Help from guidelines

Dr. Willianne Nelen

Dept. of Obstetrics & Gynaecology
Radboud University Nijmegen Medical Centre

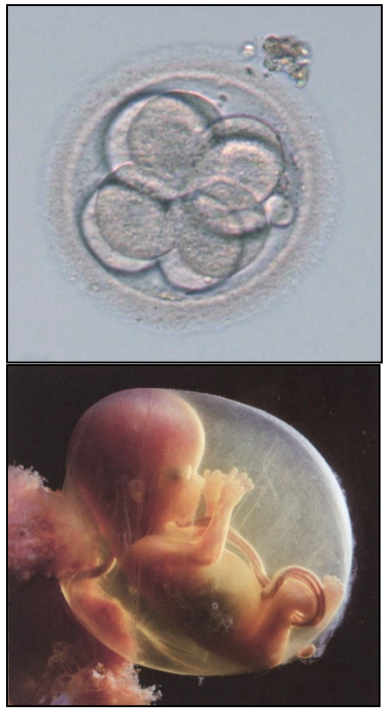
Early pregnancy

Dilemmas

- Ethics (e.g. handling embryos)
- Legislation (e.g. abortion, reimbursement)
- Societal (e.g. life style)
- Lack of evidence

↓

Variety in early pregnancy care



Clinical guidelines

systematically developed *statements to*

assist care providers and patient

in making decisions about appropriate health care

for specific clinical circumstances

Field & Lohr1992

Clinical guidelines

- Can bridge the gap between evidence and clinical practice

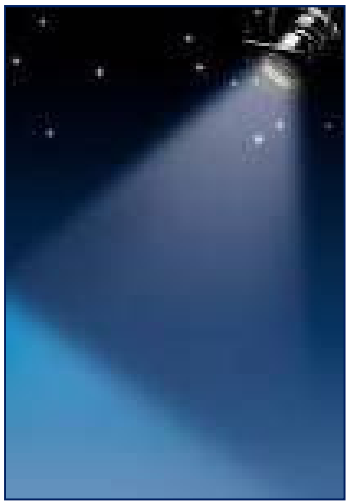
- Decrease variation in care
- Increase efficiency of care

↓

Improvement quality of care

Guidelines early pregnancy

- Availability
- Methodological quality
- Implementation
- Future



Guidelines early pregnancy

- (recurrent) Early pregnancy loss
  - ESHRE 2006 Dutch Society 2007
  - RCOG 2006 ACOG 2001
- Ectopic pregnancy
  - ACOG 2008 Dutch Society 2001
  - RCOG 2004
- Preconception care/systemic diseases
  - General (Centers for Disease Control and Prevention;2006) (Finnish Society;2007)
  - Diabetes (Am Assoc Clin Endocr; 2007) (Dutch Society; 2005)
  - HIV (RCOG;2004)
  - Hypertension (Canadian Society; 2008) (Dutch Society; 2000)
  - Folic acid supplementation (Canadian Society; 2007)

Guidelines early pregnancy

National Guideline Clearinghouse
www.guideline.gov
AHRQ

- (recurrent) Early pregnancy loss
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  - Hypertension (Canadian Society; 2008) (Dutch Society; 2000)
  - Folic acid supplementation (Canadian Society; 2007)

Clinical guidelines

Guidelines should be of high quality:

- valid
- reliable
- applicable
- clear
- timely revised
- ……

Methodological quality

AGREE instrument

- Internationally developed
- Validated
- 6 domains
- 23 key items

- www.agreecollaboration.org

AGREE Instrument

Domains

- Scope & purpose
- Stakeholder involvement
- Rigour of development
- Clarity & presentation
- Applicability
- Editorial independence

SCOPE AND PURPOSE

1.	The overall objective(s) of the guideline is (are) specifically described.	Strongly Agree	1 2 3 4 Strongly Disagree
2.	The clinical question(s) covered by the guideline is (are) specifically described.	Strongly Agree	1 2 3 4 Strongly Disagree
3.	The patients to whom the guideline is meant to apply are specifically described.	Strongly Agree	1 2 3 4 Strongly Disagree

STAKEHOLDER INVOLVEMENT

4.	The guideline development group includes individuals from all the relevant disciplines or stakeholders.	Strongly Agree	1 2 3 4 Strongly Disagree
5.	The patients' views and preferences have been sought.	Strongly Agree	1 2 3 4 Strongly Disagree

Methods

AGREE instrument

- Domain score (0-100%)

$$\frac{\text{obtained score}}{\text{maximum score}}$$

ESHRE clinical guidelines

Human Reproduction pp. 1–7, 2008

Copy Edited by: M
doi:10.1093/humrep/den120

The methodological quality of clinical guidelines of the European Society of Human Reproduction and Embryology (ESHRE)

W.L.D.M. Nelen[1,6], R.W. van der Pluijm[1], R.P.M.G. Hermens[2], C. Bergh[3], P. de Sutter[4], K.G. Nygren[5], A.M.M. Wetzels[1], R.P.T.M. Grol[2] and J.A.M. Kremer[1,6]

Results

AGREE domains	RM guideline	Range
Scope & purpose	78 %	6-81
Stakeholder involvement	17 %	4-56
Rigour development	25 %	2-73
Clarity & presentation	54 %	19-83
Applicability	6 %	0-48
Editorial independence	13 %	4-63

