PANDUAN RINGKAS

PENYUSUNAN – STRUKTUR GUIDELINE

I.PENDAHULUAN .

Dalam penyusunan guideline / pedoman yang harus menjadi perhatian utama adalah :

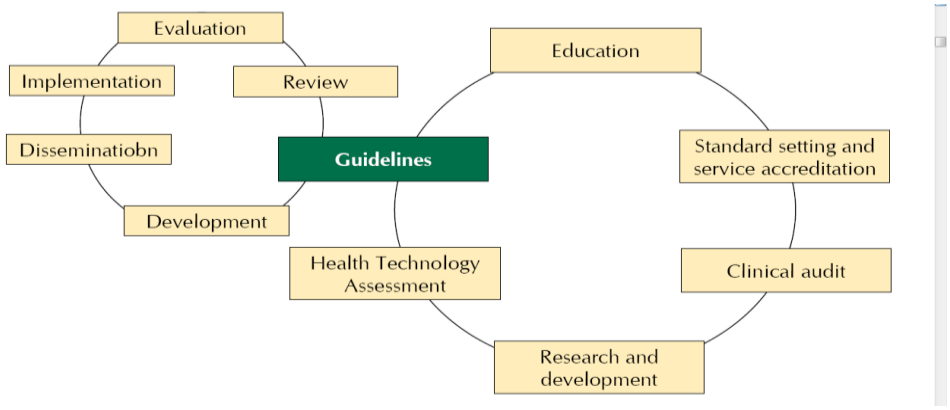
- ●topik yang dipilih harus memnuhi kebutuhan lokal
- ●oleh karena penyusunannya kompleks perlu beberapa rekomendasi alasan penyusunannya
- ●pelayanan yang aktual merupakan bukti diperlukannya penyusunan guideline / pedoman
- ●perlu nya up-to date sangat dirasakan dalam upaya peningkatan kualitas pelayanan
- ●tinjauan pustaka yang adekuat dari topik yang dipilih harus menjadi hal yang utama (khususnya keadaan lokal dimana pedoman tersebut akan di implementasikan)

RCOG, Clinical Governance Advice, No. 1d, February 2010

Table 1. Framework to aid decisions by policy makers and clinicians regarding introducing new or adapted Green-top clinical guidelines

Stage of guideline introduction	Activities
Selection of clinical topic	Consider: local burden of disease; availability of effective and efficient healthcare interventions; evidence of variation in practice; evidence of current suboptimal performance; receptivity and preparedness to change; availability of resources to implement changes
Availability of existing guideline	Consider the availability of existing guidelines (in this case Green-top guideline) and feasibility of its adaptation to local context. Remember that the resources required to develop a robust guideline *de novo* are substantial
Guideline adaptation	Consider using Rand methodology (formal consensus method with a local stakeholder group)[6]
	If no existing guideline available and resources permit, develop *de novo* using a published methodology (AGREE: Appraisal of Guidelines for Research and Evaluation in Europe)[3]
Dissemination and implementation	Seek resources for implementation: explore sources of funding through partnerships and stakeholders
	Identify available intervention options based on available resources and expertise
	Identify the most likely barriers to implementation across all levels of healthcare organisation (individual, team, organisational and environmental)
	Seek the 'best fit' between barriers and likely interventions
Consider resource implications of change	Policy makers and clinicians should be alert to the potential impact on different budgets of changes in practice resulting from adoption of guideline recommendations
	Suggest an economic impact assessment that includes dissemination of guideline, training, implementation including staff time and audit post introduction of guideline
Evaluate impact	Guideline introducers should design a means of evaluating the impact of guideline introduction, for example by means of clinical audit[10]
	Consider designating a specific centre to audit that the guideline is successfully in practice

Penyusunan guideline / pedoman, harus di anggap sebagai upaya meningkatkan kualitas pelayanan baik medik maupun klinik. Oleh karena itu dalam implementasinya kelak harus diupayakan proses audit yang berlangsung secara ongoing, hal mana terlihat pada bagan dibawah ini :



I.1. Sejarah pengembangan guideline / pedoman

- **Early guidelines**
  – Consensus methods
  – Literature reviews not always systematic
  – Not many systematic reviews
- **First evidence based guidelines**
  – Searching for all the evidence
  – Systematic reviews
  – Recommendations linked to evidence
- **Explicit evidence based guidelines**
  – Benefits, harms and costs are presented

