



GRADE

DECIDE

Frameworks for going from
evidence to decisions

Se una notte d'inverno un decisore...

Con DECIDE, dalle evidenze alle decisioni nel SSN

Roma, 1 marzo 2013

GRADE/DECIDE Frameworks for going from evidence to decisions

- Clinical recommendations
- Individual patient decisions
- Coverage decisions
- Health system and public health decisions

Confidence in decisions

“Strength of recommendation”

GRADE

The degree of confidence that the desirable effects of adherence to a recommendation outweigh the undesirable effects.

Desirable effects

- health benefits
- less burden
- savings



Undesirable effects

- harms
- more burden
- costs

RATING QUALITY OF EVIDENCE AND STRENGTH OF RECOMMENDATIONS

GRADE: going from evidence to recommendations

BMJ 2008;336;1049-1051

Categories of recommendations

GRADE

Although the degree of confidence is a continuum, we suggest using two categories: strong and weak.

- **Strong recommendation:** the panel is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects.
- **Weak recommendation:** the panel concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, but is not confident.

Recommend



Suggest



Implications of strong and weak recommendations for patients

- Strong - Most people in your situation would want the recommended course of action and only a small proportion would not
- Weak - The majority of people in your situation would want the recommended course of action, but many would not

Implications of strong and weak recommendations for clinicians

- Strong - Most patients should receive the recommended course of action
- Weak - Be prepared to help patients to make a decision that is consistent with their own values

Implications of strong and weak recommendations for policymakers

- Strong - The recommendation can be adapted as a policy in most situations
- Weak - There is a need for substantial debate and involvement of stakeholders

Determinants of strength of recommendation

GRADE

Factors	Impact on the strength of a recommendation
Balance between desirable and undesirable effects	Larger the difference between the desirable and undesirable effects, more likely a strong recommendation warranted. Narrower the gradient, more likely weak recommendation warranted
Certainty (quality) of the evidence	Higher the quality of evidence, more likely a strong recommendation warranted
Relative importance of the outcomes (“values and preferences”)	More variability in values and preferences, or more uncertainty in values and preferences, more likely weak recommendation warranted
Costs (resource use)	Higher the costs of an intervention – that is, the more resources consumed – less likely a strong recommendation warranted

Rome NHS Task Force Recommendations

1. Should women age 50 to 69 be screened for breast cancer with mammography?
2. Should women age 40 to 49 be screened for breast cancer with mammography?

Rome NHS Task Force Recommendations

Perspective: individual patient

Summary of Findings: Screening mammography in women 50 to 69

Outcomes (after 11.4 years)	Risk ratio (95% CI)	Estimated absolute effects per 10,000 women			Certainty of the effect
		No screening Per 10,000 women	Screening Per 10,000 women	Difference (95% CI)	
<i>Total deaths¹</i>	1.06 (0.96 to 1.18)	350	372	(14 fewer to 62 more per 10,000)	⊕⊕⊕○ Moderate
<i>Deaths from breast cancer¹</i>	0.79 (0.68 to 0.90)	64	50	14 fewer per 10,000 (21 to 6 fewer)	⊕⊕⊕○ Moderate
<i>Overdiagnosis of breast cancer²</i>	1.52 (1.46 to 1.58)		227	227 more per 10,000 (201 to 253 more)	⊕⊕○○ Low
<i>Recalled for at least one biopsy³</i>			1201	1201 more	⊕⊕○○ Low
<i>Bother</i>			Biannual screening mammography	Bother associated with biannual screening mammography	

* Consequences of overdiagnosis include surgery, radiotherapy and endocrine therapy of women who would not be diagnosed or treated for breast cancer without screening. Psycho-social consequences include anxiety, depression, labelling and impacts on insurance status.

Summary of Findings: Screening mammography in women 40 to 49

Outcomes (after 11.4 years)	Risk ratio (95% CI)	Estimated absolute effects per 10,000 women			Certainty of the effect
		No screening Per 10,000 women	Screening Per 10,000 women	Difference (95% CI)	
Total deaths	0.97 (0.91 to 1.04)	181	176	(16 fewer to 7 more per 10,000)	⊕⊕⊕○ Moderate
Deaths from breast cancer	0.85 (0.75 to 0.96)	32	27	5 fewer per 10,000 (8 to 1 fewer)	⊕⊕⊕○ Moderate
Overdiagnosis of breast cancer*2	1.52 (1.46 to 1.58)		69	69 more per 10,000 (61 to 77 more)	⊕⊕○○ Low
Recalled for at least one biopsy ³			595	595 more	⊕⊕○○ Low
Bother			Biannual screening mammography	Bother associated with biannual screening mammography	

* Consequences of overdiagnosis include surgery, radiotherapy and endocrine therapy of women who would not be diagnosed or treated for breast cancer without screening. Psycho-social consequences include anxiety, depression, labelling and impacts on insurance status.

