

Risk of implementing fraud or waste through Clinical Practice Guidelines

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Agenda

- About ... clinical practice guidelines (CPG)
- (Critical) Steps in Guideline Development
- Examples of fraud
 - Drug Therapy (NDMG Depression, NDMG Lower Back Pain)
- Examples of waste
 - X-Ray (NDMG Lower Back Pain)
 - Invasive Therapies (NDMG Lower Back Pain)
- Conclusions

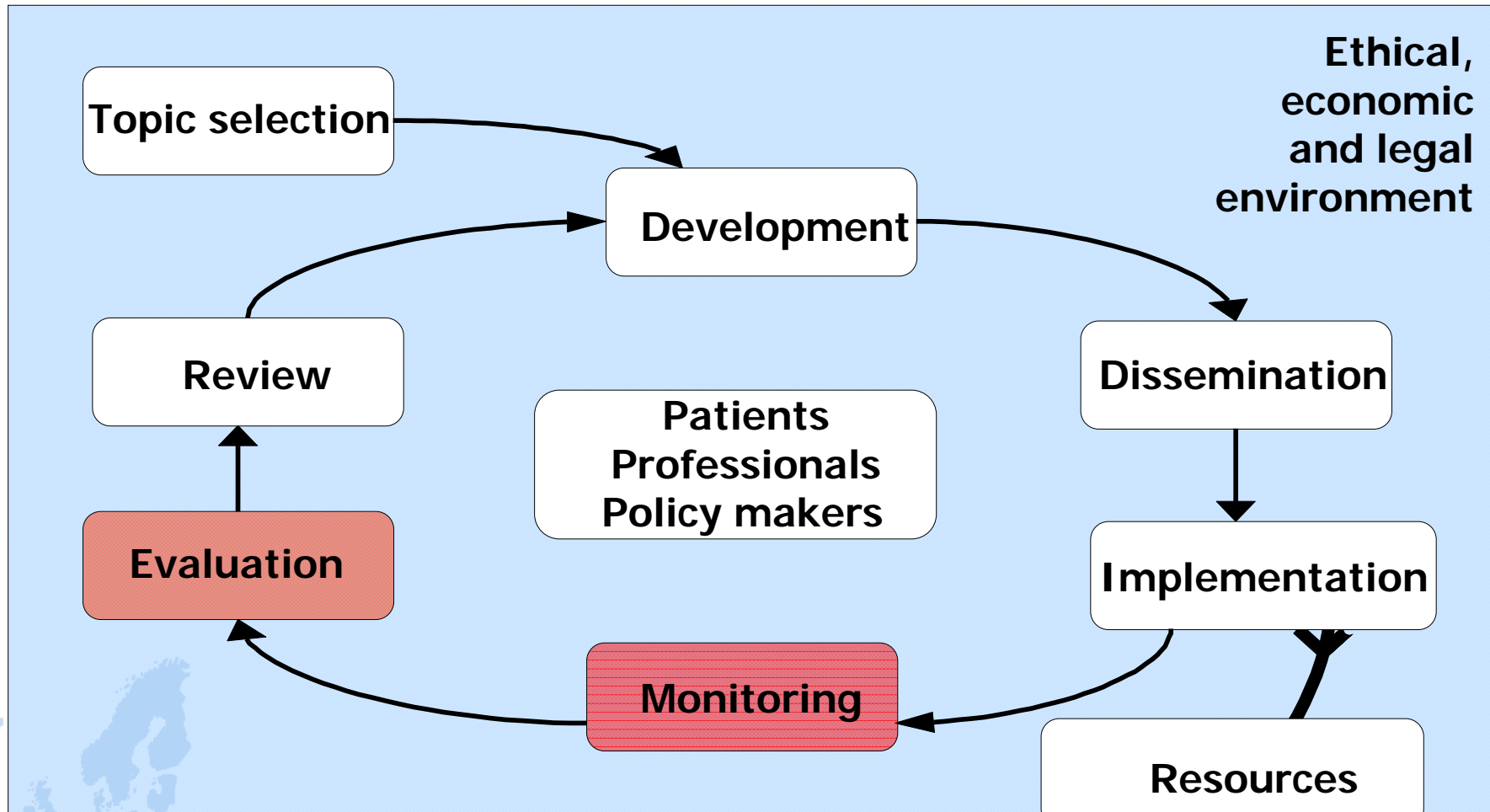


- ... are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options

• ***IOM: Clinical Practice Guidelines we can trust (2011)***



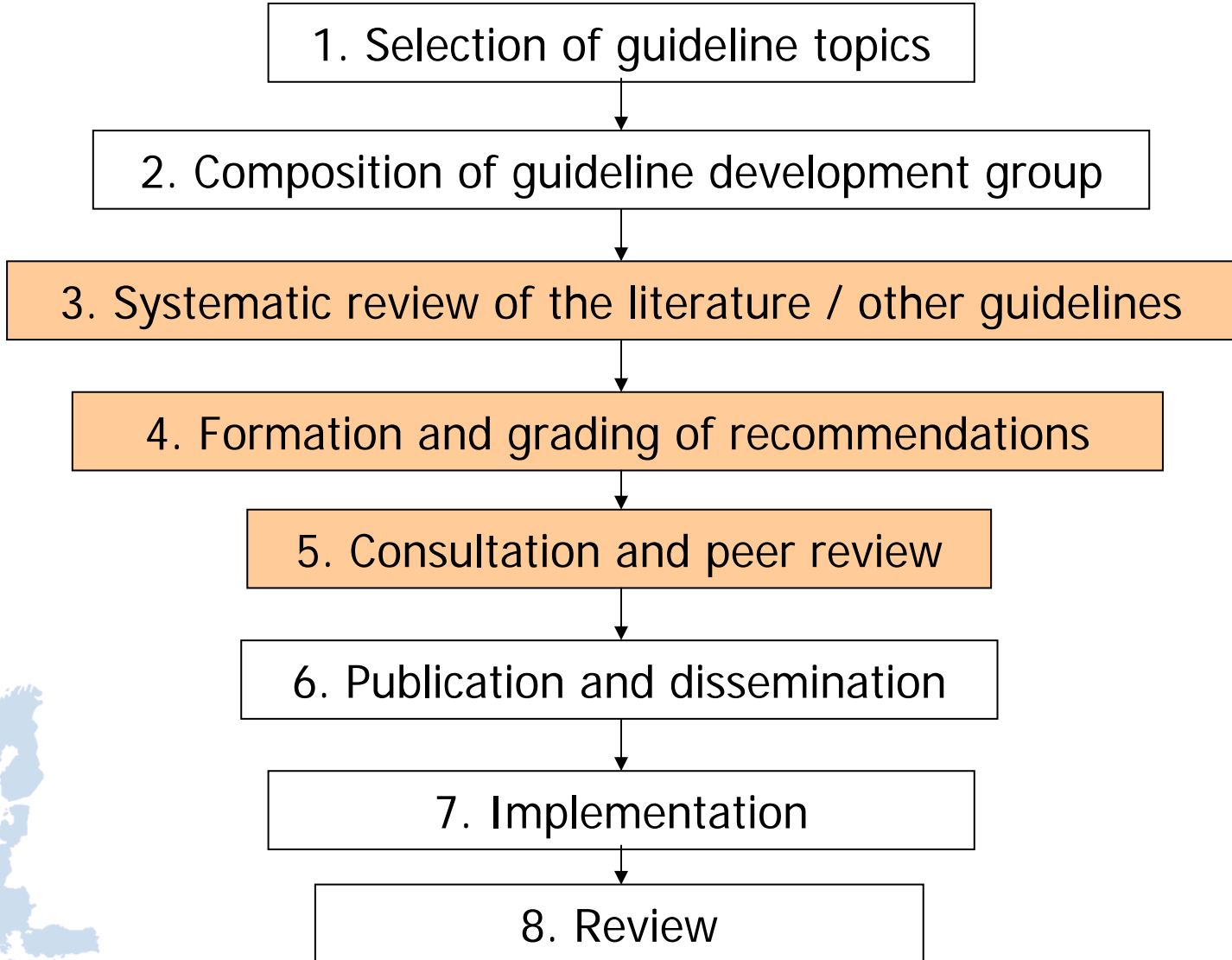
Systematic Guideline Production and Use



Council of Europe: Rec 13, 2001



Critical Steps CPG development process



Examples of Fraud

- NDMG Depression (2010)

(Editors: German Medical Association - BÄK, National Association of Statutory Health Insurance Physicians -KBV, Association of Scientific Medical Associations - AWMF)

Initially Reboxetin was listed within the register of recommended drugs

- But Publication Bias and Selective Outcome Reporting were suspected
- US FDA and German IQWiG forced the drug company to reveal unpublished studies/results

→ REBOXETIN EXCLUDED from the LIST OF RECOMMENDED MEDICATIONS

www.depression.versorgungsleitlinien.de

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Examples of Fraud



- NDMG Lower Back Pain (2010)

(Editors: German Medical Association - BÄK, National Association of Statutory Health Insurance Physicians -KBV, Association of Scientific Medical Associations - AWMF)