I.2. Alasan menyusun guideline / pedoman :

- Quality improvement of health care
- Improving cost effective care
- Supporting evidence based care
- Contributing to more effective care

I.3. Beberapa Model Pendekatan Penyusunan Guideline

- Rule-Based Specification
- Augmented Decision Analysis
  Logic and Decision Table Techniques
- Multi-steps Guidelines
  Modeled as Hierarchical Set
  Guideline Tasks (*Task-Based Paradigm*)
  Combine Procedural & Declarative Representation

Dari penjelasan-penjelasan diatas , jelas terlihat bahwa perkembangan penyusunan guideline / pedoman sudah sangat maju. Yang mana akan kita anut , itu sangat tergantung dari apa yang akan kita capai dan bagaimana pola pengelolaan pasien-pasien kita :

- Hanya sekedar sembuh
- Sembuh dengan cara yang benar
- Sembuh dengan cara yang benar, tepat waktu, sesuai kebutuhan pasien, dengan biaya yang sesuai kebutuhan . Dengan kata lain kita akan mengelola pasien dengan cara :
  - **Doing the RIGHT thing RIGHT**
  - **To the RIGHT person**
  - **At the RIGHT time**
  - **In the RIGHT place**
  - **By the RIGHT persons, resources, procedures**
  - **With the RIGHT attitude/behavior, knowledge and skills**

Validasi penyusunan guideline / pedoman sangat ditentukan oleh tiga hal yang menjadi prinsip dasar, yaitu :

- Harus **evidens-based**(based on a structured literature search and critical appraisal of thepublished scientific literature)
- Rekomendasi harus**evidence-linked** (linked to the type and quality of evidence on whichthey are based using an accepted grading scheme)
- Rangkuman rekomendasi harus melibatkan **multidisciplinary** group (representing all stakeholderspotentially affected by the guideline).

II. DEFINISI

Definisi (wikipedia) :

*A **medical guideline** (also called a **clinical guideline**, **clinical protocol** or **clinical practice guideline**) is a document with the aim of guiding decisions and criteria regarding diagnosis, management, and treatment in specific areas of healthcare*.

Definisi lain :

- *" systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances', although they are also relevant to health service managers "*
- *Modern clinical guidelines briefly identify, summarize and evaluate the highest quality evidence and most current data about prevention, diagnosis, prognosis, therapy including dosage of medications, risk/benefit and cost-effectiveness. Then they define the most important questions related to clinical practice and identify all possible decision options and their outcomes. Some guidelines contain decision or computation algorithms to be followed. Thus, they integrate the identified decision points and respective courses of action to the clinical judgment and experience of practitioners*

***Clinical practice guidelines** are, "directions or principles presenting current or future rules of policy for the health care practitioner to assist him in patient care decisions regarding diagnosis, therapy, or related clinical circumstances.*
Clinical practice guidelines are only one of the multiple tools currently available to physicians and their healthcare teams.
Clinical practice guidelines are only guidelines that are meant to provide physicians with a professionally accepted approach of treating a particular condition at a certain point in time.

***Good clinical guidelines** change the process of healthcare ensure more efficient use of healthcare resources and improve outcomes for patients.*
For example, well-constructed and up-to-date clinical guidelines :

- *provide recommendations for the care of patients by healthcare professionals*
- *can be used to develop standards to assess the clinical practice of healthcare professionals*
- *can be used in the education and training of healthcare professionals*
- *can help patients to make informed decisions, and improve communication between the patient and healthcare professionals.*

III.KEBIJAKAN PENYUSUNAN PEDOMAN (GUIDELINE)

III.1. RASIONAL (WHY) :

III.1.1. Implementasi dan pemanfaatan " clinical guidelines "

- merupakan salah satu metode untuk meningkatkan dan memelihara kualitas pelayanan kepada pasien.
- menjamin konsistensi pelayanan kepada pasien
- mengurangi risiko dan kejadian yang tidak diharapkan selama perawatan/pelayanan berlangsung
- menjamin seluruh tim bekerja dalam koridor yang jelas, konsisten dan dalam alur yang benar

III.1.2. Proses penyusunan " clinical guideline " harus melibatkan seluruh klinisi dan sangat memperhatikan keterampilan, pengetahuan, pengalaman dari para klinisi tersebut

III.1.3. " Clinical Guideline " harus berpola yang dinamis yang gunanya agar dapat senantiasa dilakukanpenyesuaian secara periodik sesuai perkembangan ilmu, teknologi secara evidens dan penglaman dari para klinisi.

