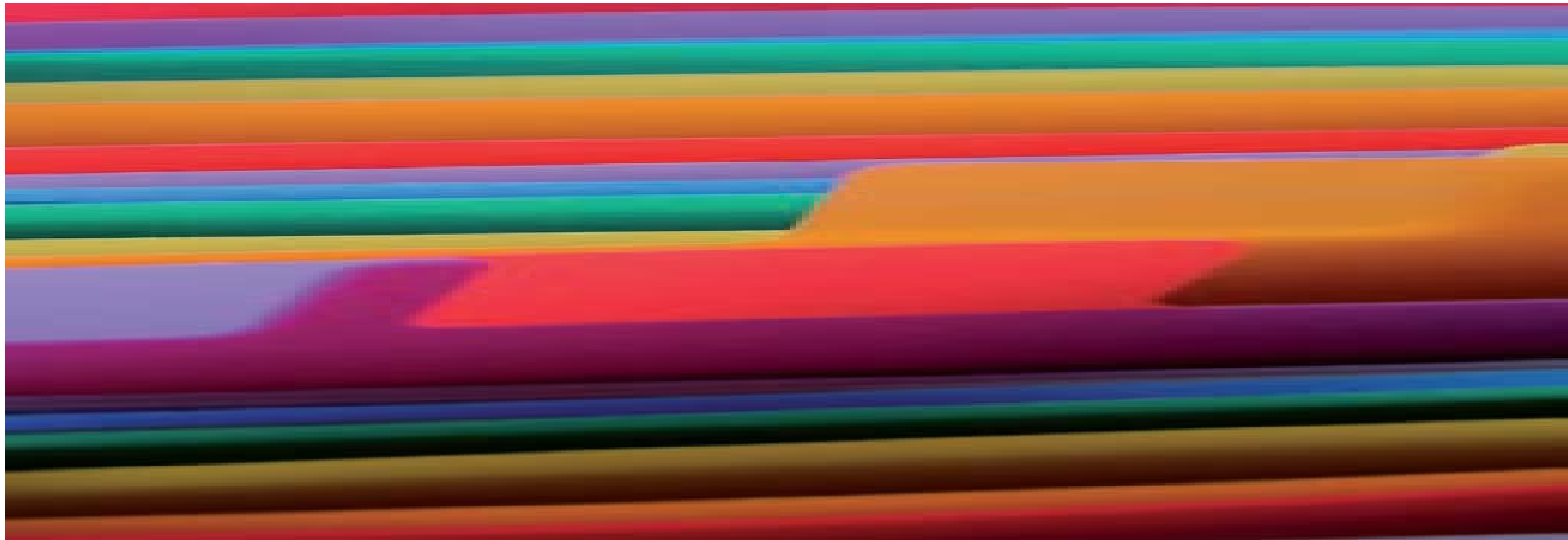




RKI workshop, Evidence based immunisation

Evidence-based methods for public health

ECDC –report Evidence-based methods for public health



How to assess the best available evidence
when time is limited and there is lack of
sound evidence, September 2011

Frode Forland, Senior Expert ECDC

NEWS

→ View all news

New ECDC report explores how methods of evidence-based medicine can be applied in the field of infectious diseases

8 September 2011



A new report addresses the question of giving scientific advice under uncertainties, in complex situations and often on short notice. The report explores how the best from the methods of classical epidemiology can be matched and possibly merged with the methodologies developed in evidence-

based medicine to give a new blend, an evidence-based methodology for infectious diseases prevention and control.

→ Read more

ECDC assessment on Avian flu outbreak in Southeast Asia indicates no change in risk to human health

1 September 2011

→ Read more

ECDC assessment on Oseltamivir-resistant influenza A(H1N1)2009 cluster reported in Australia

6 September 2011

→ Read more

Latest update: Weekly maps on West Nile fever cases in Europe

9 September 2011

→ Read more

ECDC releases two new reports on HIV and migrant health

15 August 2011

→ Read more

EPIDEMIOLOGICAL UPDATES

Epi update on Legionnaires' disease outbreak in Lazise, Italy, July-August 2011

08 September 2011

LATEST PUBLICATIONS

Bi-weekly influenza surveillance overview, 22 Aug-4 Sept 2011 - Weeks 34-35



West Nile fever maps

Weekly maps on reported human cases in EU and bordering countries, published every Friday

Read more →

TOP SIX HEALTH TOPICS

→ Chlamydia infection - spotlight 2011

Chlamydia is the most common sexually transmitted infection in Europe and particularly affects young people.

→ HIV infection/AIDS - spotlight 2010

There is evidence that increasing the uptake of HIV testing – and consequently increased access to treatment – can contribute to controlling the HIV/AIDS epidemic.

→ Antimicrobial resistance

Antibiotics are often unnecessarily or wrongly prescribed. Misuse of antibiotics leads to the emergence and selection of resistant bacteria.

→ Tuberculosis - spotlight 2011

Tackling tuberculosis in children: towards a TB-free generation. Many children still suffer from TB in the EU/EEA. Almost 40 000 cases were notified in the past decade.

→ Escherichia coli (E.coli)

STEC is a group of pathogenic Escherichia coli strains capable of producing Shiga toxins, with the potential to cause severe enteric and systemic disease in humans.

→ Measles

Measles is an acute illness caused by morbillivirus. The disease is transmitted via airborne respiratory droplets, or by direct contact with nasal and throat secretions.

HEALTH TOPICS A-Z

A B C D E F G H I L M N
O P Q R S T V W Y Z

Click a letter to jump directly to the section

COUNTRY INFORMATION

Working evidence based in public health infectious diseases



- A case is also an exposure
- An outbreak can only be studied when it is ongoing
- The evidence base is often weaker
- Often lack of time
- Wider and more complex judgements
- Uncertainties might be high
- The role of context is crucial



Mandate of the Methods Working Group



- Develop methods and tools to strengthen evidence-based work within the public health/ infectious disease field
- Adjust EBM tools, standards and checklists
- Evaluate the usefulness of existing grading systems
- Assess how standards like the AGREE instrument and “Guidelines for guidelines” can be adjusted
- Consider strengths and weaknesses of different consensus methods
- Assess and propose further research needs in the field of methods development

Background



A new ECDC technical report, [Evidence-based methodologies for public health](#), addresses the question of giving scientific advice under uncertainties, in complex situations and often on short notice.

Targeted at policymakers and public health professionals, the report explores how the best from the methods of classical epidemiology can be matched and possibly merged with the methodologies developed in evidence-based medicine (EBM) to give a new blend, an evidence-based methodology for infectious diseases prevention and control.