Not recommended

Results

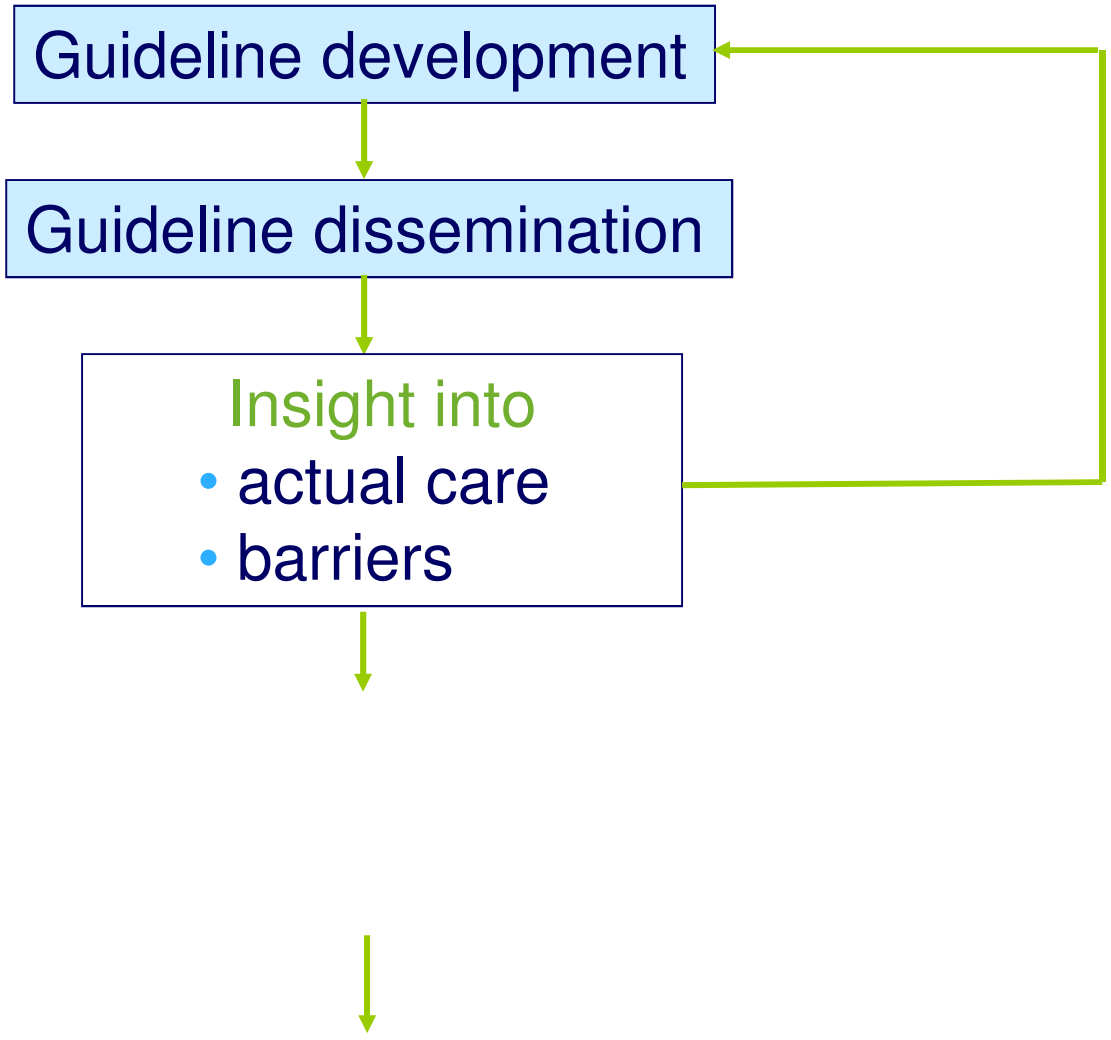
Improvements

- patient involvement
- methodology evidence selection
- implementation tools
- statements

Implementation

stepwise and profound introduction of a guideline aiming to integrate its recommendations profoundly into the daily performance of health-care professionals