III.2. LINGKUP (WHO, WHERE AND WHEN):

III.2.1. Seluruh Staf Klinisi harus terlibat dalam penyusunannya, dimana saja dan kapan saja mereka bertugas

III.3. PRINSIP

III.3.1. Tujuan perencanaan penyusunannya harus di setujui bersama dan harus merefleksikan " best practice "

III.3.2. Harus disepakati bersama pula secara periodik secara reguler dilakukan review dan "up-to date"

III.3.3. Pemanfaatan yang efektif dari " guidelines " akan memberi hasil yang signifikan sebagai alat untuk meningkatkan kualitas pelayanan, karena :

- ada jaminan tim bekerja secara efektif karena ada panduan dalam bekerja
- senantiasa ada review secara sistematis dan implementasi dari " best clinical practice "
- ada kerangka kerja untuk perbaikan dan peningkatan kualitas pelayanan secara terus menerus dan ada umpan balik secara berkala
- meningkatkan kewaspadaan dan pengertian antar anggota tim kerja
- ada kerja sama seluruh tim (pasien, dokter, manajemen)

III.3.4. Penting diketahui dan dipahami bahwa " Clinical Guideline " ***are not mandatory*** and ***are not a substitution for clinical judgement***. Harus dipahami bahwa apabila dokter tidak mengikuti guidelines tersebut harus dijelaskan dan dicatat mengapa tidak diikuti, ini memberi pemahaman bahwa dokter memerlukan juga " judgement "

III.4.Definisi :

III.4.1. Clinical Guidelines : *Systematicallly developed statements which assist in decision making aboutappropriate healthcare for specific clinical conditions. (Field & Lohr 1992 / NICE)*

III.4.2. Clinical Protocol : *Detailed descriptions of the steps taken to deliver care or treatment to a patient*

III.4.3. Clinical Procedure : *Operational sub sections of protocols. Details procedures used at an individualpatient level which may apply in a number of protocols*