Link to the report:

<http://www.ecdc.europa.eu/en/publications/>



Main conclusion



By exploring how EBM methods could be applied in public health advice under different time scales, the authors have found that many methods, tools and templates are already developed, well suited for public health needs and should be more widely used.

However, in some areas there is a need to further develop and fine-tune some the instruments to better fit the needs of public health in the area of infectious diseases.



Evidence based public health

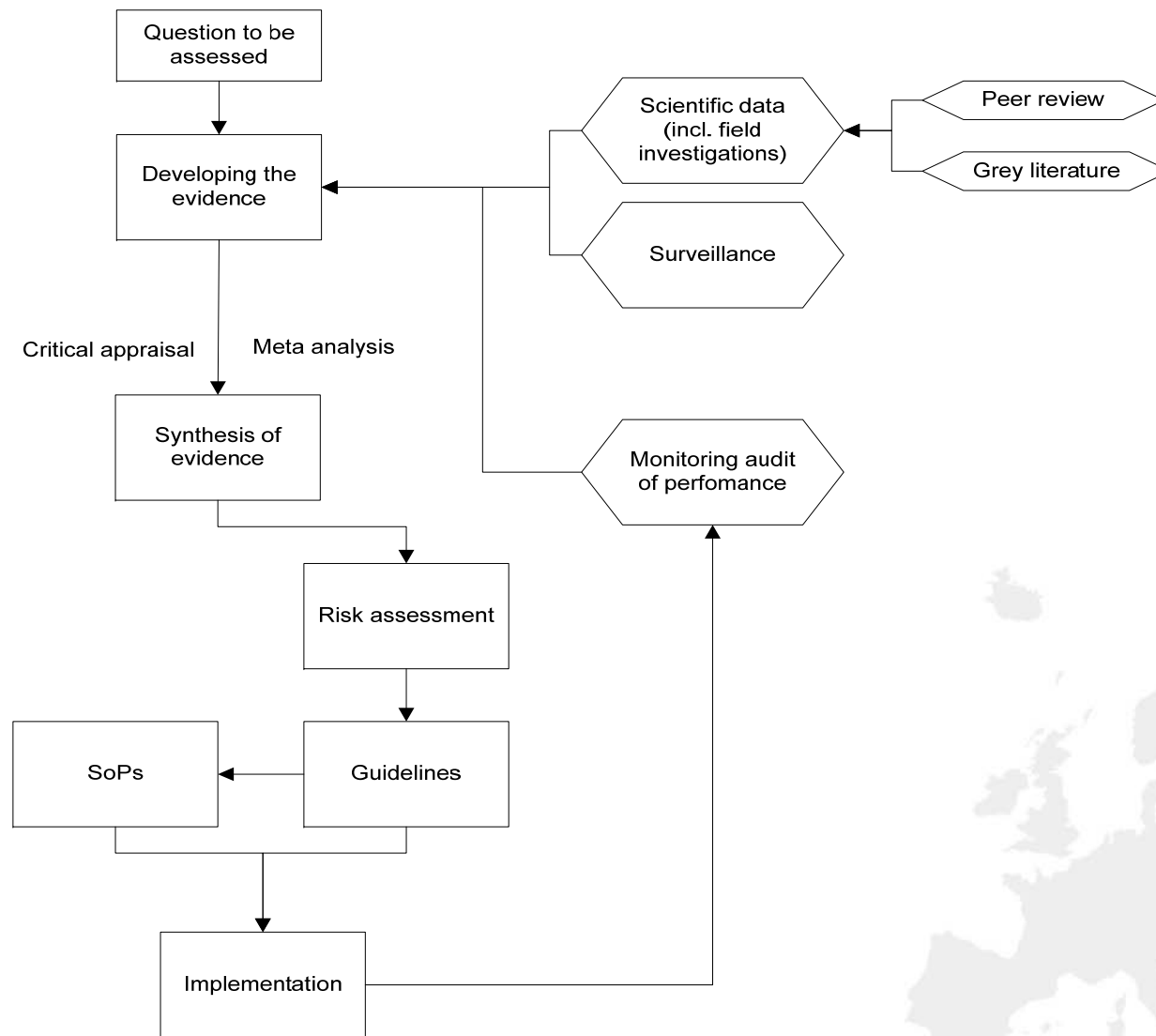


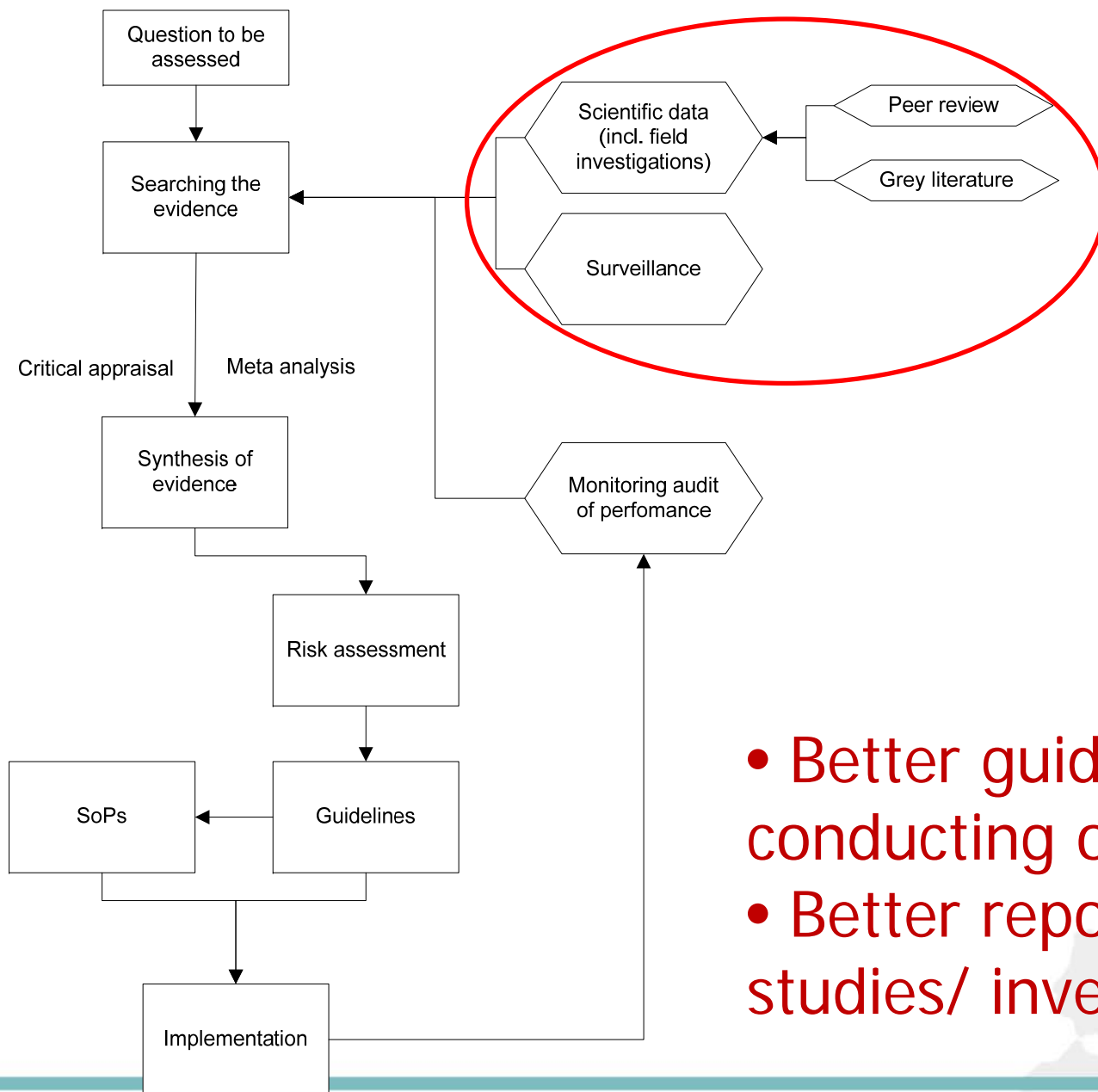
Proposed definition:

- Integration of the best available evidence with the knowledge and considered judgements from stakeholders and experts to benefit the needs of a population

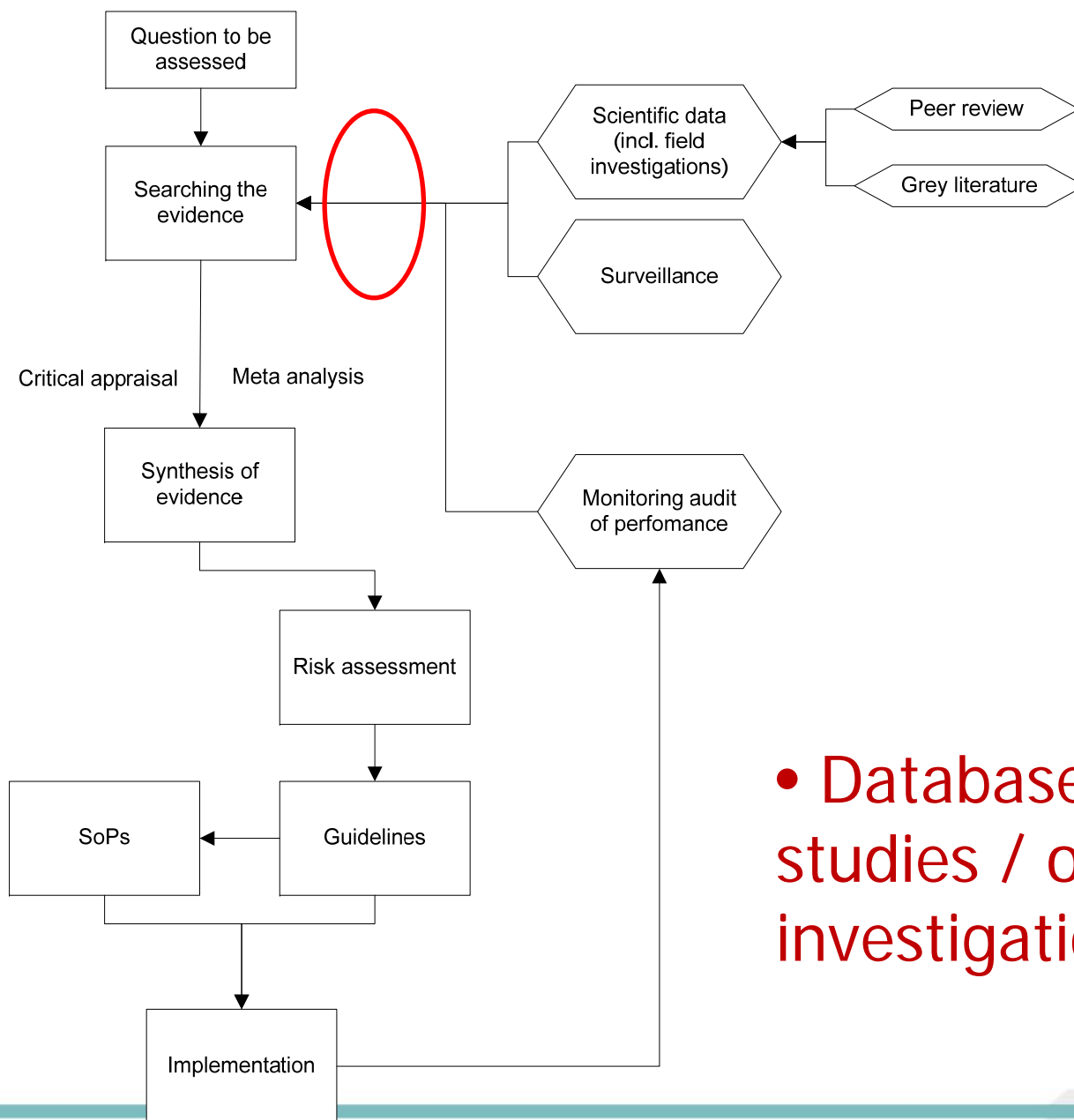