Grol and Wensing 2001

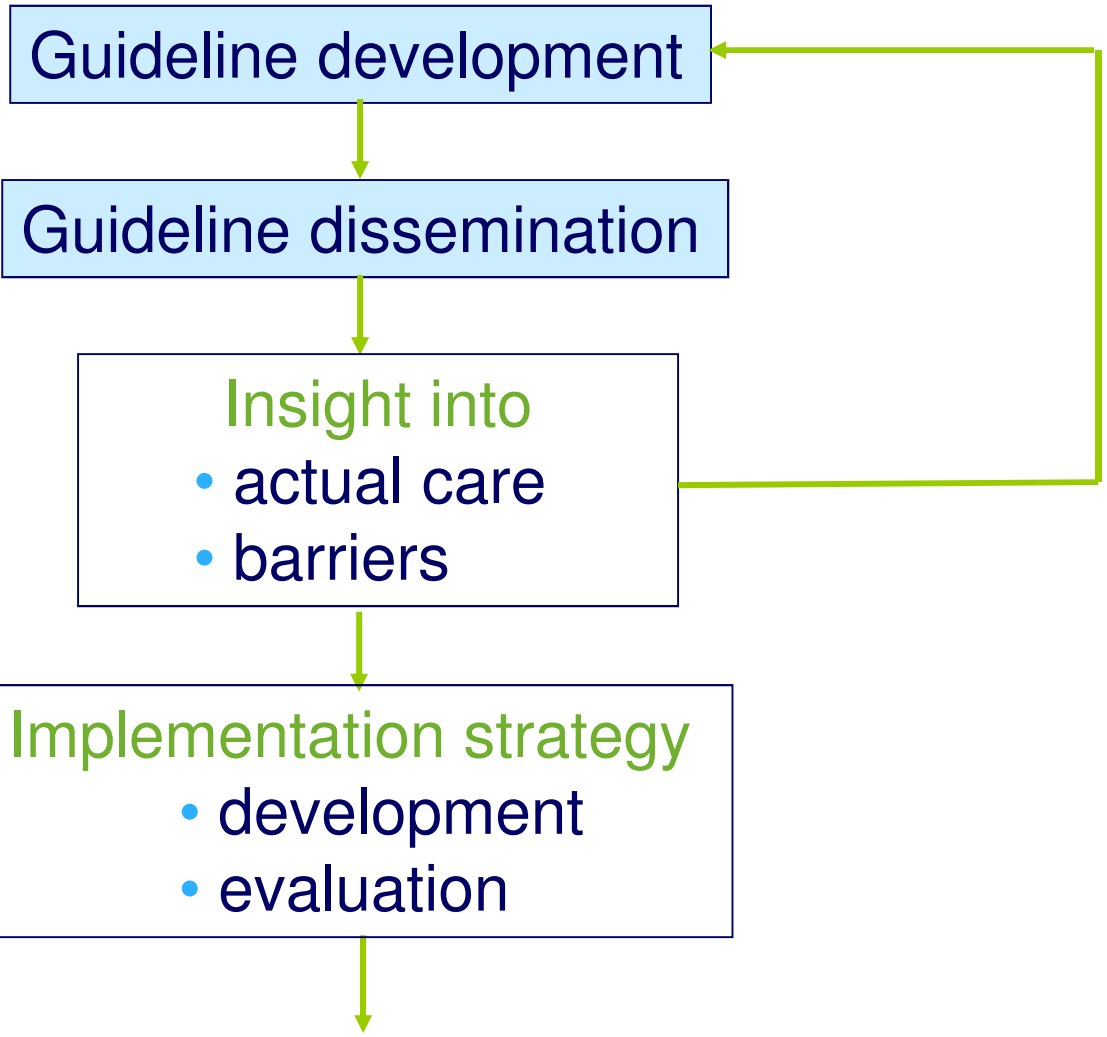

Guideline development
Guideline dissemination
Insight into
• actual care
• barriers
IMPLEMENTATION

Implementation

Barriers

- Guideline related — controversial item(s), outdated, conflicts of interest members development group
- Physician related — lack of awareness or self-efficacy, disagreement
- Patient related — conflicting expectations, co-morbidity
- Environment related — conflicting legislation, lack of reimbursement or facilities

Cabana et al 1999



I M P L E M E N T A T I O N

Implementation

Human Reproduction Vol.22, No.5 pp. 1298–1303, 2007
Advance Access publication February 22, 2007
doi:10.1093/humrep/dem014

Management of recurrent miscarriage: evaluating the impact of a guideline

M.T.M.Franssen[1,5], J.C.Korevaar[2], F.van derVeen[1], K.Boer[3], N.J.Leschot[4] and M.Goddijn[1]

Evaluation

- Change in clinical management recurrent miscarriage
- After introduction national clinical guideline
- The Netherlands
- Survey (83% response rate)

Implementation

Conclusions

- Adherence to national clinical guideline is poor
  - Many diagnostic tests as routine instead of on indication
  - Ineffective therapy offered

    (aspirin, heparin, antibiotics)

Manual

Aim

- Reference tool to assist individual members of ESHRE guideline development groups step wisely

http://www.eshre.com/ - Microsoft Internet Explorer

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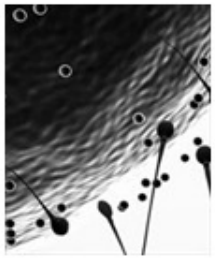

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The 25th Annual Meeting in Amsterdam, The Netherlands, 28 June - 1 July 2009

Important registration deadline:
15 April 2009 for early fee registration and refundable cancellations

Next ESHRE Activity

Sperm DNA:
organisation, protection and vulnerability – from basic science to clinical application
Stockholm, Sweden
21-22 May 2009

Direct links

Good clinical treatment position paper

New board members Paramedical Group, candidates are requested to submit their CV before 31 March 2009

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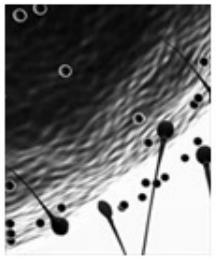

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- Links

Legal Matters and Guidelines

Legal documentation

ESHRE tries to collect information on the legal status of embryo research and donor anonymity across Europe. This information is already available for some countries.