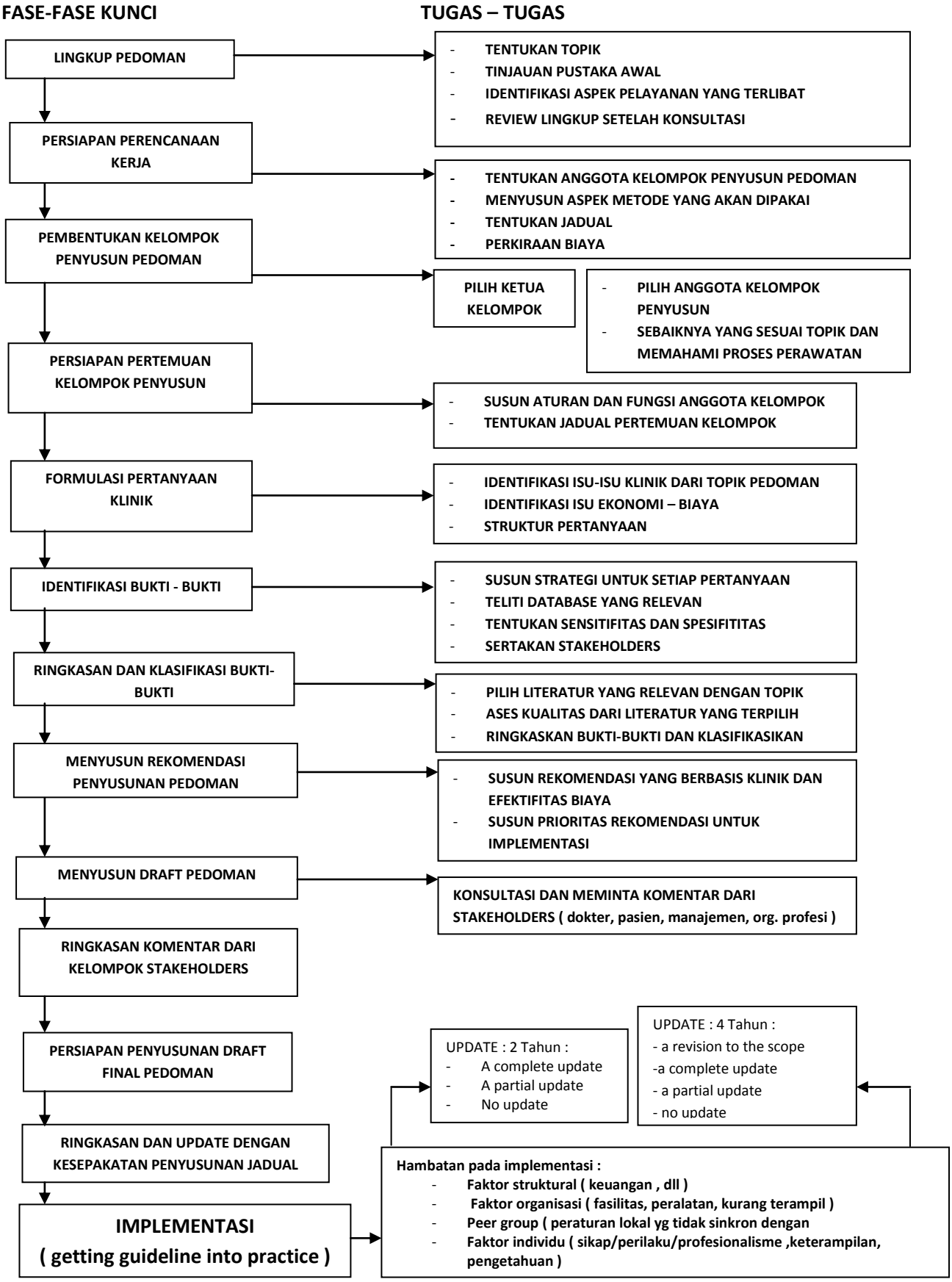
III.4.4. Integrated care pathways : *determines locally agreed, multidisciplinary practice, based on guidelines andevidence where available, for a specific patient/client group. It forms part or all of theclinical record, documents the care given and facilitates the evaluation ofcontinuous quality improvement.* (National Pathways Association)

III.5. The statement(s) of the Standard that is to be achieved (What)

Kecenderungan model pedoman (guideline) masa kini, berubah :

- Regional guideline from professional group To Nasional Guideline Programme
- From Informal Consensus To Evidens Based
- From Monodisiplinary To Multidisiplinary
- From Focus on development To Focus in implementation
- From Limited life expectancy To Living guideline (update)
- From Paper version To Internet
- From Guideline for clinician To patient version and patient involvement

IV.PROSES PENYUSUNAN PEDOMAN (GUIDELINE)



V. LANGKAH-LANGKAH PENYUSUNAN GUIDELINE / PEDOMAN

1. Topic Identification
2. Suitability screen
3. Form a multidisciplinary working party
4. Formulate clinical questions
5. Identify evidence (internal and external)
6. Evaluate evidence
7. Develop balance sheet
8. Develop recommendations
9. Implementation and dissemination
10. Update (evaluate and improve)

V.1.Topic Identification

- What are the areas where there is a gap between the evidence and current practice ?
  - Health Status
  - Patient/Provider Satisfaction
  - Cost/Utilization
- The topic is complex and there is debate
- Implementation is feasible

V.2.Suitability screen

Does the project have a driver/owner?

- Is there evidence of a gap?
- Can we measure the proposed change?
- Is there a suitable guideline that could be identified?
- Is there adequate literature to make an evidence based decision about practice?
- How much effort would it take to close the gap?
- Is there a reasonable likelihood that we could implement the change?