The evidence cycle

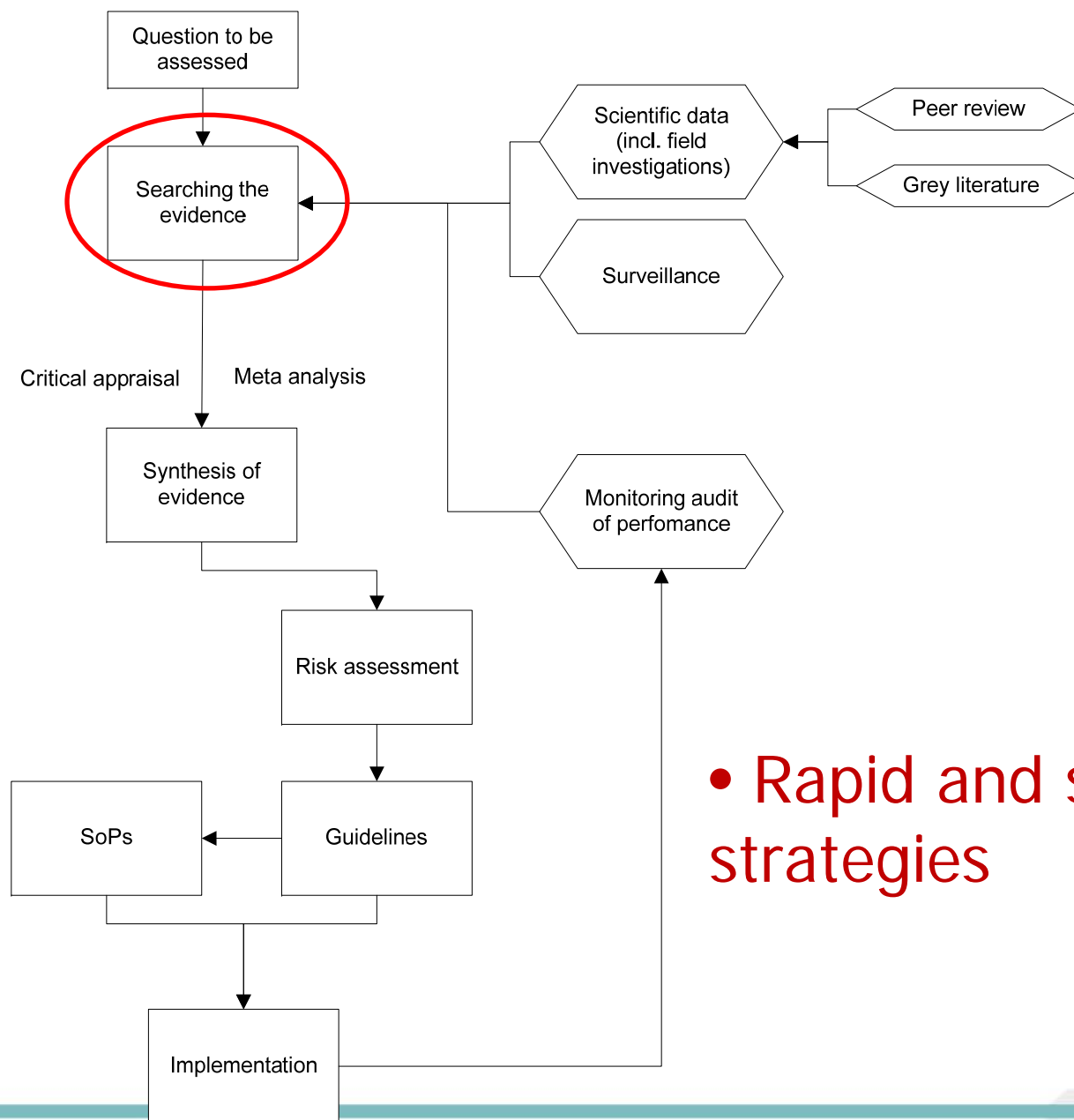




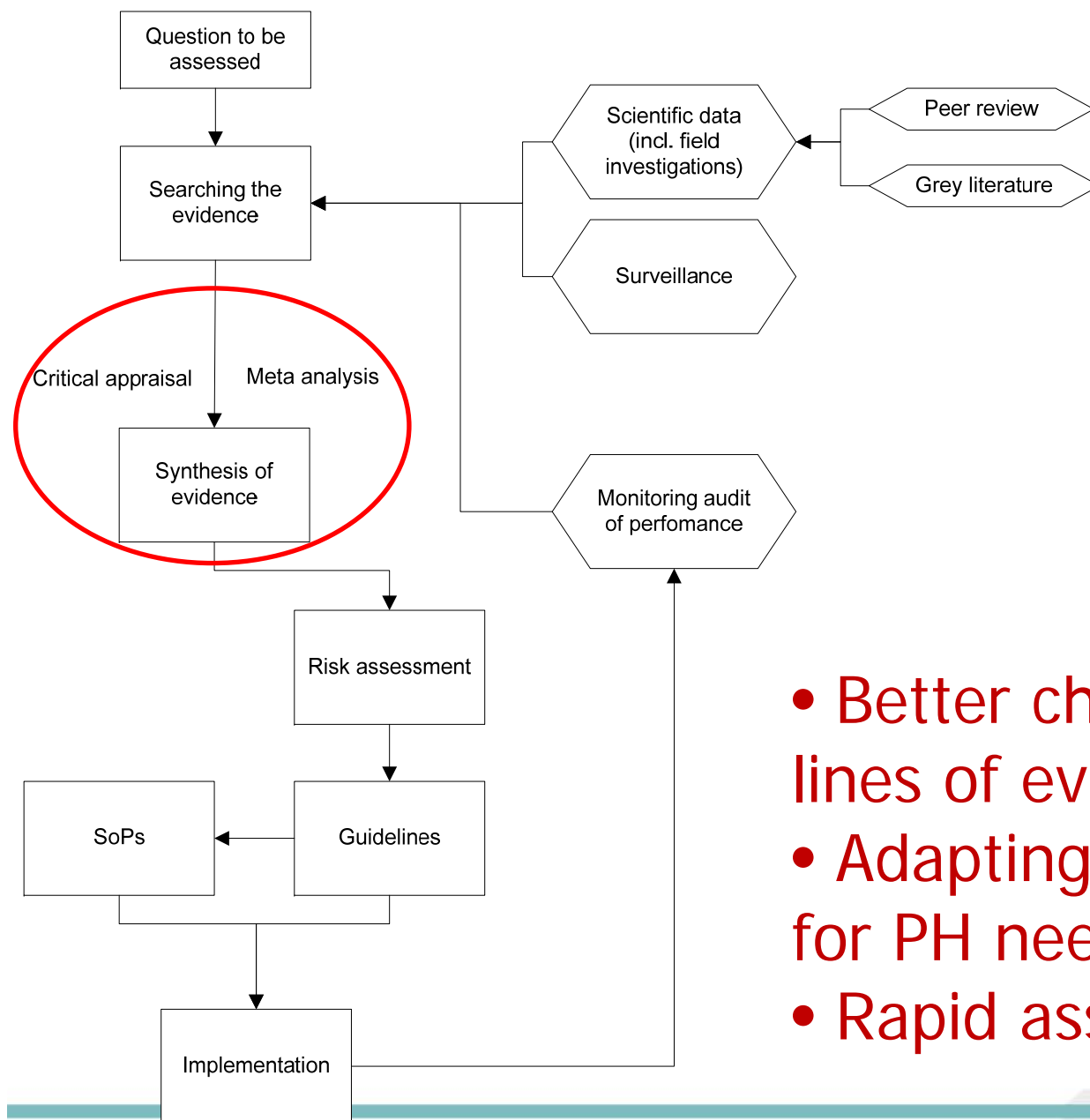
- Better guidelines for conducting outbreak studies
- Better reporting of outbreak studies/ investigations