Read more

Guidelines

Read more

What's new

Summary of the Swedish situation

Austrian legal situation

Ukrainian legislation

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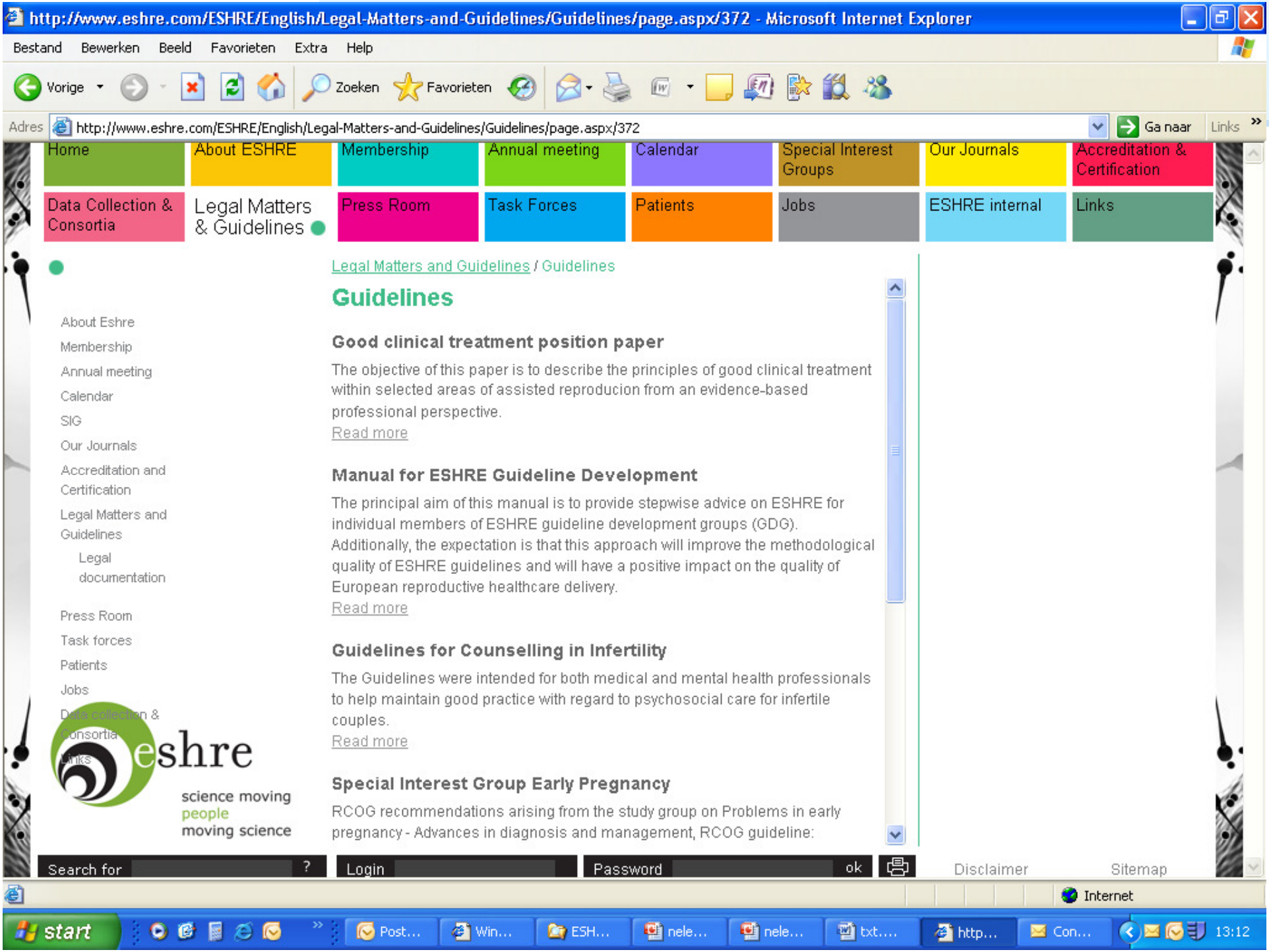
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Good clinical treatment position paper
The objective of this paper is to describe the principles of good clinical treatment within selected areas of assisted reproducion from an evidence-based professional perspective.
Read more
Manual for ESHRE Guideline Development
The principal aim of this manual is to provide stepwise advice on ESHRE for individual members of ESHRE guideline development groups (GDG). Additionally, the expectation is that this approach will improve the methodological quality of ESHRE guidelines and will have a positive impact on the quality of European reproductive healthcare delivery.
Read more
Guidelines for Counselling in Infertility
The Guidelines were intended for both medical and mental health professionals to help maintain good practice with regard to psychosocial care for infertile couples.
Read more
Special Interest Group Early Pregnancy
