Leitlinienentwicklung:
Perspektiven der internationalen Zusammenarbeit

Hans C. Korting, München
Dermatologische Qualitätssicherung
Leitlinien und Empfehlungen
1. Auflage 2000
Herausgegeben von
Korting H.C., Callies R.,
Reusch M., Schlaeger M.,
Schöpf E., Sterry W.

Dermatologische Qualitätssicherung
Leitlinien und Empfehlungen
6. Auflage 2009
Herausgegeben von
H. C. Korting • R. Callies • M. Reusch •
M. Schlaeger • W. Sterry

ABW · Wissenschaftsverlag
European Dermatology Forum annual meeting

Member area

Annual Meeting 2011

Upcoming Meetings of Interest
## SOP for creation of European Dermatology Guidelines

<table>
<thead>
<tr>
<th>Step</th>
<th>Responsible</th>
<th>Task</th>
<th>Months duration</th>
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<td>Decision of topic of specific guideline</td>
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<td>Confirmation of the choice and level of guideline (S1, S2 or S3) plus suggestion to the Guideline Committee of potential chairman and subcommittee members</td>
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<td>Foundation of subcommittee for specific guidelines. Nomination of EDF members (50%) as well as identification of possible EADV members (25% of members for the subcommittee) who could work within the subcommittee. Chairman of EDF guideline committee asks EADV president for approval. Finally nomination of a chairperson of the subcommittee by the group.</td>
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<td>EDF-GSubC</td>
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EDF guidelines published as book in 2009

| Guidelines                                      | Responsible authors          | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
|-------------------------------------------------|------------------------------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|
| Melanoma (S1 – S2)                              | Garbe                        |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |
| Cutaneous malignant lymphoma                    | Whittaker                    |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |
| Basal cell carcinoma                            | Stockfleth                   |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |
| Actinic keratosis (S2)                          | Stockfleth, Kerl             |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |
| Chronic urticaria                               | Zuberbier                    |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |
| Venous leg ulcers (S3)                          | Neumann                      |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |
| Immunoglobulines (S1)                           | Enk                          |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |
| Psoriasis (S3)                                  | Rzany                        |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |
| Photodermatoses                                 | Murphy                       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |
| Physical and cholinergic urticaria              | Maurer                       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |
| Dermatopathology                               | Kerl, Sterry                 |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |
Current Perspective

Diagnosis and treatment of melanoma: European consensus-based interdisciplinary guideline

Claus Garbe a,* m, Ketty Peris b m, Axel Hauschild c m, Philippe Saiag d m, Mark Middleton e m, Alain Spatz f m, Jean-Jacques Grob g m, Josep Malvehy h m, Julia Newton-Bishop i m, Alexander Stratigos j m, Hubert Pehamberger k m, Alexander Eggermont l m

a Center for Dermatooncology, Department of Dermatology, Liebermeisterstr. 25, 72076 Tübingen, Germany
European S3-Guidelines on the systemic treatment of psoriasis vulgaris

Leitlinie

S3-Leitlinie zur Therapie der Psoriasis vulgaris

Alexander Nast¹, Ina B. Kopp², Matthias Augustin³, Kirstin-Benita Banditt⁴, Wolf-Henning Boehncke⁵, Markus Follmann⁶, Markus Friedrich⁷, Matthias Huber⁸, Christina Kahl¹, Joachim Klaus⁹, Joachim Koza⁹, Inga Kreiselmaier¹⁰, Johannes Mohr¹¹, Ulrich Mrowietz¹⁰, Hans-Michael Ockenfels¹², Hans-Dieter Orzechowski¹³, Jörg Prinz¹³, Kristian Reich¹⁴, Thomas Rosenbach¹⁵, Stefanie Rosumeck¹, Martin Schlaeger¹⁶, Gerhard Schmid-Ott¹⁷, Michael Sebastian¹⁸, Volker Streit¹⁹, Tobias Weberschock⁵, Berthold Rzany¹

(1) Division of Evidence Based Medicine (dEBM), Klinik für Dermatologie, Venerologie und Allergologie, Charité - Universitätsmedizin Berlin
Deutschsprachige Autoren der nationalen sowie europäischen S3-Leitlinie zur Psoriasistherapie in alphabetischer Reihung (I)