V.3.Multidisciplinary team

- Clinicians
  – Primary and secondary care
  – Allied health care workers
- Consumers, patient representatives
- Epidemiologists
- Information experts
- Health economists
- Health managers

V.4.Developing clinical questions

- Well developed questions form the basis of theevidence-based guideline structure
- Focuses guideline team on important issues &the most relevant evidence
- Requires a structured approach (5 parts)
  – **P**atients - Participant
  – **E**xposure/Interventions
  – **C**omparison
  – **O**utcomes
  – **T**ime

Framing a 5 part PECOT question

Participant	Exposure (Causes, Factor, Rx, Desease)	Comparison	Outcome	Time
How would I describe a group of patients like mine ?	Which main exposure am I considering ?	What is the main alternative to compare with the exposure ?	What can I hope accomplished ? What does this exposure affect ?	Over what time period is it reasonable to expect an affect ?

V.5.Identifying the evidens

- Comprehensive searching
- Avoid applying limitations toreducepublication bias
  – Non English studies included
  – Unpublished data sought
- Use PECOT framework to drive searching
- Also includes internal data

V.6.Evaluate the evidens

- Critical appraisal
  – Study quality checklists
- Develop evidence tables
  – Quantification
- Summarise outcomes

Scales of composite scores published

• Generally agreed that they are not usefulin differentiating high and low qualitystudies

• Better approach is to analyse theindividual components of study quality
  – Blinding
  – Concealment of allocation
  – Intention to treat analysis

V.7.Balance sheet

- Benefits, harms (and costs) considered
  – for the current situation and if the guideline was implemented
- Not a full economic analysis
  – Simple analysis of projected costs if apply guideline
- Delivers the 'value' of the Guideline
  – Resource utilisation
- The 'final chapter' of an explicit evidencebased guideline

V.8.Developing the reommendations and Algoritm

Probably the part of the guideline most often read

- Considers applicability:
  – for whom will the intervention do more harm than good ?
  – to whom should the recommended intervention be offered ?
- Each recommendation should advise a course of action, followed by an indication of the strength of the recommendation

Considered judgement form

For each clinical question:

- Volume of evidence
- Consistency of evidence
- Applicability of evidence
- Clinical impact of evidence

- Evidence Summary with levels/scores
- Recommendation with grade

V.9.Implementation and Dissemination

- Dissemination/Implementation
  – Increasingly electronic
- Target
  – Clinicians
  – Patients
  – Policy makers

V.10.Update (evaluate and improve)

- Update
  – Evaluation first (quality indicators?)

Step in guideline development :

	Sistematis	Pragmatis	Evidence
Top selection	✓	✓	
M-D working party	✓	✓	
Cilinical question	✓	✓	**?**
Literature search	✓		✓
Critical appraisal	✓		✓
Balance sheets	✓	✓	**?**
Recommendation	✓	✓	**?**
Implementation			✓
Update		✓	✓ **?**

Strongest Level of Evidence :

- Meta-analyses
- Systematic Reviews
- Randomized Controlled Trials (RCT)
- Controlled Clinical Trials (CCT)
- Clinical Trials (CT)
- Cohort studies / Patient control studies
- Other

Levels of Evidence :

- A1 --- Meta-analysis of randomised trials of A2-level, withconsistency between the independent studies
- A2 --- Double-blind randomised controlled clinical trial of good quality
- B ----- Other comparative studies (cohort, case-control-studies)
- C ----- Non-comparative study
- D ----- Expert opinion

Identifying and selecting the evidens :

- Systematic reviews
- Randomised Controlled Trials
- Observational studies
- Diagnostic studies
- Economic studies

Judging the level of evidens :

- Quantity, quality and consistency of evidens
- External validity (generalisability of studies)
- Directness of application to the target population for the guideline

Tantangan dalam metodologi penyusunan guideline / pedoman :

- Incorporating patient preferences
- Dealing with uncertainty
- Grading levels of evidence/recommendations
- Adaptation of guidelines
- Updating of guidelines
- Incorporating quality indicators
- Electronic clinical decision support

