspicious for melanoma and for which a primary diagnostic excision is difficult, a sample biopsy or partial excision can be performed.	EC		
5.42.	On clinical suspicion of a basal cell carcinoma or a squamous cell carcinoma, the tumour can undergo complete primary excision with a small safety margin or a sample biopsy can be taken beforehand.	0	3	[90]
5.43.	Each histopathological report (cf. quality assurance agreement) must contain a description of the microscopic findings and the formulation of a diagnosis. The type of tumour must be stated in accordance with the WHO classification and the histological staging in accordance with the currently valid TNM classification (UICC).	EC		
5.44.	[In Germany,] the aspects of quality assurance are defined in accordance with the agreement on quality assurance measures laid down in section 135(2) SGB V[1] on the histopathological examination in association with skin cancer screening [91] of 12 August 2009.	EC		

[1] German social act

5.4. Doctor-patient communication

No.	Recommendations/Statements	GoR	LoE	Ressources
5.45.	Prior to the doctor-patient conversation, the patient should be issued with an information sheet on the early detection of skin cancer (skin cancer screening) that provides information about the pros and cons of early detection in simple language without engendering any anxiety. The subject matter should be kept to the checklist agreed in connection with the German National Cancer Control Plan *Recommended content of information about early detection measures* [92]. In addition, reference should be made to the possibility that outstanding queries can be clarified in the subsequent doctor-patient conversation. During the doctor-patient conversation, which should take place in a quiet and undisturbed atmosphere, the checklist should also serve as a guide. Emphasis should be placed on the following aspects: • Procedure of the skin cancer screening, • Pros and cons of skin cancer screening, • Primary prevention information, • Personal risk profile and resultant consequences (risk communication). A period of time commensurate with the patient's personal preferences should be allowed to elapse between the provision of information and the decision. Associated professional groups and, where applicable, relatives should be included in the communication process.			EC
5.46.	A negative examination result must be communicated to the patient personally by the doctor carrying out the early detection in a counselling immediately after the examination. It must be pointed out that the result of the examination reflects the current status. In addition, the patient's individual risk factors must be explained to him and he must be motivated to practise primary preventive behaviour and skin self-examination. The patient must also be informed that he can visit the doctor again at any time in the event of any uncertainties about self-recorded skin findings.			EC

No.	Recommendations/Statements	GoR	LoE	Ressources
5.47.	The suspicion of skin cancer must be communicated to the patient personally by the doctor carrying out the early detection in a counselling immediately after the examination. Family physicians (specialists in general medicine working in family practice, internal specialists, medical practitioners and non-specialist practitioners): following the communication of a suspicion, the subsequent procedure must be explained, including a referral to the dermatologist for further investigations. Dermatologist: the subsequent diagnostic investigations of the clinical suspicion must be communicated and explained. The patient must be informed that the findings will be communicated in a personal conversation and that he has the possibility of including a person of trust in this conversation. The patient must be asked about resources for psychological support during the waiting period and encouraged to practise self-care. The detailed interview must take place following receipt of the histological report. Information about the exclusion or demonstration of skin cancer (following histological confirmation of the findings) must not be given over the telephone.			EC
5.48.	The period between the measures to confirm the diagnosis and the communication of the diagnosis must be kept as short as possible. Exclusion of skin cancer: the patient must be told of the histological exclusion of skin cancer. In addition, the patient must be given an explanation about his individual risk factors and he must be encouraged to practise primary preventive behaviour and skin self-examination. The patient must also be informed that he can visit the doctor again at any time in the event of any uncertainties about self-recorded skin findings. Confirmation of skin cancer: the finding of skin cancer must be communicated to the patient in detail with the diagnosis and grading in a personal (face-to-face) conversation. The existing diagnostic and therapeutic steps consistent with the current state of scientific knowledge must be conveyed comprehensibly to the patient over several sessions.			EC

5.5. Implementation and quality assurance of skin cancer screening

No.	Recommendations/Statements	GoR	LoE	Ressources
5.49.	Skin cancer screening must be conducted only by qualified physicians who have successfully completed a recognised advanced education course lasting several hours on the conduct of skin cancer screening.		EC	
5.50.	A counselling approach and/or further advice on skin cancer screening can be offered and carried out by health professionals who are not medical practitioners (health assistants, practice nurses, nursing professions, other specialist professions within the healthcare system). The precondition for this is: • completion of appropriate professional training and • successful completion of a recognised advanced education course lasting several hours on counselling in connection with skin cancer screening.		EC	
5.51.	Advanced education/advanced education programmes in skin cancer screening for physicians and other health professionals (health assistants, practice nurses, nursing professions, other specialist professions in the healthcare system) must be extensively offered and carried out by certified trainers.		EC	