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Blau: Autoren beider Leitlinien
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## Status on New European Guidelines (I)

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- **Finished**: Green
- **In progress according to schedule**: Yellow
- **Overdue**: Red

*Not approved by UEMS*
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<td>Vitiligo</td>
<td>Taieb/Picardo</td>
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- Green: finished
- Yellow: in progress according to schedule
- Red: overdue
Europäische Leitlinien: Besondere Vorkommnisse im Kontext der Psoriasis-Leitlinie (I)

- 5/2009: Zustimmung durch die UEMS nach Modifikation (keine Stellungnahme seitens der EADV)
- 8/2009: Elektronische Veröffentlichung der Leitlinie
Europäische Leitlinien: Besondere Vorkommnisse im Kontext der Psoriasis-Leitlinie (II)

- **9/2009**: E-Mail von Co-Autor Prof. Giunta:
  - „I’m really sorry to arise these issues after the online publication, but ...“
  - „Regarding the new S3 Guidelines, I noticed 3 inaccuracies that I do believe it is mandatory to change in the chapter we wrote on Etanercept."

- **10/2009**: Revision der Leitlinie im Sinne eines Erratum
14TH MEETING OF THE

European Dermatology Forum

JANUARY 21-22, 2011
LUZERN, SWITZERLAND

Meeting Program

Friday, January 21, 2011

11.00 – 12.30 EDF working groups
Guidelines
Education
Genodermatoses Database
Meeting

Saturday, January 22, 2011

8.00 - 9.00 Liaison meeting

9.00 - 10.00 Reports of the European sister societies

Chairpersons: Peter Fritsch, Annamari Ranki

1) EADV
   2) ESDR
   3) UEMS
   4) ILDS

   Frank Powell
   Vincent Piguet
   Magdalena Czarnecka-Operacz
   Jean-Hilaire Saurat

Discussion
The guideline was developed within the framework of the COST ACTION B13 "Low back pain guidelines for its management", issued by the European Commission. ...

Backpain Europe ... to develop and produce European evidence-based guidelines for the management ...
WG4 Pelvic girdle pain
CONCEPT VERSION

EUROPEAN GUIDELINES
ON THE DIAGNOSIS AND TREATMENT OF PELVIC GIRDLE PAIN.

COST ACTION B13
“LOW BACK PAIN: GUIDELINES FOR ITS MANAGEMENT”
The guidelines are developed within the framework of the COST ACTION B13 “Low back pain: guidelines for its management”, issued by the European Commission, Research Directorate-General, Department of Policy, Coordination and Strategy.

Andry Vleeming (chairman)  Clinical anatomist  (NL)
Hanne B Albert  Physical therapist  (DK)
Hans Christian Östgaard  Orthopedic surgeon  (SWE)
Britt Stuge  Physical therapist  (NOR)
Bengt Sturesson  Orthopedic surgeon  (SWE)
WG4 Pelvic girdle pain

Objectives
The focus of Working Group 4 (WG4) is to produce a guideline on pelvic girdle pain (PGP). The WG4 will formulate a rationale to support the proposition that PGP is a specific form of back pain. The guideline will provide recommendations on the diagnosis and treatment of pelvic girdle pain. The guideline seeks to improve the clinical management of PGP by making recommendations that are acceptable to healthcare professionals and their respective organizations. Other objectives are to initiate new research and to promote consistency in definitions, diagnosis and treatment between the various healthcare providers.
Aims, goals, structures

Objectives

The main objectives of this COST action are:

- to develop and produce European evidence-based guidelines for the management of acute low back pain in primary care
- to develop and produce European evidence-based guidelines for the management of chronic low back pain in primary care
- to develop and produce European evidence-based guidelines for the prevention of low back pain in primary care
- to promote implementation of these guidelines

To ensure an evidence-based approach, recommendations will be based on Cochrane and other systematic reviews and on existing national guidelines. The guidelines should help health care providers to make evidence-based decisions, should improve the quality and outcome of health care, should lead to a more rational and efficient use of resources, and should identify gaps in the existing scientific evidence in order to prioritise future research.

Working Groups

Three Working Groups have been established:
1) working group on European guidelines for acute low back pain,
2) working group on European guidelines for chronic low back pain,
3) working group on European guidelines for prevention of low back pain.