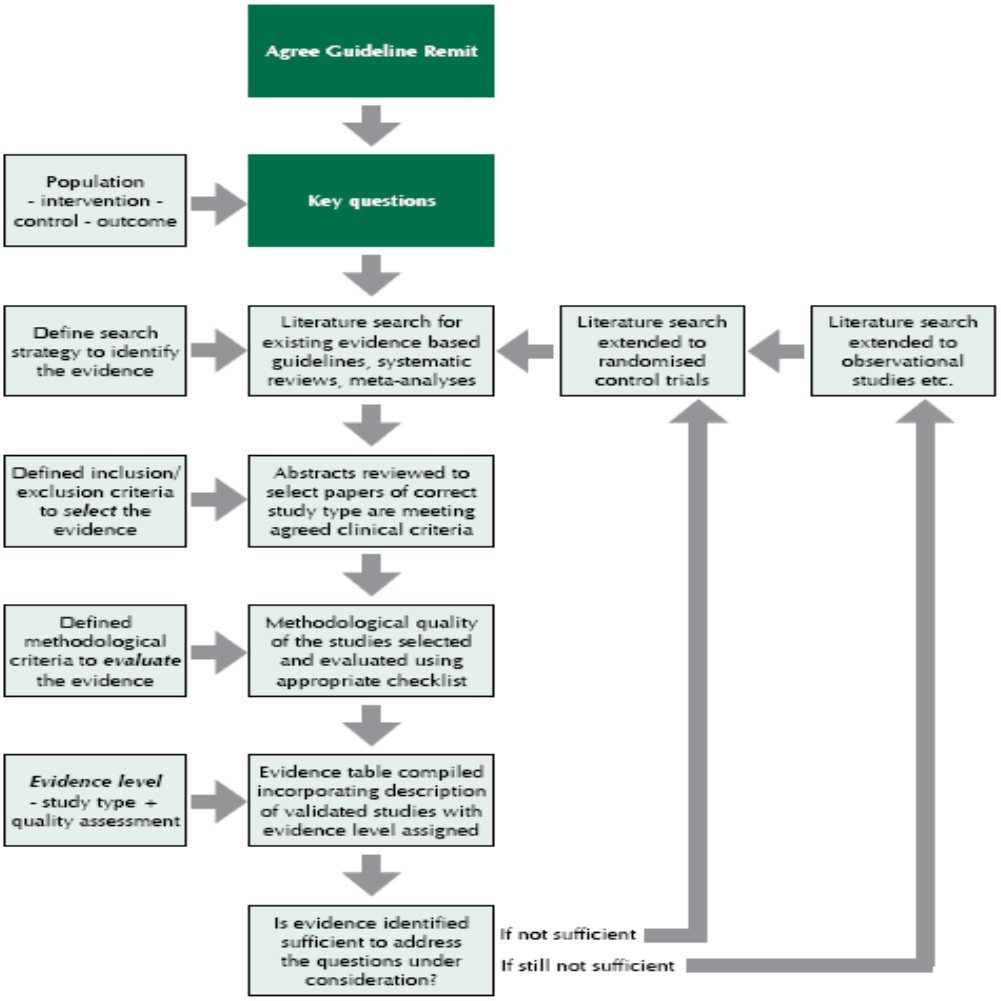
Kelompok Penyusun Guideline terdiri dari :

- clinical expertise (medical, surgical, nursing, allied health etc)
- other specialist expertise (health economics, social services, etc)
- practical understanding of problem faced in the delivery of care (manager, administrator)
- communication and team working skills
- critical appraisal skills

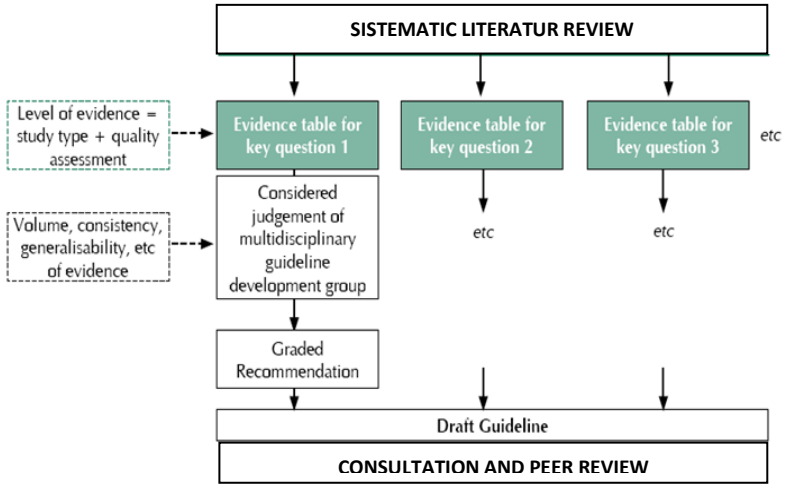
Contoh untuk menyusun Pedoman Ante Natal Care, perlu tim penyusun yang terdiri dari :