No.	Recommendations/Statements	GoR	LoE	Ressources
5.52.	Advanced education provision in skin cancer screening for physicians or other health professionals (health assitants, practice nurses, nursing professions, other specialist professions in the healthcare system) must impart practical and theoretical knowledge and methods. To this end, the following content matter must be included in a curriculum: • Epidemiology of skin cancer (MM, NMSC), • Aetiology, risk factors and groups, • Clinical pictures (MM, NMSC), • Definition of prevention (primary, secondary and tertiary prevention), • Early detection of cancer as a screening measure, • Legal framework conditions, • Benefit and harms of early detection measures/screening programmes, • Criteria for assessing early detection measures, • Key performance indicators of a screening test, • Skin cancer screening, • Measures for targeting potential participants, • Requirements for advice about an informed decision in the context of skin cancer screening, • Screening test: visual standardised whole-body examination, • Targeted case history-taking, • Reporting of findings and advice, • Quality assurance of pathology (histopathological differential diagnoses), • Quality requirement of histopathology, • Histopathological diagrams, • The histopathological report (completeness, significance of contents), • Referral, • Documentation, • Invoicing, • Notification to cancer registries, • Interdisciplinary co-operation, • Principles of communication, • Communication between family physician and dermatologist, dermatologist and pathologist, physician and patient, • Communication tools for conversation techniques.			EC

No.	Recommendations/Statements	GoR	LoE	Ressources
5.53.	Curricula for the training, advanced education and continuing professional development of physicians or other health professionals (health assistants, practice nurses, nursing professions, other specialist professions in the healthcare system) in primary care provision can include the following subject areas in relation to the primary and secondary prevention of skin cancer: • Epidemiology, • Diagnostic procedures including dermatoscopy and clinical algorithms, aided by photographic images of skin lesions, • Advice (primary and secondary prevention), • Communication, • Treatment. Curricula can be divided into one of more intervention units and incorporate the following educational means and conditions: course attendance, web-based, interactive, multimedia, role play, conveyed theoretically and/or practically.	0	1-	[69, 93-104]
5.54.	Pharmacy staff can be trained in primary skin cancer prevention.	0	1-	[105]

No.	Recommendations/Statements	GoR	LoE	Ressources
5.55.	In skin cancer screening, participating physicians must collect the following data for each patient examined for skin cancer: <u>Family physician (specialists in general medicine working in family practice, internal specialists, medical practitioners, non-specialist physicians):</u> • Clear personal identification of the examinee (screening ID or pseudonym in the cancer registry), • Identification of the physician, • Age and sex of examinee, • Date of examination, • Presumptive diagnosis, differentiated by type of skin cancer (malingnant melanoma, squamous cell carcinoma, basal cell carcinoma). <u>Dermatologists (specialists in skin and venereological diseases) must record the following data in addition to those mentioned above:</u> • On referral: presumptive diagnosis of the referring physician and date of first examination, • Date of examination (dermatologist), • Presumptive diagnosis (dermatologist), differentiated by type of skin cancer (malingnant melanoma, squamous cell carcinoma, basal cell carcinoma), • Following excision: excision date, histopathological findings and where applicable tumour stage (tumour thickness or spread, where applicable TNM stage, grading).			EC
5.56.	If an invitation system is introduced for skin cancer screening, the following data on the invitation of the general population must be recorded: <u>Agency issuing the invitation (central agency or health insurance company):</u> • Clear personal identification of the invitee (screening ID or pseudonym in the cancer registry), • Date of invitation • Age and sex of invitee, • Rejection / exclusion (active rejection of skin cancer screening or skin cancer screening not applicable, e.g. with prevalent skin cancer).			EC

No.	Dessenting opinion of DEGAM
5.57.	In view of the unconfirmed evidence for skin cancer screening and the in any case already high level of doctor-patient contacts in general practices compared to international standard, the German College of General Practitioners and Family Physicians (DEGAM) does not recommend an invitation system.