All three working groups will work according to a similar working plan, aiming at evidence-based guidelines.
European Union guidelines

Please Note:

Where European Union (EU) guidelines adopted in Australia include references to EU legislation (including EC Directives and Regulations), the requirements contained in the referenced EU legislation are not applicable to the evaluation of prescription medicines by the TGA. The Australian legislative requirements applying to prescription medicines are contained in the Therapeutic Goods Act 1989 and the Therapeutic Goods Regulations 1990, as well as in various legislative instruments such as Therapeutic Goods Orders, Notices and Determinations, see Legislation.

EU guidelines - newly published

The following guidelines have been published in the last 4 months:

- CPMP/ICH/286/95
- ICH Topic M3 (R2)

Note For Guidance on Non-Clinical Safety Studies for the Conduct of Human Clinical Trials and Marketing

Authorisation for Pharmaceuticals

Published: TGA Internet site
Effective: 5 November 2010
ICH Topic M.3 (R2)
Non-Clinical Safety Studies for the Conduct of
Human Clinical Trials and Marketing Authorization for Pharmaceuticals

Step 4

NOTE FOR GUIDANCE ON NON-CLINICAL SAFETY STUDIES FOR THE CONDUCT
OF HUMAN CLINICAL TRIALS AND MARKETING AUTHORIZATION FOR
PHARMACEUTICALS
(CPMP/ICH/286/95)

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<td>DATE FOR COMING INTO OPERATION</td>
<td>December 2009</td>
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For comments and questions please contact: ich@emea.europa.eu
Sanofi Pasteur withdraws its marketing authorisation application for Emerflur, pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)

The European Medicines Agency has been formally notified by Sanofi Pasteur of its decision to withdraw its application for a centralised marketing authorisation for Emerflur, a pandemic influenza vaccine (split virion, inactivated, adjuvanted) A/Vietnam/1194/2004 NIBRG-14, 30 μg of haemagglutinin + aluminium hydroxide adjuvant, suspension for injection. ... Read more
The Committee for Medicinal Products for Human Use (CHMP) prepares scientific guidelines, in consultation with the competent authorities of the EU Member States, to help applicants prepare marketing-authorisation applications for medicinal products for human use.

Guidelines are intended to provide a basis for practical harmonisation of the manner in which the EU Member States and the European Medicines Agency interpret and apply the detailed requirements for the demonstration of quality, safety and efficacy contained in the Community directives. They also help to ensure that applications for marketing authorisation are prepared in a manner that will be recognised as valid by the Agency.

For the assurance of quality of medicinal products, guidelines are complementary instruments to European Pharmacopoeia monographs and chapters.
European Guideline for the Management of Pelvic Inflammatory Disease

Date: August 2008

Proposed Date for Review: December 2009

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GUIDELINES

EANM/ESC guidelines for radionuclide imaging of cardiac function

B. Hesse • T. B. Lindhardt • W. Acampa •
C. Anagnostopoulos • J. Ballinger • J. J. Bax •
L. Edenbrandt • A. Flotats • G. Germano •
T. Gmeiner Stopar • P. Franken • A. Kelion • A. Kjaer •
D. Le Guludec • M. Ljungberg • A. F. Maenhout •
C. Marcassa • J. Marving • F. McKiddie •
W. M. Schaefer • L. Stegger • R. Underwood

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University Hospital of Copenhagen,
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Copenhagen, Denmark
e-mail: bhesse@rh.hosp.dk
Preamble

The European guidelines for radionuclide imaging of cardiac function have been developed under the auspices of the European Council on Nuclear Cardiology (the joint group of the Cardiovascular Committee of the European Association of Nuclear Medicine and of the Working Group on Nuclear Cardiology of the European Society of Cardiology). The aim of the authors has been to present the state-of-the-art applications and protocols approved by experts in the field and to disseminate this information to the European nuclear cardiology community. The guidelines are designed to assist physicians and other healthcare

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Aachen University of Technology,  
Aachen, Germany

L. Stegger  
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Münster, Germany

R. Underwood  
Department of Nuclear Medicine, Royal Brompton Hospital,  
London, UK
Future tasks in European guideline management: relevant alternatives