RCOG recommendations arising from the study group on Problems in early pregnancy - Advances in diagnosis and management, RCOG guideline:
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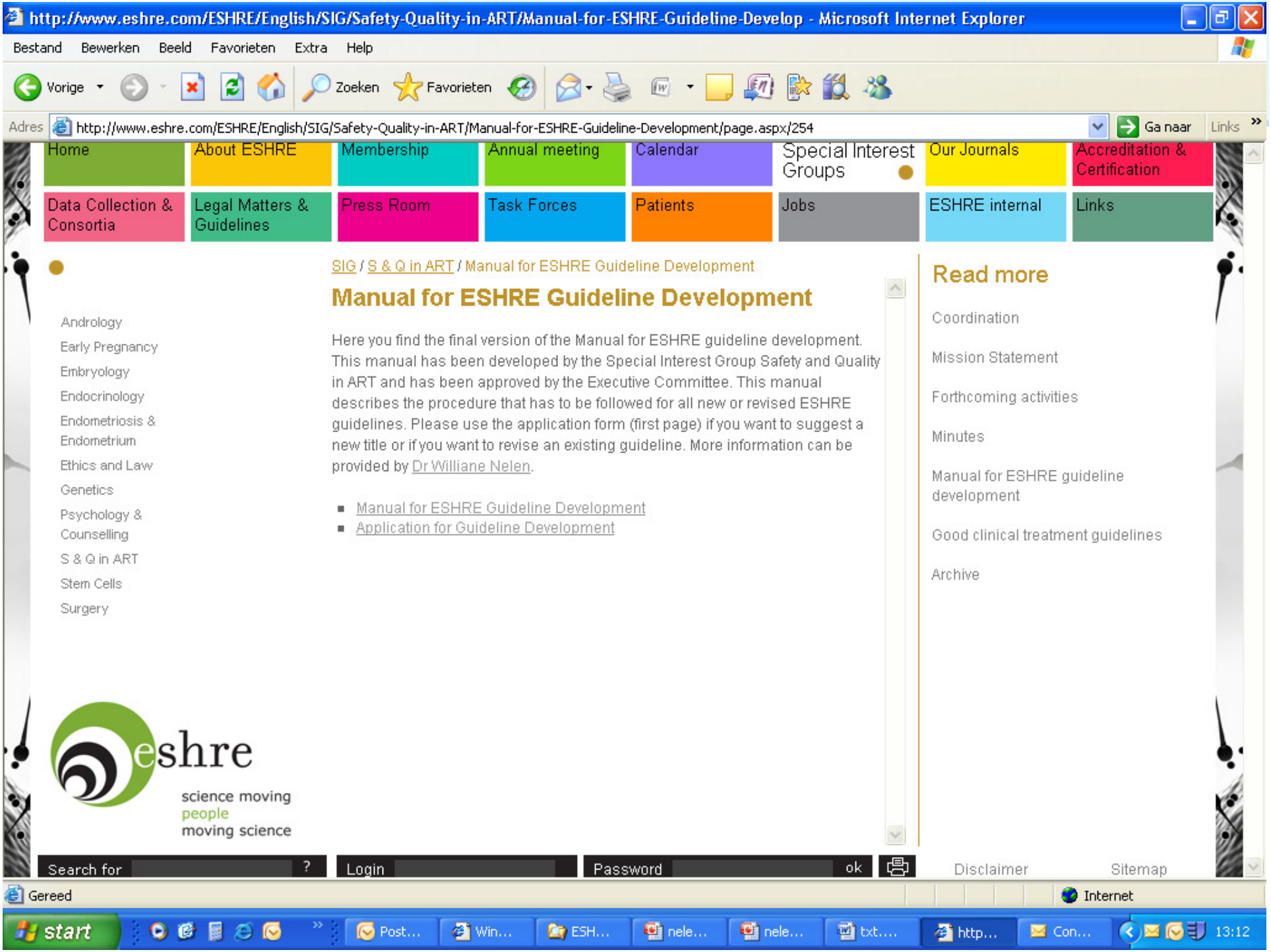
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SIG / S & Q in ART / Manual for ESHRE Guideline Development
Manual for ESHRE Guideline Development
Here you find the final version of the Manual for ESHRE guideline development. This manual has been developed by the Special Interest Group Safety and Quality in ART and has been approved by the Executive Committee. This manual describes the procedure that has to be followed for all new or revised ESHRE guidelines. Please use the application form (first page) if you want to suggest a new title or if you want to revise an existing guideline. More information can be provided by Dr Williane Nelen.
Manual for ESHRE Guideline Development
Application for Guideline Development
Andrology
Early Pregnancy
Embryology
Endocrinology
Endometriosis & Endometrium
Ethics and Law
Genetics
Psychology & Counselling
S & Q in ART
Stem Cells
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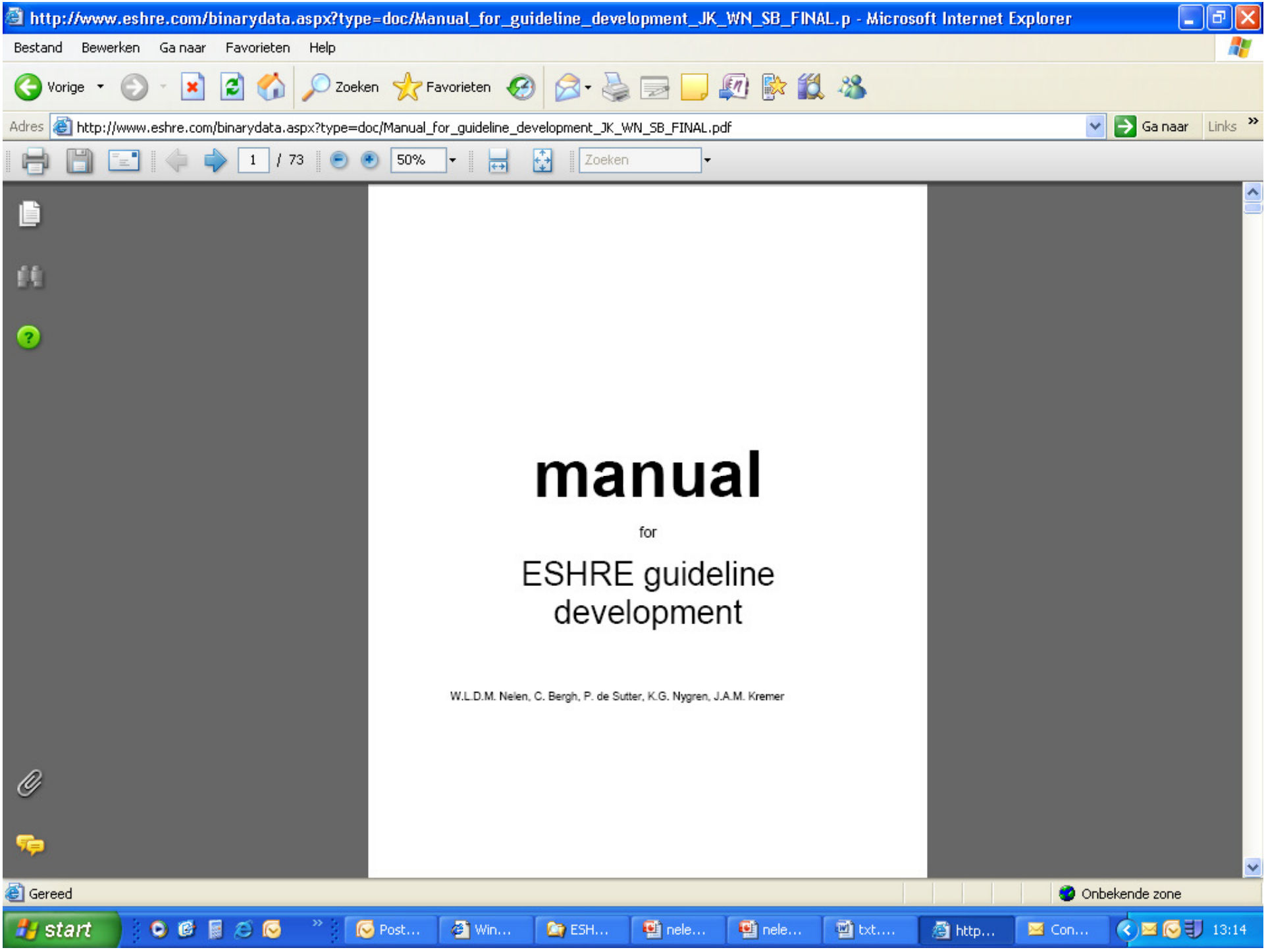
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Manual

