

Implementation of Medical Research Data in Clinical Practice

Production & Use of Clinical Guidelines

**EUROPEAN
SCIENCE
FOUNDATION**
SETTING SCIENCE AGENDAS FOR EUROPE

FORWARD LOOK

Implementation
of Medical Research
in Clinical Practice



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ESF Forward Look Launch

Berlin, May 2011



Outline of presentation

CPG development & use:

- What does the ESF Forward Look recommend?



FORWARD LOOK

Implementation
of Medical Research
in Clinical Practice

- Best practice in guideline production and use: Differences between ESF & IOM recommendations?

Clinical Practice
Guidelines We Can Trust



Standards for Developing Trustworthy Clinical Practice Guidelines (CPGs)

- The next steps in guidelines : From white papers to use.

Why ESF-FL addresses CPGs



FORWARD LOOK

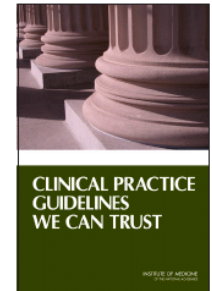
Implementation
of Medical Research
in Clinical Practice

- Knowledge Generation
- Knowledge Interpretation
- **Knowledge Implementation in Clinical Practice**
- Perspectives from General Practice
- Patient and Public Involvement in Research
- Diversity Across Europe

- A huge amount of medical research is carried out
- Getting this information to healthcare professionals and patients is a challenge.
- One key way of getting new information to healthcare professionals is through issuing clinical guidelines.

IOM Rationale for CPGs

Clinical Practice
Guidelines We Can Trust

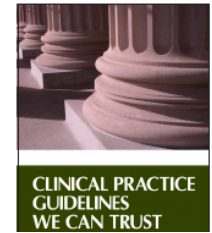


Standards for Developing Trustworthy Clinical Practice Guidelines (CPGs)

- Clinical decisions are made under uncertainty.
- Translation of scientific evidence (by means of guidelines) reduces uncertainty in clinical practice.
- Requisite to this promise are
 - Clinicians' and patients' **access to trustworthy CPGs** informed by high-quality evidence
 - a **CPG development process reflective of best practices.**

Trustworthy Guidelines

IOM Definitions 2011



To be *trustworthy*, CPGs should

- Be based on a **systematic review** of the existing evidence;
- Be developed by a knowledgeable, **multidisciplinary panel** of experts & representatives from key affected groups;
- Consider important patient subgroups & **patient preferences**;
- Be based on an **explicit and transparent process** that minimizes distortions, biases, and conflicts of interest;
- Provide a clear explanation of the logical relationships between alternative care options and health outcomes, provide **ratings** of both the **quality of evidence** & the **strength of recommendations**;
- Be reconsidered & **revised** as appropriate **when important new evidence** warrants modifications of recommendations.

ESF Recommend. on CPG Production

Good practice points	ESF	IOM	Reality
Use of acknowledged quality criteria for CPG develop. (explicit & transparent process that minimizes biases)	X	X	- X
Transparency on development & funding (CPG reports)	X	X	- (X)
Conflict of Interest declaration & management	X	X	- (X)
Based on full, state of the art systematic reviews	X	X	- (X)
Rating of evidence quality & recommendation strength	X	X	- (X)
Declaration of normative & ethical considerations	X	X	-
Multidisciplinary production	X	X	- X
Involvement of target groups	X	X	- X
Patient / public involvement	X	X	- X
Use of comprehensible & unambiguous language	X	X	- (X)
Timely reviewing & updating (explicit policies)	X	X	- (X)
Centrally programmed development & updating	X		- (X)