- Guideline development coordination with corresponding bodies of EDF addressing the various medical specialties collaborating with UEMS, possibly forming a new European umbrella organisation,

- Guideline development coordination by various national umbrella organisations such as AWMF, possibly forming a new European umbrella organisation
The UEMS Section of Dermato-Venereology

Homepage Section: www.uems-dv.org

President Section: Professor Magdalena Czarnecka-Operacz, MD, PhD
PL - POZNAN

E-mail: mczarnecko@vmp.edu.pl

Secretary Section: Prof. Peter STEIJLEN
Baetsenhoewen 4
NL - 6321 PR WIJRE

E-mail: petero@vzmc.nl
Dear colleagues,

Looking back at my first months I can declare that I am very proud to be the new Chair of G-I-N.

We experienced a fantastic congress in the wonderful setting of Chicago, with almost 450 colleagues from 31 countries around the world. High

Come and meet with us at one of our next annual conference!

The 8th G-I-N Conference will take place in Seoul, South Korea (e’World Design Capital 2010) on 28-31 August 2011.

The scientific committee of the 2011 conference is working on the preparation of stimulating plenary sessions around the theme:

“Linking evidence, policy, and practice.”

Mark your calendars:
Introduction
The Guidelines International network, G-I-N, is a global network, founded in 2002. It has grown to comprise 94 organisations and 77 individual members representing 46 countries from all continents. The network supports evidence-based health care and improved health outcomes by reducing inappropriate variation throughout the world.

G-I-N mission...
... to lead, strengthen and support collaboration and work within the guideline development, adaptation and implementation community
G-I-N: Hauptziele

• Providing a network and partnerships for guideline organisations, implementers, end-users, researchers, students and other stakeholders

• Assisting members in reducing duplication of effort and improving the efficiency and effectiveness of evidence-based guideline development, adaptation, dissemination and implementation

• Promoting best practice through the development of opportunities for learning and building capacity, and the establishment of high quality standards of guideline development, adaptation, dissemination and implementation.
AGREE Instrument

Download the Agree Instrument
You can download the Agree Instrument or view it on-line. Simply click on the right link.

Agree Instrument - PDF Version [link]
Online copy to view while browsing.
(needs Adobe Acrobat Reader to be viewed)

Agree Instrument - Compressed version [link]
Suitable for storing in your hard-drive.
(needs Winzip to extract it and Adobe Acrobat Reader to be viewed)

Check for translations of the AGREE instrument in your language [link]
What is AGREE?
AGREE is an international collaboration of researchers and policy makers who seek to improve the quality and effectiveness of clinical practice guidelines by establishing a shared framework for their development, reporting and assessment.

Who are the participants?
The collaboration has the participation of a core of European countries: Denmark, Finland, France, Germany, Italy, the Netherlands, Spain, Switzerland and the United Kingdom as well as Canada, New Zealand and the USA (See list of AGREE members).
Global medical guidelines: a relevant option?

- Guidelines by WHO as examples,
- Guideline by CIOMS as another example.
Global medical guidelines by WHO

2003 World Health Organization (WHO)/International Society of Hypertension (ISH) statement on management of hypertension
World Health Organization, International Society of Hypertension Writing Group

Prevention of cardiovascular disease: guideline for assessment and management of cardiovascular risk

Overview

The publication provides guidance on reducing disability and premature deaths from coronary heart disease, cerebrovascular disease and peripheral vascular disease in people at high risk, who have not yet experienced a cardiovascular event. People with established cardiovascular disease are at very high risk of adverse outcomes. The guidelines contain information on how to assess cardiovascular risk and how to manage cardiovascular risk in people at high risk of cardiovascular disease. They include guidance on how to manage cardiovascular disease in people at high risk of cardiovascular disease who have already had an event. The guidelines are based on data and expertise described in previous WHO guidelines. The WHO/ISH risk prediction charts that accompany these guidelines allow treatment to be tailored according to simple predictions of absolute cardiovascular risk.

Recommendations are made for management of major cardiovascular risk factors through changes in lifestyle and prophylactic drug therapies. The guidelines provide a framework for the development of national guidance on cardiovascular disease that takes into account the particular political, economic, social and medical circumstances.