- American College of Cardiology Foundation and American Heart Association (ACC/AHA)
- Dutch Institute for Healthcare Improvement (CBO)
- Canadian Medical Association (CMA)
- European Society of Cardiology (ESC)
- National Health and Medical Research Council (NHMRC)
- National Institute for Health and Clinical Excellence (NICE)
- New Zealand Guidelines Group (NZZG)
- Scottish Intercollegiate Guidelines Network (SIGN)
- World Health Organization (WHO)
- AGREE Instrument

Manual

Structure

- From proposal through to publication and beyond
- Stepwise
- Each chapter:
  - description
  - flowchart
  - tips

Chapter 7

Summarizing evidence

Studies identified during the stepwise literature search need to be reviewed to identify the most appropriate data to help answer the key questions and to ensure that the recommendations are based on the best available evidence. This process should be explicit and transparent and should be carried out through a systematic review process. This involves four major steps: selecting relevant studies; assessing their quality; synthesising the results; and grading the evidence.

Selection evidence

Papers have been preliminary selected based on the title and abstract by the ESHRE research specialist (figure 6.2).
First, the titles of the retrieved citations are scanned and those that fall outside the topic of the guideline are eliminated. Subsequently, a quick check of the remaining abstracts identifies additional papers not relevant to the key questions and those are also excluded. The remaining abstracts are investigated if those studies fulfil the set of selection criteria agreed by the GDG. If no or incomplete information is available in the abstract, verification of the full-text is performed to select those papers considering the next step: assessment of the quality of each study to ensure its validity and applicability. The study selection process is clearly documented and details the applied inclusion criteria.

Quality assessment

Quality assessment of the preliminary evidence selection is necessary to base its conclusions on the highest quality evidence available. The quality is assessed of individual studies. However, of meta-analyses or systematic reviews the quality is assessed as much as possible of the meta-analysis or review itself only and not of the individual included studies. To minimise any potential bias in the assessment, independent assessment by two reviewers is desirable. Therefore, both the ESHRE research specialist and the responsible GDG members perform by a checklist the quality assessment according to a modified Cochrane Collaboration methodology (appendix X). Differences in assessment should be discussed to afford the possibility of reaching consensus. In extraordinary cases a third independent person can be asked for assistance. Factors that warrant assessment are those related to:

- applicability of findings
- validity of individual studies

Applicability, which is also called external validity or generalisability, is related to the definition of the components (PICO) of the formulated key questions (chapter 5). Comparison of the available articles with the defined PICO components guides the selection of papers with the relevant evidence.
The validity of a study is the extent to which its design and conduct are likely to prevent systematic errors, or bias. There are four potential sources of systematic bias in healthcare trials:

Steps & Tips

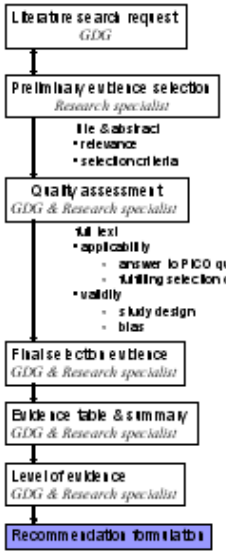


Figure 7.1 Schematic stepwise evidence summarizing and grading

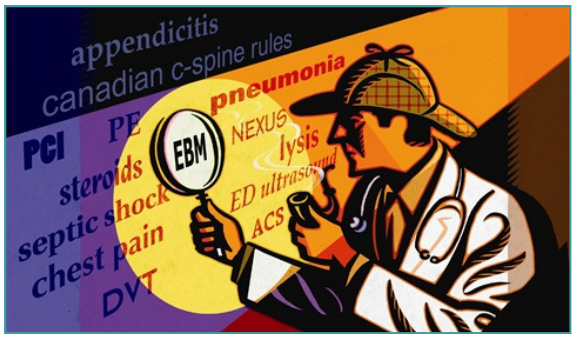
- Record the set of selection criteria
- Record the level of evidence
- Document and store the evidence inclusion process
- Document and store the evidence tables

Manual

Main points ESHRE guidelines

- Recommendations on a particular clinical issue
  (e.g. endometriosis, ectopic pregnancy, preconception care)

- Evidence-based guidelines
  - scientific evidence priority
  - based on best available evidence
    (most relevant and highest level)
    not on all evidence available



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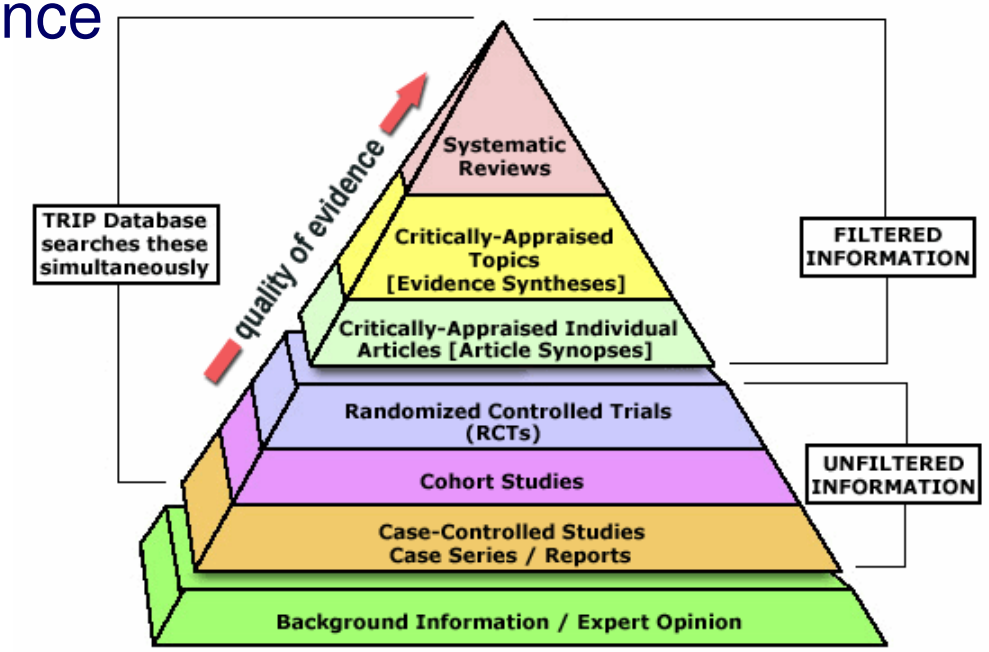
Main points ESHRE guidelines

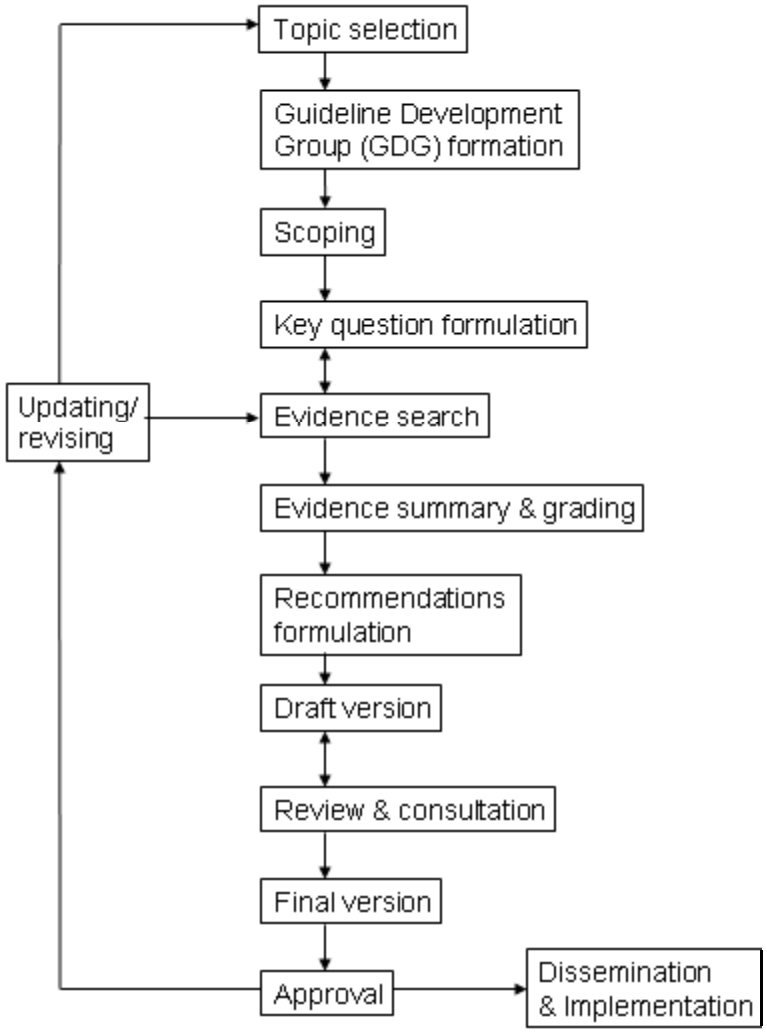
- Explicit link between recommendations and its evidence
  - levels of evidence
  - references