- 2 spesialis obstetri
- 2 bidan
- 2 dokter umum
- 1 spesialis anak
- 1 radiolog
- 1 wakil dari Confidential Enquiries into Maternal Death
- 2 wakil masyarakat
- 4 ahli dalam metode penyusunan (information scientist, systematic reviewer, health economist, adminstrator organisasi – manajemen rumah sakit)

Systematic literature review :



Forming guidelines recommendation:



Jadi secara singkat kerangka proses penyusunan guideline / pedoman dapat dilihat sebagai berikut:

1. Introduction

- 1.1 The aim of this document
- 1.2 Updating the document

2. Scoping the guideline

- 2.1 Purpose of the scope
- 2.2 Drafting the scope
- 2.3 The consultation process
- 2.4 Finalising the scope after consultation

3. Preparing the workplan

- 3.1 Structure of the workplan

4. Forming and running a Guideline Development Group

- 4.1 Forming the GDG
- 4.2 Identifying interests and conflict of interest
- 4.3 Identifying and meeting training needs
- 4.4 Running the GDG
- 4.5 Further reading

5. Developing clinical questions

- 5.1 Number of questions
- 5.2 Selecting questions from the scope
- 5.3 Formulating and structuring clinical questions
- 5.4 Further reading

6. Identifying the evidence

- 6.1 Database searching
- 6.2 Stakeholders' submissions of evidence
- 6.3 Additional requirements for service-delivery guidance
- 6.4 Further reading

7. Reviewing and grading the evidence

- 7.1 Selecting studies of relevance
- 7.2 Assessing the quality of studies
- 7.3 Summarising the evidence
- 7.4 Using the quality checklists to grade the evidence
- 7.5 Further reading

8. Incorporating health economics in guidelines and assessing resource impact

- 8.1 The role of health economists in guideline development
- 8.2 Modelling approaches
- 8.3 Economic evidence and guideline recommendations
- 8.4 Estimating the resource and cost impact of the recommendations
- 8.5 Further reading

9. Making group decisions and reaching consensus

- 9.1 Focus groups
- 9.2 Formal consensus methods
- 9.3 Further reading

10. Creating guideline recommendations

10.1 Translating the evidence into recommendations
10.2 Wording the guideline recommendations
10.3 Classifying the recommendations
10.4 Prioritising recommendations for implementation
10.5 Further reading

11. Developing audit criteria

11.1 Audit criteria in the guideline
11.2 Mapping recommendations for prioritisation
11.3 Drafting the audit table
11.4 Further reading

12. Writing the guideline

12.1 Principles for writing guidelines
12.2 Guideline structure
12.3 The guideline
12.4 Quick-reference guide
12.5 Information for the public

13. Updating guidelines and correcting errors

13.1 Statement of Intent
13.2 Further reading

VI. STRUKTUR GUIDELINE / PEDOMAN

Tiap Pedoman mempunyai struktur masing-masing, umumnya terdiri seperti dibawah ini :

1. Purpose and scope
2. Introduction and background
3. Identification and assesment of evidens
4. Definition
5. Prediction and prevention
6. How should be managed ?
7. How should be treated complication ?
8. Risk management
9. Support
10. Auditable standards
11. References

Lihat contoh guideline (lampiran)

- VBAC (RCOG, Green-top, Guideline No. 45, Februari 2007,)
- PLASENTA PREVIA – ACRETA (RCOG, GUIDELINE No. 27 , revised Oktober 2005)
- PREVENTION AND MANAGEMENT OF POSTPARTUM HAEMORRHAGE (Green-top Guideline No. 52 May 2009, Minor revision November 2009)

Demikianlah telah disusun panduan ringkas dan contoh struktur pedoman, semoga dapat bermanfaatbagi kita semua dalam upaya meningkatkan kualitas profesionalisme dalam berprofesi .

Jakarta, 19 Maret 2010

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CHAIRULSJAH SJAHRUDDIN