(This publication was released on 24 August 2007)
NEW - CIOMS Working Group IX

We are pleased to announce the launch of CIOMS Working Group IX on "Practical Considerations for Development and Application of a Toolkit for Medicinal Product Risk Management." The plan is to develop a pragmatic consensus guidelines to be used by industry and regulators.

Read more... Click Here

PANEL DISCUSSION

It is with great pleasure that CIOMS can announce to our members the speakers in the CIOMS International Panel Discussion in memory of Professor Zbigniew Bankowski on the topic: The Implementation of ethical principles in medicine from bench to bedside: How the physician may integrate the treatment of his patient with science (research and ethics).

The panel discussion will be held in the memory of Professor Zbigniew Bankowski and will take place on Tuesday 30 November 2010 from 08:45 to 11:45 in room M505 at WHO Headquarters in Geneva.

SPEAKERS

Practical Aspects of Signal Detection in Pharmacovigilance

Report of CIOMS Working Group VIII

The Report of CIOMS Working Group VIII aims primarily to provide a comprehensive resource for those considering how to strengthen their pharmacovigilance systems and practices, and to give practical advice.

Read more... Click Here

International Ethical Guidelines for Epidemiological Studies

The Guidelines set forth ethical guidance on how epidemiologists - as well as those who sponsor, review, or participate in the studies they conduct - should identify and respond to the ethical issues that are raised by the process of producing this information.

Read more... Click Here
The **Council for International Organizations of Medical Sciences (CIOMS)** is an international, nongovernmental, not-for-profit organization established jointly by [WHO](http://wikidoc.org/) and [UNESCO](http://wikidoc.org/) in **1949**.

CIOMS serves the scientific interests of the international biomedical community in general and has been active in promulgating guidelines for the ethical conduct of research, among other activities. CIOMS promulgated guidelines in 1993 entitled *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. These 15 guidelines address issues including informed consent, standards for external review, recruitment of participants, and more. The Guidelines are general instructions and principles of ethical biomedical research.
International Ethical Guidelines for Biomedical Research Involving Human Subjects

Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO)

Geneva 2002
CIOMS Guidelines

- The **CIOMS Guidelines**, formally known as *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, is a set of ethical principles regarding *human experimentation*.

- Created in **1993** by the **Council for International Organizations of Medical Sciences** (CIOMS) and updated in **2002**, these 21 guidelines (15 in the original report) address issues including *informed consent*, standards for external review, recruitment of participants, and more. The Guidelines are general instructions and principles of ethical biomedical research.

http://wikidoc.org/
Global medical guideline by CIOMS

NEW PUBLICATION

Council for International Organizations of Medical Sciences (CIOMS)

CIOMS

International Ethical Guidelines for Epidemiological Studies

The Guidelines set forth ethical guidance on how, as epidemiologists – as well as those who sponsor, review, or participate in the studies they conduct – should identify and respond to the ethical issues that are raised by the process of producing this information.

Epidemiology has made essential contributions to the improvement in human health achieved over the past century. It can be reasonably expected that the field will continue to do so by using ever more powerful and sophisticated analytical tools to increase the understanding of the distribution of health and illness and of their many physical, chemical, biological, behavioral, social and environmental determinants. Indeed, better understanding of the health of the public depends on making the greater use of the tools of epidemiology. At the same time, it is essential that they have knowledge, and the changes for the good that it prompts, be derived from studies conducted according to recognized ethical standards. By focusing on the distinctive aspects of epidemiological research, this document aims to provide the field with just such a set of ethical standards.

ISBN 92 836 081 X

Price Swiss francs <5.–

Order from CIOMS,
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CH-1211 Geneva 27, Switzerland.

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Fax. (+41 22) 791-45 85
Organisational aspects of global medical guidelines: a global scenario

- International League of Dermatological Societies (ILDS) joins CIOMS,
- CIOMS coordinates global guideline work,
- CIOMS collaborates with the World Health Organization (WHO) acting as a clearing house based on the AGREE instrument.
Global medical guidelines: the complexity challenge

• Problem: management of diseases may have to be different in highly developed and emerging/developing countries,

• Solution: for every major disease management is defined reflecting the current situation in the health care system: the "two velocities approach".
The evolving medical guidelines scheme: a trias

- National guidelines,
- Supra-national guidelines, if considered helpful (EU, NAFTA?, and others),
- Global guidelines