Guideline **Production** & Use

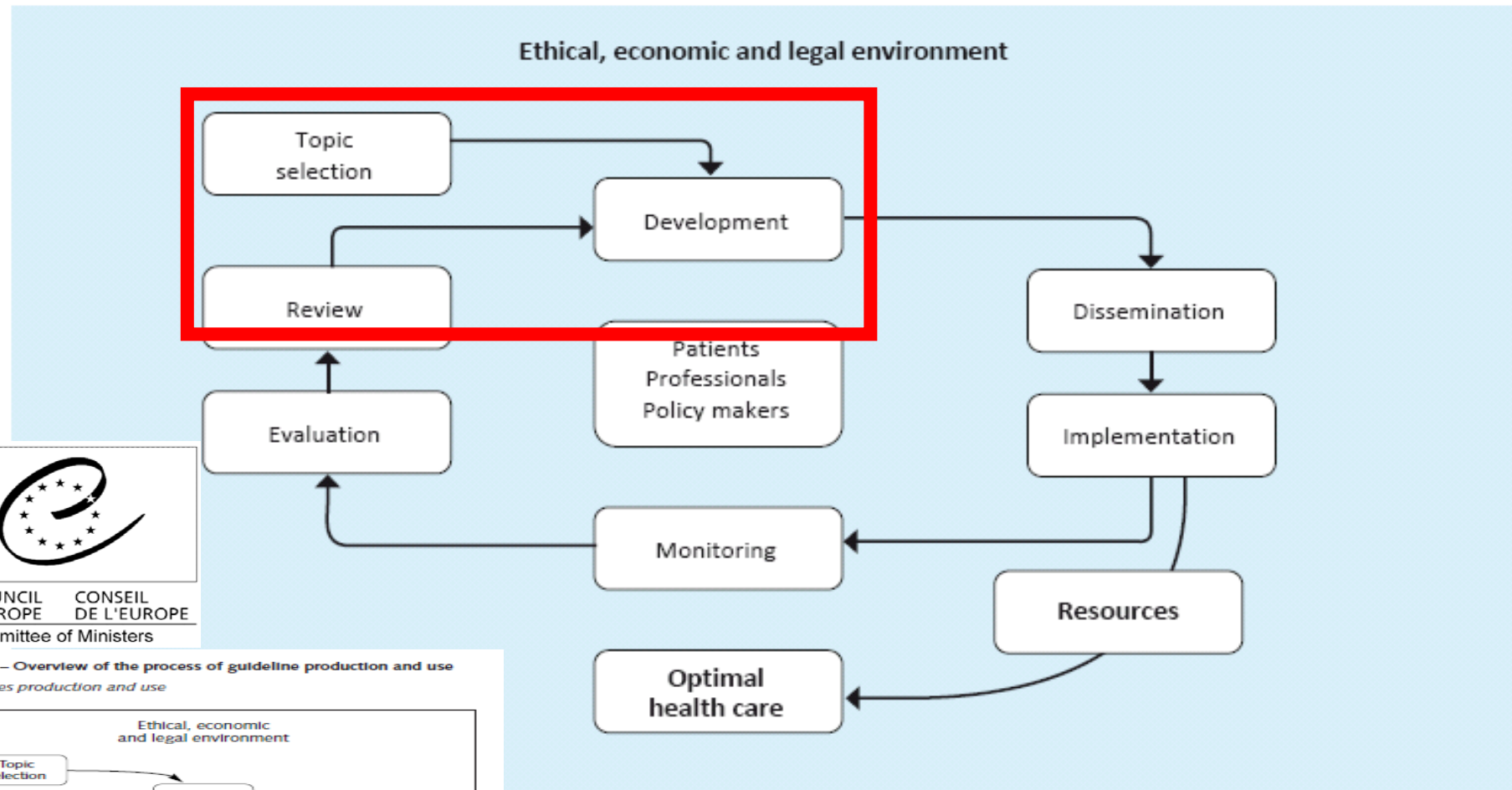
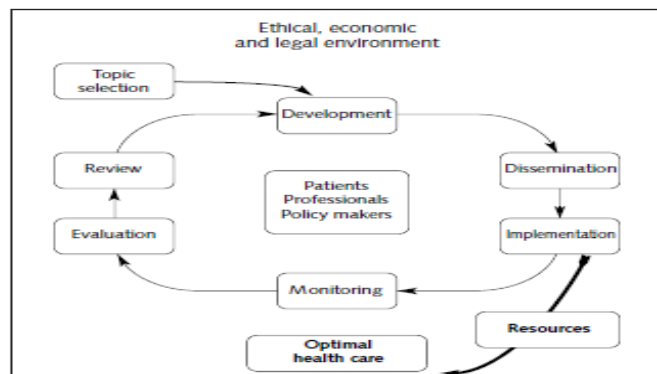