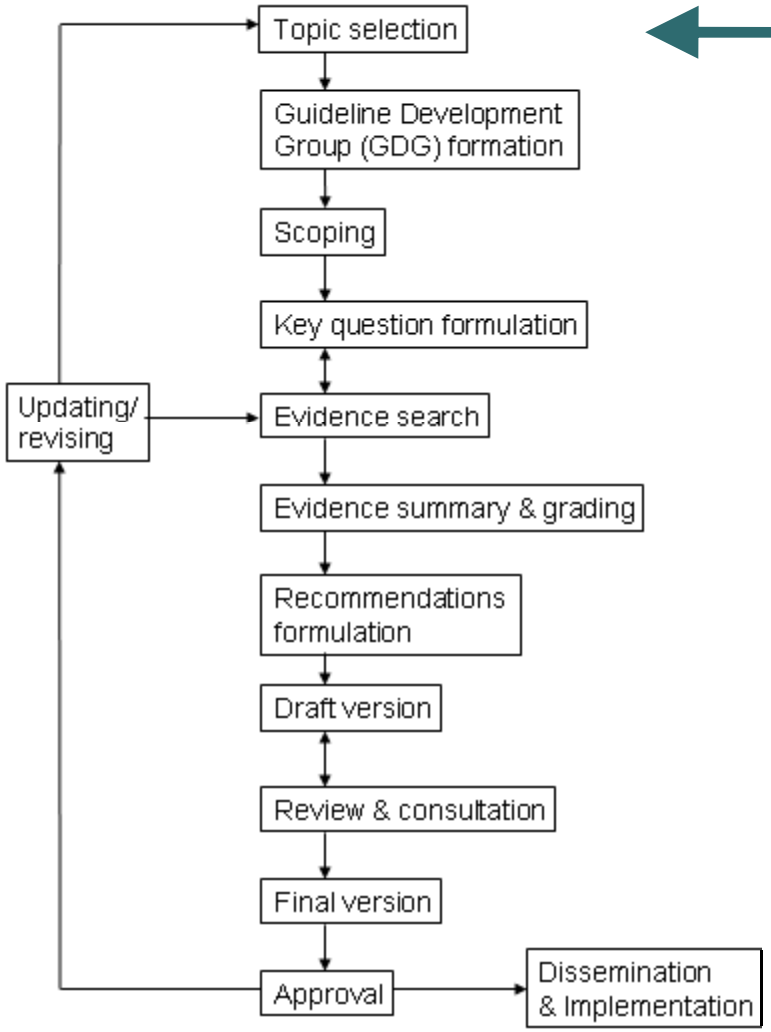


Manual

Main points ESHRE guidelines

- Adaptation and translation by National Societies is welcomed
- Guideline development a cycle of interdependent activities


Topic selection
Guideline Development Group (GDG) formation
Scoping
Key question formulation
Updating/ revising
Evidence search
Evidence summary & grading
Recommendations formulation
Draft version
Review & consultation
Final version
Approval
Dissemination & Implementation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Final version
Approval
Dissemination & Implementation

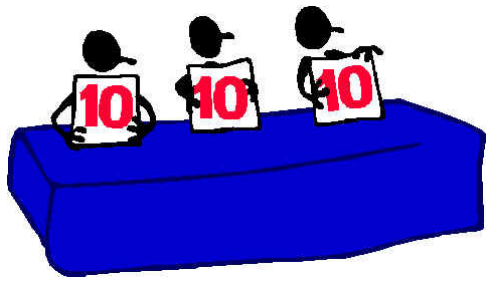
Topic selection

Main points

- Once a year

- Application form downloaded from ESHRE website (Appendix A)
  - relevance topic (e.g. volume, costs)
  - actual practice variation
  - potential benefit
  - indicated size and strength evidence

- Final decision Executive Committee



Guideline development

Main points

- 18-24 months
- ESHRE research specialist
  - literature search
  - quality assessment
  - facilitating update
- Training for guideline development group members

Conclusions

Improvement

- Availability guidelines
- Methodological quality guidelines
- Implementation guidelines

High quality of (European) early pregnancy care

- ESHRE

Requests:
w.nelen@obgyn.umcn.nl