Flupirtin was recommended NOT TO USE for pain therapy in lower back pain

- Only two studies with no/weak evidence for efficacy
- Pharmacovigilance reports on serious side effects
- Company and associated scientist used consultation period to influence and threaten guideline group

→ Now Guideline Program Organisations are SUED!



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Examples of Waste

- NDMG Lower Back Pain (2010)

(Editors: German Medical Association - BÄK, National Association of Statutory Health Insurance Physicians -KBV, Association of Scientific Medical Associations - AWMF)

CPG development group „fought“ in many meetings on necessity of X-Ray in LBP

- Good evidence for weak/no association between LBP and diagnostic findings
- Moderate evidence for serious side effects as increased risk for chronification and induction of unfavorable coping strategies

→ Orthopedists insisted on a minority vote for X-Ray of LB

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- **NDMG Lower Back Pain (2010)**

(Editors: German Medical Association - BÄK, National Association of Statutory Health Insurance Physicians - KBV, Association of Scientific Medical Associations - AWMF)

CPG development group „fought“ in many meetings on necessity of invasive therapies for LBP

- Good evidence for weak/no long term effects on LBP
- Moderate evidence for serious side effects as increased risk for chronification and induction of unfavorable coping strategies

→ Invasive Therapies are not recommended



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Integrated Care Contract based on NDMG for LBP

- Contract between the Berlin Association of Statutory Health Insurance Physicians (KV Berlin) and a Statutory Health Insurance Company (KKH Allianz)
- Aims of the contract based on the recommendations of NDMG for LBP
 - REDUCTION of NOT RECOMMENDED INTERVENTIONS within 2 YEARS
 - Medication by 30%
 - Orthopedic and prosthetic devices by 50%
 - Physiotherapy and rehabilitation by 30%



Conclusions

- CPG development process is challenged by attempts to implement unnecessary and potentially harmful procedures
- Potential sources are:
 - Influences on guideline topics
 - Influences on composition of guideline group
 - Biased evidence base
 - Influence on guideline experts (doctors, other medical professions, patients)
 - Influence of guideline experts



Source: weareinstitutionalized.blogspot.com/2011/06/h...

Conclusions

- Attempts may occur during the whole development process



Source:<http://topnews.in/health/files/healthcare-fraud.jpg>



Conclusions



- Evidence based CPGs are worldwide an accepted tool to improve quality in health care by recommending procedures based on:
 - scientifically sound evidence
 - broad multidisciplinary consensus
 - patients preferences
- Quality management of CPG development process is paramount!



Source: www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx

Thank you!
Questions or comments are welcome!
See you in Berlin 2012!