Figure 1 – Overview of the process of guideline production and use
Guidelines production and use



use (Council of Europe 2001)

2001 → **2011**



FORWARD LOOK

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ESF Recommend. on CPG Production

Good practice points	ESF	IOM	Reality
Use of acknowledged quality criteria for CPG develop. (explicit & transparent process that minimizes biases)	x	x	- x
Transparency on development & funding (CPG reports)	x	x	- (x)
Conflict of Interest declaration & management	x	x	- (x)
<p>Major issues:</p> <ul style="list-style-type: none"> • Clinicians receive much of their information from industry and thereby from a biased source. • CPGs may be influenced by bias – due to interests of drugs companies and other conflicts of interest. 			

ESF Recommend. on CPG Production

Good practice points	ESF	IOM	Reality
Use of acknowledged quality criteria for CPG develop. (explicit & transparent process that minimizes biases)	x	x	- x
Transparency on development & funding (CPG reports)	x	x	- (x)
Conflict of Interest declaration & management	x	x	- (x)
Based on full, state of the art systematic reviews	x	x	- (x)
Rating of evidence quality & recommendation strength	x	x	- (x)
Declaration of normative & ethical considerations	x	x	-
<p>Major issues:</p> <ul style="list-style-type: none"> • CPGs are sometimes not based on full SR. • Research results are introduced in clinical practice although not robust & sufficiently assessed. • <u><i>Review production is a challenge if not financed.</i></u> 			

ESF Recommend. on CPG Production

Good practice points	ESF	IOM	Reality
Multidisciplinary production	X	X	- X
Involvement of target groups	X	X	- X
Patient / public involvement	X	X	- X

Major issues:

CPGs often

- too narrowly focused because produced by specialists & not by a multidiscipl. team includ. other healthcare profess. & patients
- not used because lack of ownership.

Problems may arise & errors introduced if CPGs translated from one language / healthcare system to another.

ESF Recommend. on CPG Production

Good practice points	ESF	IOM	Reality
Use of acknowledged quality criteria for CPG develop. (explicit & transparent process that minimizes biases)	x	x	- x
Transparency on development & funding (CPG reports)	x	x	- (x)
Conf			(x)
Base			(x)
Ratir			(x)
Decl			
Multi			(x)
Invol			(x)
Patient / public involvement	x	x	- x
Use of comprehensible & unambiguous language	x	x	- (x)

Major issues:

- CPGs often not suitable [for patients to read], as they are not understandable [by laypeople].
- [Use of unambiguous (standardized) language is crucial for IT implementation].

ESF Recommend. on **CPG Production**

Good practice points	ESF	IOM	Reality
Use of acknowledged quality criteria for CPG develop. (explicit & transparent process that minimizes biases)	x	x	- x
Transparency on development & funding (CPG reports)	x	x	- (x)
Conflict of Interest declaration & management	x	x	- (x)
Based on full, state of the art systematic reviews	x	x	- (x)
Rating of evidence quality & recommendation strength	x	x	- (x)
Declaration of normative & ethical considerations	x	x	-
Multidisciplinary production	x	x	- x
Involvement of target groups	x	x	- x
Patient / public involvement	x	x	- x
Use of comprehensible & unambiguous language	x	x	- (x)
Timely reviewing & updating (explicit policies)	x	x	- (x)
Centrally programmed development & updating	x		- (x)

CPG Production – the Debate: **Who should produce guidelines?** Central organisations or clinicians / learned societies?

	Central organisations	Clinicians - learned societies
Pros	<p>Thorough knowledge of methods for assessing research data & literature</p> <p>Less influenced by Col regarding</p> <ul style="list-style-type: none"> - industrial connections - bias towards augmenting own power 	<p>Thorough knowledge of clinical practice & research in their area</p>
Cons	<p>Lack of clinical experience / up to date clinical competencies</p> <p>Potentially open to Col:</p> <ul style="list-style-type: none"> - goal to keep health expenditure down - bias towards augmenting power / influence of sponsoring organisation 	<p>Lack of methodological competencies</p> <p>Potentially open to Col:</p> <ul style="list-style-type: none"> - industrial connections - bias towards augmenting own power - possibility of increasing private income.