- Database for observational studies / outbreak investigations - pilot at ECDC



- Rapid and sensitive search strategies



- Better checklist for other lines of evidence
- Adapting grading systems for PH needs
- Rapid assessment tools

Where GRADE fits



Prioritize problems, establish panel, conflict of interest

Systematic review

Searches, selection of studies, data collection and analysis

Assess the relative importance of outcomes

Prepare evidence profile:
Quality of evidence for each outcome and summary of findings

Assess overall quality of evidence

Decide direction and strength of recommendation

GRADE

Draft guideline

Consult with stakeholders and / or external peer reviewer

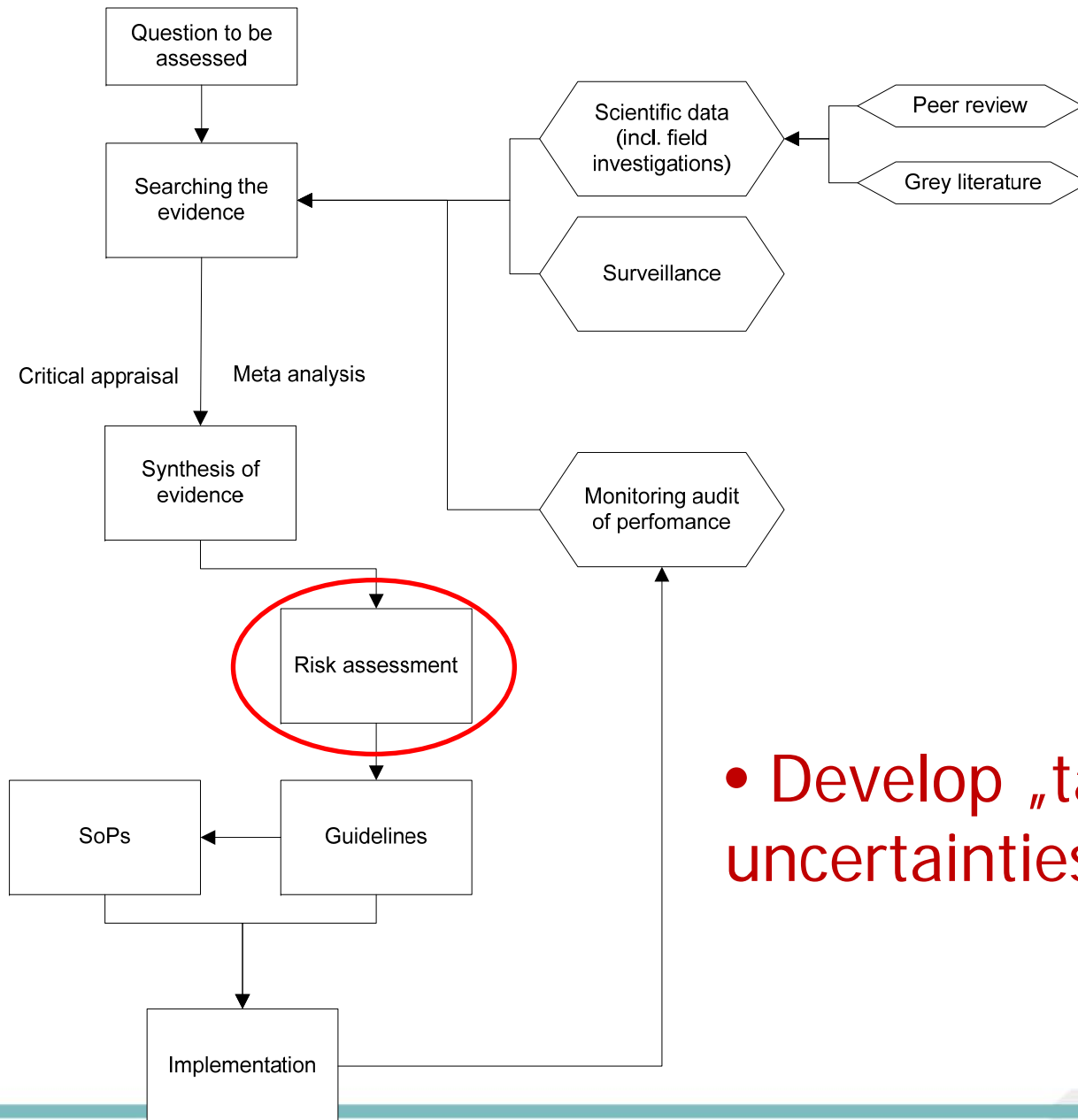
Disseminate guideline

Implement the guideline and evaluate

Challenges of applying GRADE

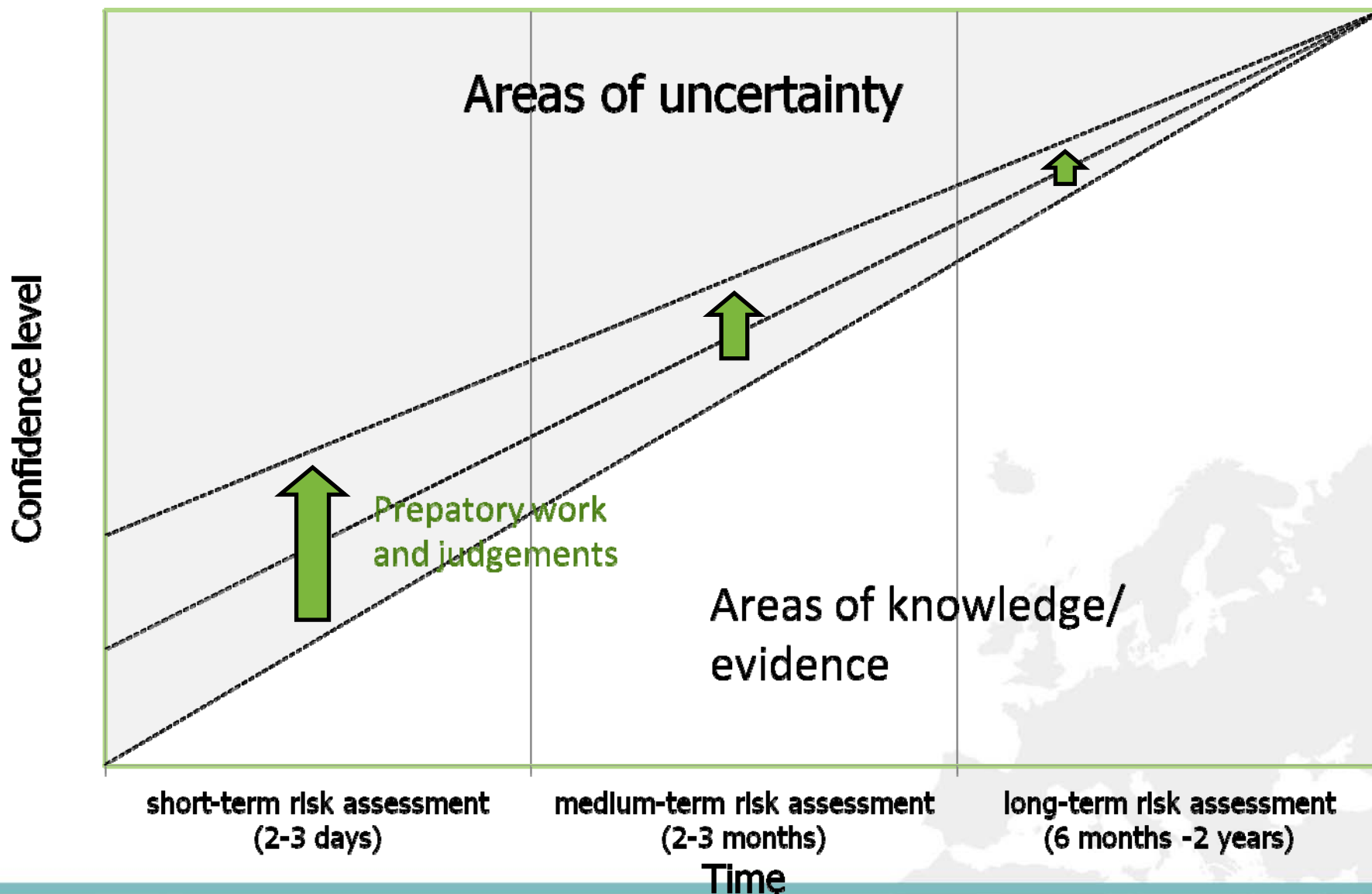


| Problem | GRADE comment | Possible solution |
|--|---|---|
| GRADE is not addressing all the relevant steps of a public health advice | More steps, ethical, legal etc can easily be incorporated | ECDC to continue discussions with GRADE on how to do this |
| GRADE nomenclature is not giving credit to observational studies | Important to stick to one nomenclature, whatever problem | More neutral terms could be used |
| GRADE is poorly developed in the area of observational studies | Need to develop better checklists | Develop the GRADE-ing system laterally to incorporate other lines of evidence |