No.	Recommendations/Statements	GoR	LoE	Ressources
5.58.	Data recorded about skin cancer screening must be forwarded by family physicians and dermatologists to an evaluation centre where, together with the invitation data where applicable, they must be collated and evaluated for the quality management of skin cancer screening. In order to determine interval carcinomas and to evaluate mortality, a comparison must be undertaken with the cancer registry. The comparative data must be provided for the purposes of scientific evaluation. When a malignant finding is obtained, the responsible cancer registry must be notified by the examining physicians (including pathologists).			EC
5.59.	Skin cancer screening data must be recorded electronically by all those involved and transmitted electronically.			EC
5.60.	Documentation of the examination results for participants in skin cancer screening must be done under pseudonymised conditions taking due accounts of suitable methods and data protection concepts. The additional collection of a declaration of consent must be omitted. For non-participants, time-limited pseudonymised data storage of the invitation data is recommended for the purpose of evaluating outcomes (particularly skin cancer-related mortality). All data recording, data storage and transmission processes must be closely agreed with the data protection authorities.			EC
5.61.	Quality assurance measures for skin cancer screening must include structure, process and outcome quality. Because of the absence of scientifically-based quality assurance measures, quality indicators must be confirmed by evidence-based methods and where necessary new indicators developed.			EC

6. Informing the general population / public

No.	Recommendations/Statements	GoR	LoE	Ressources
6.1.	Information about the early detection of skin cancer must be guided by the recommendations of the [German] National Cancer Control Plan on an "informed decision" to enable the potential screenee deciding for or against participation in skin cancer screening examination.	EC		
6.2.	Strategies and measures whose aim is to reach the population with prevention messages and to allow an "informed decision" for or against participation in skin cancer screening must be tailored to the different target groups.	EC		
6.3.	Informing the adult population in a social setting can help promote cancer awareness.	ST	1++	[106]
6.4.	Children, adolescents and young adults with computer or online skills can be informed via computer or online.	0	1-	[107-109]
6.5.	Information can also be given via agents of socialisation, peers and other multiplicators.	EC		
6.6.	Adults should be informed repeatedly.	B	1+	[110-112]
6.7.	Adults should be informed by means of multimedia.	B	1+	[109-114]
6.8.	People at increased risk should be informed by means of tailored communication.	B	1+	[110, 115]
6.9.	Schoolchildren should be offered information via multiple media, along with information for their teachers.	B	2-	[108, 116, 117]
6.10.	Educational and training programmes on primary and secondary prevention of skin cancer should be structured multimedially and interactively and incorporate several channels of communication.	B	1-	[107-111, 114, 117-120]
6.11.	Educational and training programmes on primary and secondary prevention of skin cancer should use the simplest, most realistic and vivid forms of visualisation possible in structuring materials and take account of the limits to the acquisition of new skills by individual target groups beyond the transmission of knowledge.	B	1-	[112, 113]

No.	Recommendations/Statements	GoR	LoE	Ressources
6.12.	Educational and training programmes on primary and secondary prevention of skin cancer should address the target persons individually (individual-level interventions) and at the same time include individualised information and feedback elements.	B	1+	[106, 107, 110, 118, 121]
6.13.	Communication interventions in connection with primary and secondary skin cancer prevention should be evaluated formatively and summatively. The evaluation parameters used should be derived from a theoretically established model.	EC		
6.14.	Evaluations of interventions in connection with primary and secondary skin cancer prevention must work with empirically established measurement procedures geared specifically to the particular outcomes.	EC		
6.15.	In evaluating the efficacy of interventions for the primary prevention of skin cancer, skin cancer prevention-specific attitude and behaviour parameters should be used, as well as indicators of contact frequency/intensity, to assess methods of communication and their quality and effectiveness.	B	1+	[110, 118, 120, 122]
6.16.	To evaluate the effectiveness of a communication-based intervention in terms of informed decision-making in connection with primary and secondary skin cancer prevention, at least the following parameters must be determined: • relevant knowledge, • attitude towards the measure, action or behaviour, • participation or behaviour.	EC		

7. Quality indicators

For various reasons, no quality indicators could be derived based on this guideline. The reasons are explained in detail in the long version of this guideline.

8. List of Tables

9. List of figures

10. References

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