CPG Production – the Debate: Who should produce guidelines? Central organisations or clinicians / learned societies?

	Central organisations	Clinicians - learned societies
Pros	<p>Thorough knowledge of methods for</p> <p>as</p> <p>Le</p> <p>- i</p> <p>- p</p>	<p>Thorough knowledge of methods for</p> <p>as</p> <p>Le</p> <p>- i</p> <p>- p</p>
Cons	<p>La</p> <p>da</p> <p>Pe</p> <p>- s</p> <p>- c</p> <p>- l</p> <p>i</p>	<p>La</p> <p>da</p> <p>Pe</p> <p>- s</p> <p>- c</p> <p>- l</p> <p>i</p>
	organisation	

The solution:

1. Joint action of clinicians & methodologists
2. Independent CPG group moderation
3. Col management
4. Method training
5. Centrally programmed development
6. Public reporting of CPG production

Guideline Production & Use

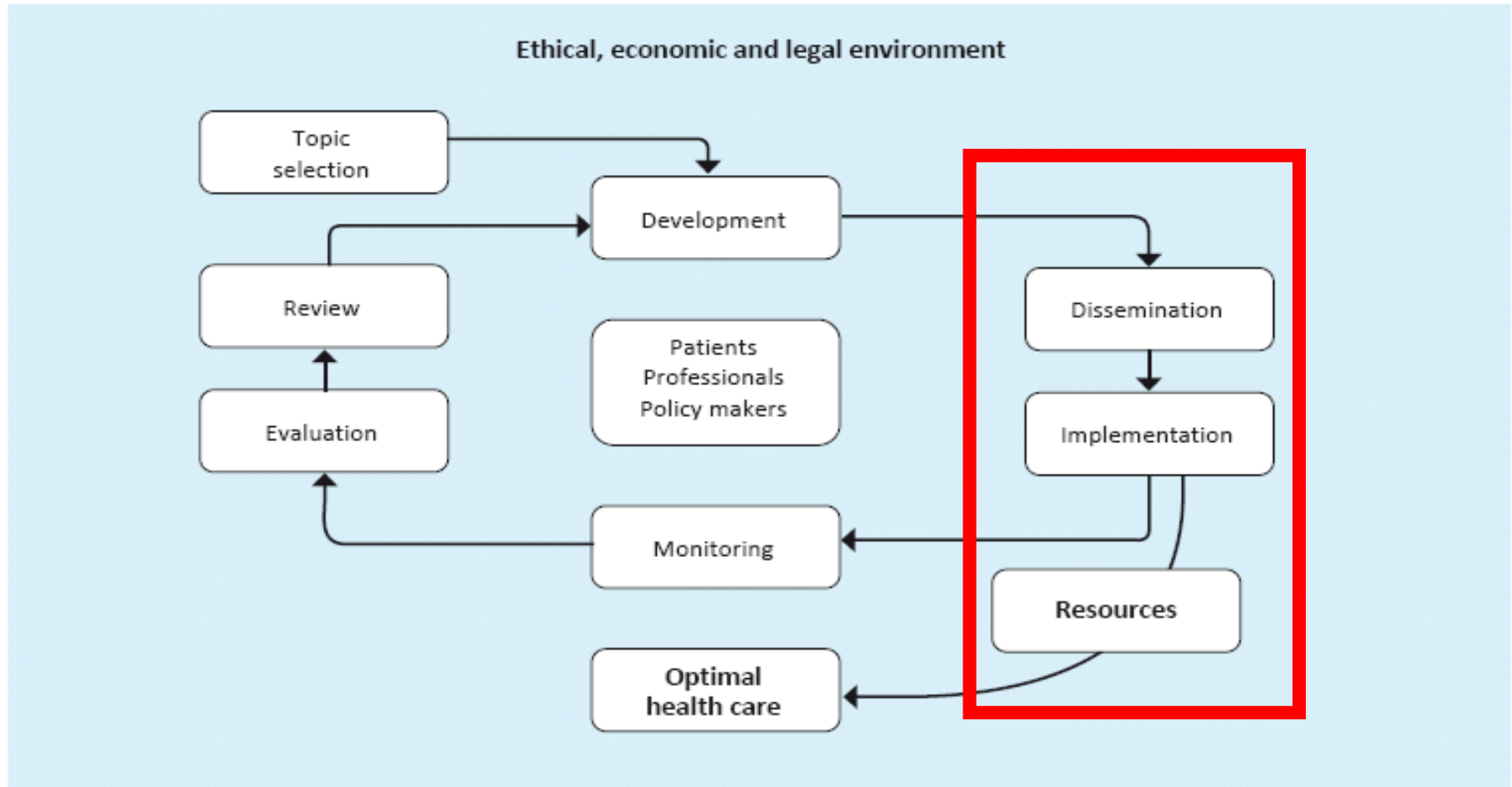
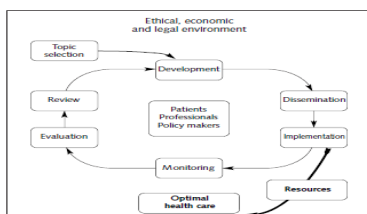