| The GRADE system is comprehensive - takes time to use | There is need to develop better methods for rapid reviews | Develop a rapid line of grading for e.g. rapid risk assessments |



- Develop „tables of uncertainties“

The relation between level of confidence and time



Uncertainties



- Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner and should be quantified to the extent that is scientifically achievable (Codex Alimentarius)
- Three basic requirements for addressing uncertainties in risk assessments;
 - 1) systematically identify and evaluate the sources of uncertainties,
 - 2) evaluate their combined effect on the outcome of the assessment
 - 3) and communicate this to the risk managers (policy makers).

Uncertainties in PH



- Uncertainties can arise at all steps and stages of a public health guidance development process
- It is an aim to reduce uncertainties to a minimum
- Even in Cochrane reviews, there are several decisions taken by the reviewers where subjective judgements are done, definitions, inclusion/ exclusion criteria, cut off levels + +
- Public health decision making is often complex, stepwise and multifaceted – keep it complex!



Other lines of evidence



Examples of such lines are


- studies of exposure
- studies of spread
- studies of causality
- outbreak investigations
- lab research
- animal experiments
- mathematic modelling.

Application of the precautionary principle is also relevant to judgements of evidence in a public health setting; e.g. no evidence of harm should not be interpreted as if there is evidence for no harm.