Figure 7. Process of guideline production and use (Council of Europe 2001)



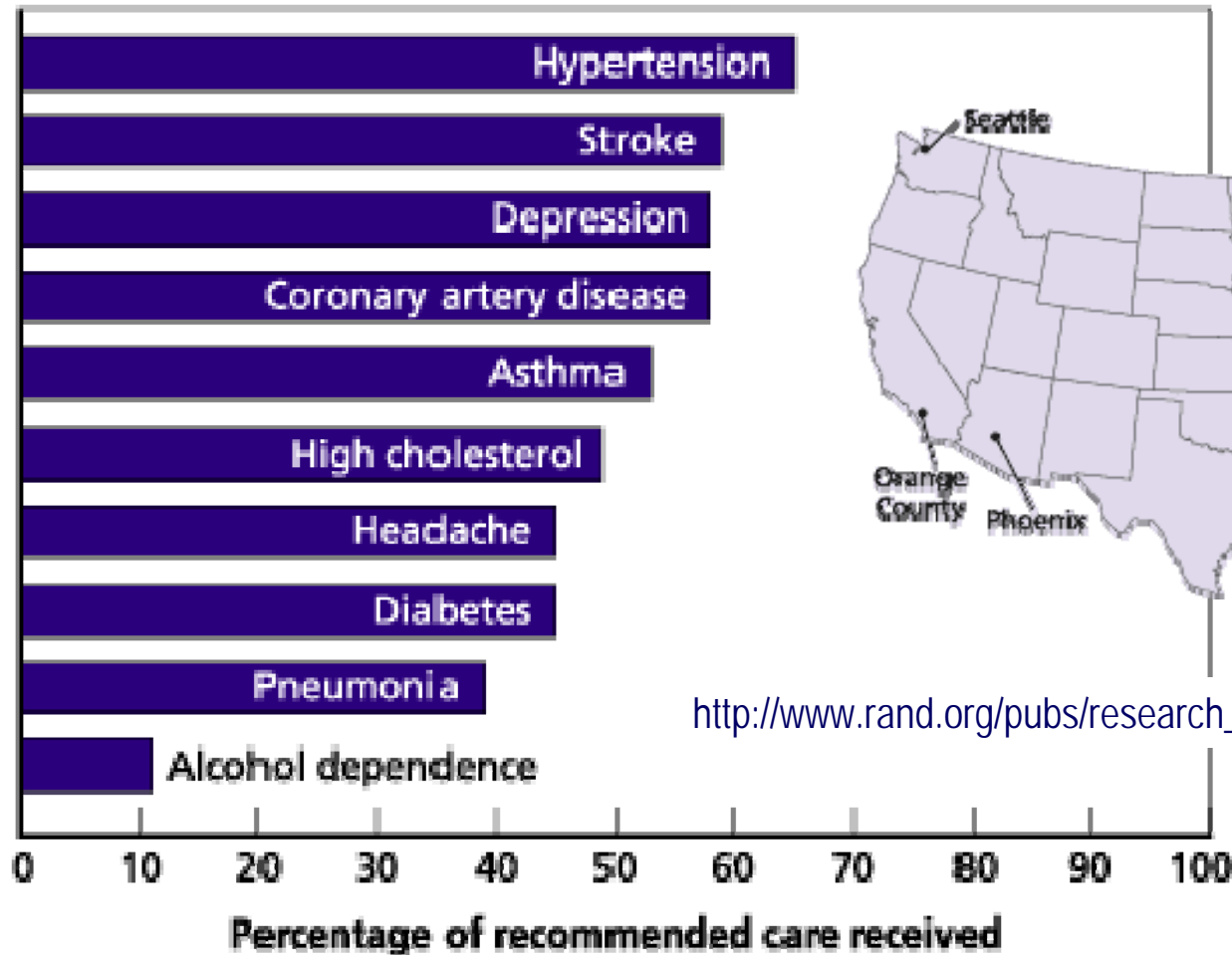
2001 → 2011



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How many people receive CPG based healthcare?



http://www.rand.org/pubs/research_briefs/2006/RAND_RB9053-2.pdf

ESF Recommendations for CPG Use

Good practice points	ESF	Reality
IT based open access CPG databases to be provided	x	- x
Production & distribution of CPG lay versions	x	- (x)
CPG use documented in healthcare quality reports	x	- (x)
Timely & effective distribution to target groups	x	-
Learned societies together with national bodies to organize systematic & effective CPG marketing	x	-
CPG methods introduction in medical curricula	x	-
General public education about EBM, HTA, CPGs	x	-

Research Result Implementation – Next steps:

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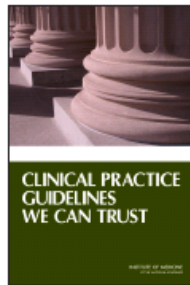