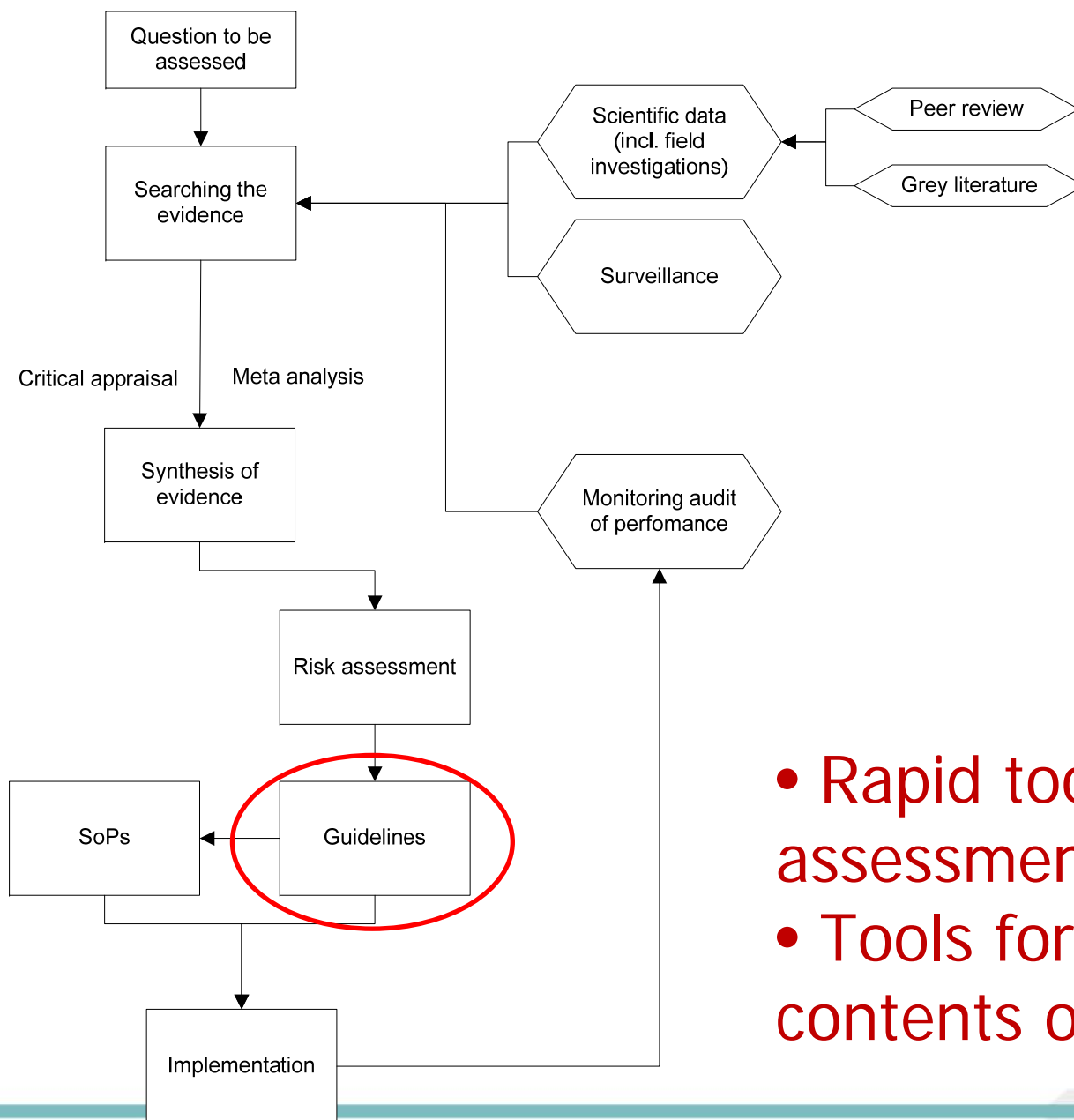


| Stage | Tasks | Tools |
|----------------|---------------------------|---|
| Stage 0 | Preparatory | Ongoing alerting systems Updated systematic reviews of evidence |
| Stage 1 | Incident verification | Protocol for verification of incidents Checklist for basic epidemiological indicators |
| Stage 2 | Assessment of risk | Definitions of 'trigger levels' and 'stopping rules', rapid search strategies, communication between experts, risk assessment framework |
| Stage 3 | Developing advice | Considered judgement form Checklist on other available guidance. Risk conception list/checklist. Express uncertainties |
| Stage 4 | Implementation | Risk communication templates, media briefing templates |
| Stage 5 | Monitoring and evaluation | Rapid audit and lessons learned |

SIGN

| | | | | | | | | | |
|---|--|----------------|----------------|----------------|----------------|----------------|----------------|----------------|---------------|
|  S I G N | Considered judgement pro forma Strength of Evidence | | | | | | | Part B | |
| <p>Key question:</p> <p>Outcome measures:</p> <p>O₁</p> <p>O₂</p> <p>O₃</p> | | | | | | | | | |
| <p>1. Draft recommendation</p> <p><i>Draft a recommendation based on the evidence statement (part A, section 7)</i></p> | | | | | | | | | |
| <p><i>Indicate here if there is insufficient evidence (low volume) to make a recommendation and make a recommendation for research in section 6.</i></p> | | | | | | | | | |
| <p>2. Judgement on the strength of recommendation</p> <p><i>Make a judgement taking into account the factors that can affect the strength of the recommendation.</i></p> | | | | | | | | | |
| | | O ₁ | O ₂ | O ₃ | O ₄ | O ₅ | O ₆ | O ₇ | |
| <p>Quality evidence</p> <p>The higher the quality of evidence, the more likely is a strong recommendation.</p> | | High | | | | | | | strong |
| | | Mod | | | | | | | |
| | | Low | | | | | | | |
| | | Very low | | | | | | | weak |
| <p>Balance of benefits versus harms and burdens</p> <p><i>Explain here the balance of benefits vs harms</i></p> | | | | | | | | | |

| | | |
|---|-------------------------|--|
| The larger the difference between the desirable and undesirable outcomes, the more likely a strong recommendation warranted. The smaller the net benefit and the lower certainty for that benefit, the more likely is a conditional recommendation warranted. | Clearly outweigh | Recommend |
| | Probably outweigh | Consider |
| | Not known | Make a recommendation for research (<i>section 6</i>) Input to DUETS (<i>section 7</i>) |
| | Probably don't outweigh | Consider against |
| | Clearly don't outweigh | Recommend against |
| Are the net benefits worth the costs <i>Outline here the costs of the intervention</i> | | |
| The higher the costs of an intervention – that is, the more resources consumed the more likely is a conditional recommendation warranted | Yes | Recommend/consider |
| | Not known | Involve SHTG/SMC (<i>section 8</i>) |
| | No | Recommend/consider against |
| 3. Contextual issues <i>Comment here on the applicability of the recommendation in the NHS in Scotland</i> | | |
| | | Reference |
| <i>Prevalence</i> | | |
| <i>Resources required (eg training, equipment)</i> | | |
| <i>Patient issues and preferences</i> | | |
| <i>National policies and initiatives</i> | | |
| <i>SMC advice</i> | | |



- Rapid tools for guidelines assessments
- Tools for assessing contents of guidelines

Guideline evaluation tools

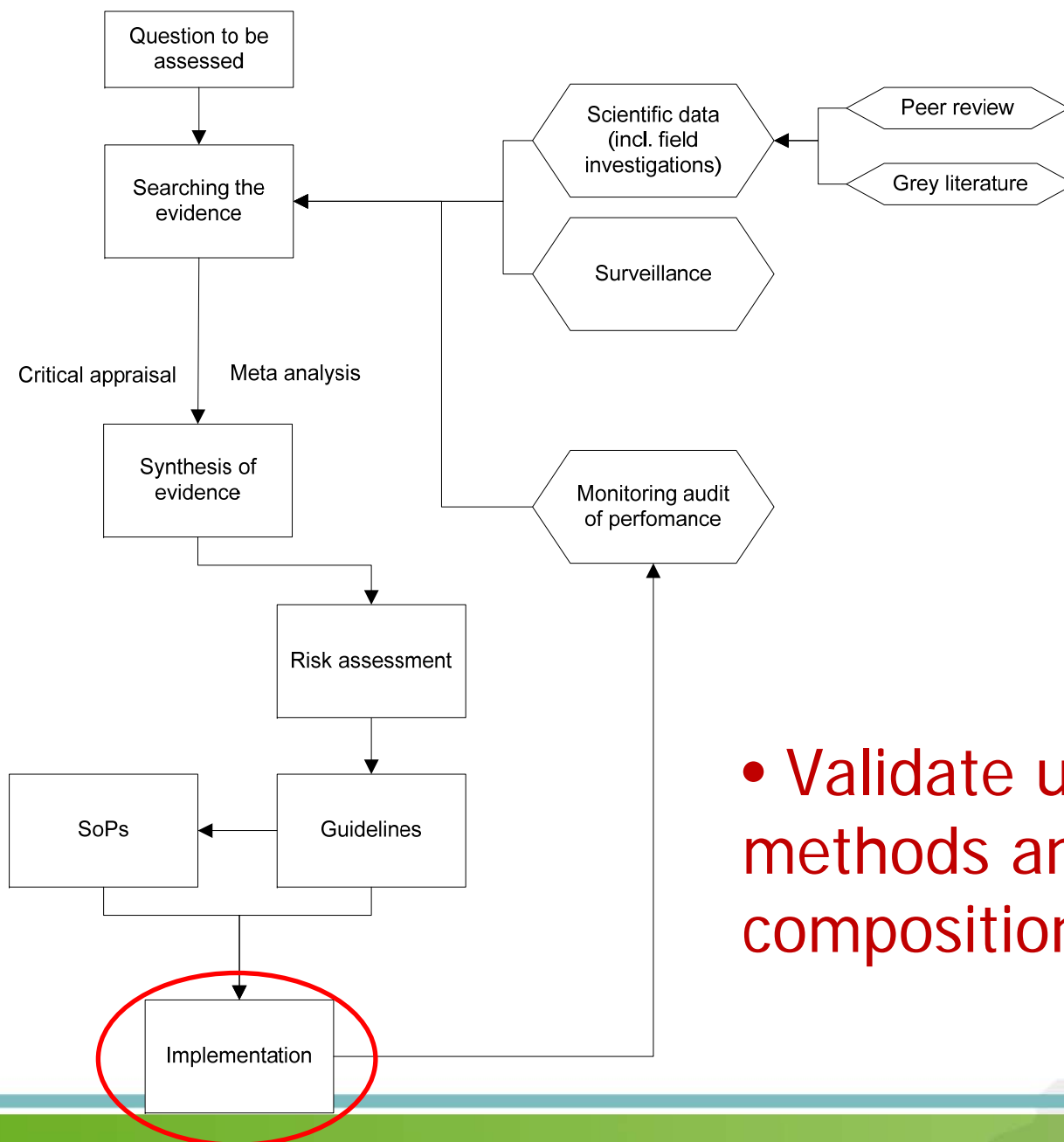


The **AGREE II** instrument is applicable to evaluate public health guidelines

Proposed additions

- How to communicate the guidance to public, media and to patients
- Considerations of ethics, equity and diversity
- Considerations of delivery structures in PH systems
- Considerations of legal frameworks
- Health economics
- Trade-off between harms and benefits





- Validate use of consensus methods and group composition

The use of Consensus methods

The role of experts

'Unpack the expert' and be transparent about the process

- When there is no published evidence
- In composition of panels
- To judge upon the evidence
 - Preliminary judgement in an urgency
 - As members of panels
 - In a review process of an advice
- Many elements from formal consensus processes can be used also under time constraints

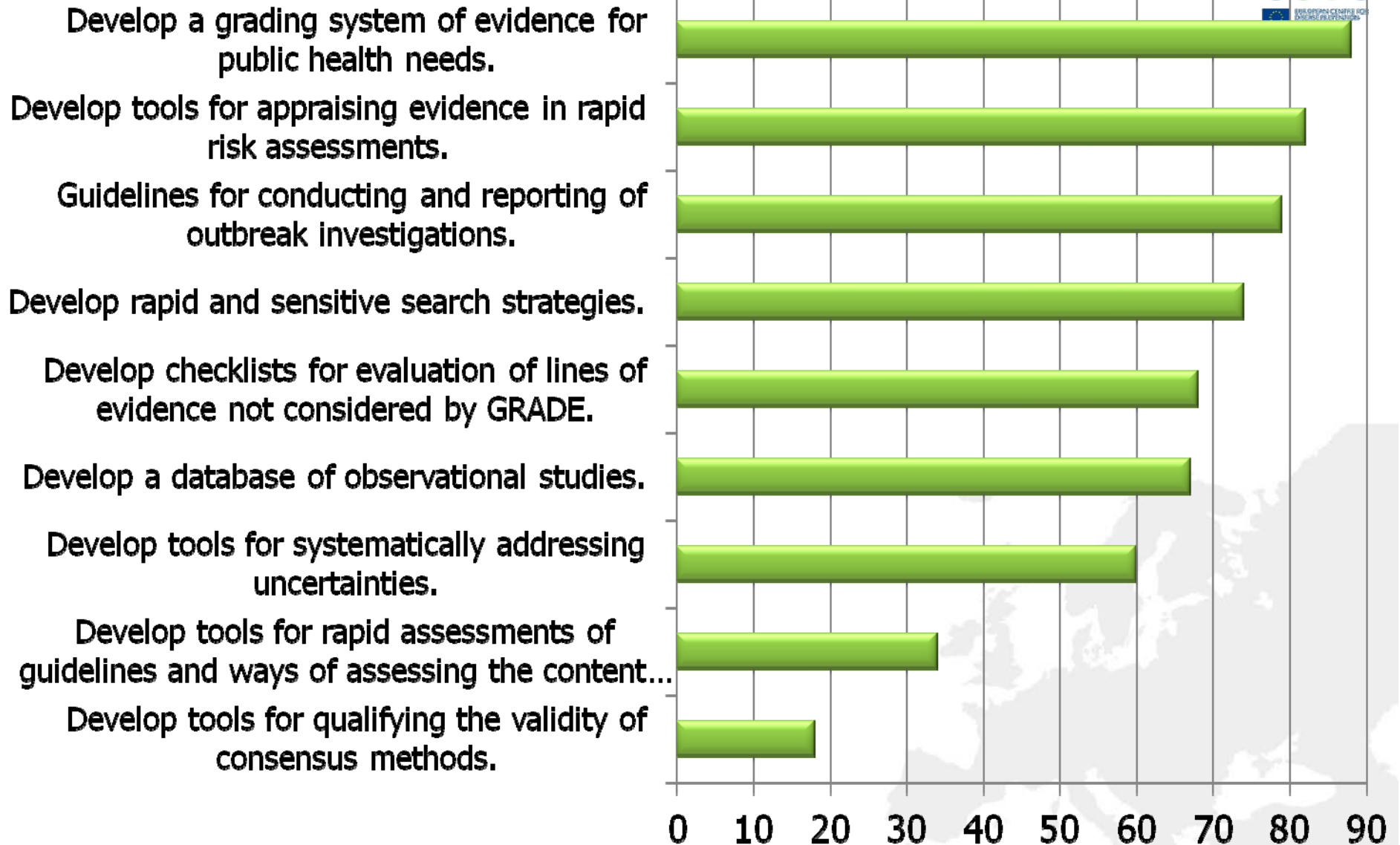


More on consensus



- For urgent (2-3 days) RA; One round of collegial review
- For semi-urgent (2-3 months); At least one round of remote rating of a consensus process
- For non-urgent (6-24 months); Three rounds, remote, face to face and remote again
- The facilitator of a guidance group should be selected for her communication-, group management- and conflict resolution skills – and should not have strong academic bias

Prioritized topics



n=13

points