The grid contains six images: a scientist at a microscope, a patient in a CT scanner, a lab technician, a hospital sign, a sleeping child, and a surgeon.

Clinical Practice Guidelines We Can Trust

DEVELOPING A METHODOLOGY FOR DRAWING UP GUIDELINES ON BEST MEDICAL PRACTICES

Recommendation Rec(2001)13 adopted by the Committee of Ministers of the Council of Europe on 10 October 2001 and explanatory memorandum

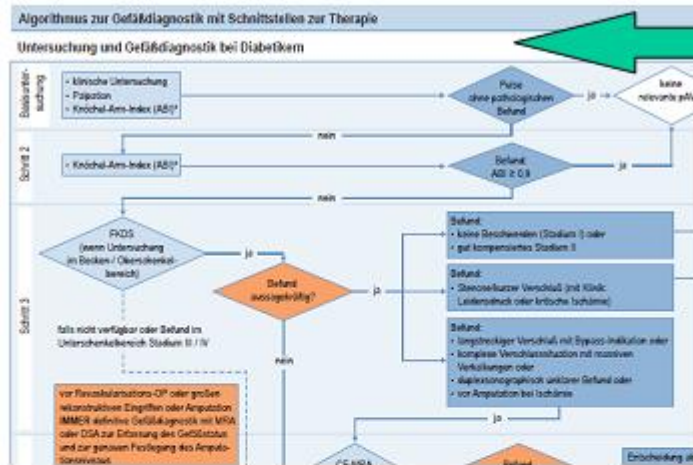
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Saving the nation • Improving health
For more information visit www.iom.edu/cpgstandards



Practice Guidelines (CPGs)

From Guideline White Papers & Guidelines to Guideline Use

Guideline Implementation - Step 6: DM-CPG based Decision Aids, Pat. Information, Reminders, CME Tools



Prof. Decision Aids

Fußdokumentationsbogen der Deutschen Diabetes-Gesellschaft

Risikostratifizierung:

Kategorie	Beschreibung	Untersuchungen	Rekurrenzhäufigkeit
1	keine sensorische Neuropathie	1 x jährlich	Niedriges Risiko
2	sensorische Neuropathie	1 x alle 6 Monate	Erhöhtes Risiko*
3	sensorische Neuropathie und Zeichen einer peripheren ischaemischen Verschlusskrankheit (unterer Fußabschnitt)	1 x alle 3 Monate	Hohes Risiko**

Gefäßbefund: Puls, Temperatur, Verformung, Hautzustand, ABI, Knöchel-Arm-Index (Doppel-Verstärkungsmaßnahme)

Nervenbefund: Neuropathie (Distal, sensorisch, motorisch, autonome), rechts/links ohne path. Befund

Klassifikation nach Wagner:

Kategorie	Beschreibung	Wagner-Ärztliche Klassifikation
0	keine Läsion, ggf. Fußdeformation oder Zerküftung	0
1	oberflächliche Ulzeration	1
2	tiefe Ulzera bis zur Gelenkkapsel, im Bereich des Knöchels	2
3	tiefe Ulzera mit Abszessbildung, Osteomyelitis, Infektion der Gelenkkapsel	3
4	gangränöse Nekrose im Fußfuß- oder Fußrückenbereich	4
5	Nekrose des gesamten Fußes	5

Documentation Sheets

CME Programmes

PATIENTENINFORMATION

Ein Service der **KBV Kassenärztliche Bundesvereinigung**

Diabetes und Augen Juni 2010

LIEBE PATIENTIN, LIEBER PATIENT,

WAS HAT DIABETES MIT IHREN AUGEN ZU TUN?

Diabetes mellitus kann Schäden an Ihrer Netzhaut im Auge hervorrufen. Ihr Arzt spricht dann von einer diabetischen Retinopathie oder einer diabetischen Makulopathie. Beides kann dazu führen, dass Sie schlechter sehen. Deshalb sind Vorbeugung und Behandlung sehr wichtig.

RISIKOFAKTOREN UND WARNZEICHEN

Häufig spüren Sie die Veränderungen im Auge zunächst nicht. Eine Reihe von Einflüssen kann Netzhautschäden aber begünstigen (Risikofaktoren), und einige Zeichen können darauf hinweisen (Warnzeichen).

Ein erhöhtes Risiko für Ihre Augen besteht:

- wenn Ihre Diabeteserkrankung lange nicht erkannt wurde

WANN GEHEN SIE ZUM AUGENARZT?

Ein Besuch wird empfohlen:

- gleich nachdem Sie erfahren, dass Sie Diabetes haben
- einmal im Jahr, solange keine Schäden an der Netzhaut festgestellt werden
- in kürzeren Abständen, wenn Schäden an der Netzhaut vorhanden sind
- sofort, wenn Warnzeichen auftreten, zum Beispiel Sehverschlechterungen, Leseschwierigkeiten, verschwommenes Sehen oder „Rußregen“ vor den Augen.

UNTERSUCHUNGEN

Patient Leaflets

Guideline Implementation - Step 6:

DM-CPG based Decision Aids, Pat. Information, Reminders, CME Tools

Promoting adoption of CPGs (IOM 2011- modif.)

Multifaceted implementation strategies - Targets: individuals & healthcare systems

Tools:

- CPG for education, mass media, opinion leaders, academic detailing (outreach education)
- CPG based quality management (performance gap assessment + audit & feedback)
- CPG recommendations at the point of delivery by means of electron. Clinical Decision Support systems

EBM / Guideline Science being accepted for academic career.

ESF Top Recommend. (with respect to CPGs) to strengthen implementation of medical research in clinical practice

- **Strengthen work**, collaboration / coordination / funding in **the fields of ... CPGs**.
- Generate, through multidiscipl. teams & with patient involvement, high quality evidence-based CPGs according to common standards & criteria.

Implement & improve CPGs in clinical practice through IT tools, audit & feedback, clinical indicators & continuous updates.

Strengthen **research evidence base for effect. implem. strategies**.

Increase use & implementation of high quality ... CPGs in hospitals primary care & all administrative processes including financing of treatment and technologies.

Thank you for your attention!



www.gin2012.org

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