Should women age 50 to 69 be screened for breast cancer with mammography?

Factors that can weaken the strength of a recommendation	Judgement	Explanation
Small net benefit	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Low quality of evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Uncertainty or differences in “values and preferences”	<input type="checkbox"/> Yes <input type="checkbox"/> No	
High costs	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Should women age 50 to 69 be screened for breast cancer with mammography?

	Strong	Weak		Weak	Strong
Your view of the balance of desirable and undesirable consequences of the intervention	Desirable consequences clearly outweigh undesirable consequences	Desirable consequences probably outweigh undesirable consequences	Consequences equally balanced or uncertain	Undesirable consequences probably outweigh desirable consequences	Undesirable consequences clearly outweigh desirable consequences
Recommendation	We recommend to screen	We suggest to screen	No specific recommendation	We suggest not to screen	We recommend not to screen
Vote					

Should women age 40 to 49 be screened for breast cancer with mammography?

Factors that can weaken the strength of a recommendation	Judgement	Explanation
Small net benefit	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Low quality of evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Uncertainty or differences in “values and preferences”	<input type="checkbox"/> Yes <input type="checkbox"/> No	
High costs	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Should women age 40 to 49 be screened for breast cancer with mammography?

	Strong	Weak		Weak	Strong
Your view of the balance of desirable and undesirable consequences of the intervention	Desirable consequences clearly outweigh undesirable consequences	Desirable consequences probably outweigh undesirable consequences	Consequences equally balanced or uncertain	Undesirable consequences probably outweigh desirable consequences	Undesirable consequences clearly outweigh desirable consequences
Recommendation	We recommend to screen	We suggest to screen	No specific recommendation	We suggest not to screen	We recommend not to screen
Vote					

Questions or comments about
clinical recommendations?

Should you, your wife, your sister or your mother (someone who is 50 years old) be screened for breast cancer with mammography every 2 years for 10 years?

Factors that can weaken the strength of a recommendation	Judgement	Explanation
Small net benefit	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Low quality of evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No	The quality of the evidence is moderate
Uncertainty or differences in “values and preferences”	<input type="checkbox"/> Yes <input type="checkbox"/> No	Variability in values is not relevant. How certain are you about your values (or those of your wife, sister or mother)?
High costs	<input type="checkbox"/> Yes <input type="checkbox"/> No	Only your (or her) out of pocket costs are relevant.

Should you, your wife, your sister or your mother (someone who is 50 years old) be screened for breast cancer with mammography every 2 years for 10 years?

	Yes	Probably	Don't know	Probably not	No
Your view of the balance of desirable and undesirable consequences of the intervention	Desirable consequences clearly outweigh undesirable consequences	Desirable consequences probably outweigh undesirable consequences	Consequences equally balanced or uncertain	Undesirable consequences probably outweigh desirable consequences	Undesirable consequences clearly outweigh desirable consequences
Decision	Yes	Consider using a decisions aid			No

Should health insurance pay for screening mammography for women age 40 to 49?

Factors that can weaken the strength of a recommendation	Judgement	Explanation
Small net benefit	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Low quality of evidence	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Uncertainty or differences in “values and preferences”	<input type="checkbox"/> Yes <input type="checkbox"/> No	Variability in “values and preferences” is not relevant
High costs	<input type="checkbox"/> Yes <input type="checkbox"/> No	Only costs (and savings) to the insurer are relevant.

Should health insurance pay for screening mammography for women age 40 to 49?

	Yes	Probably	Don't know	Probably not	No
Your view of the balance of desirable and undesirable consequences of the intervention (including costs)	Desirable consequences clearly outweigh undesirable consequences	Desirable consequences probably outweigh undesirable consequences	Consequences equally balanced or uncertain	Undesirable consequences probably outweigh desirable consequences	Undesirable consequences clearly outweigh desirable consequences

Coverage decision	Yes	<input type="checkbox"/> Cover with evidence development <input type="checkbox"/> Restricted coverage <input type="checkbox"/> Cover with price reduction	No
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Factors considered by the National Insurance Administration (NIA) in the 1990's

A review of NIA documents for applications in the 1990's found eight factors that possibly influenced decisions:

- The treatment effect
- Side effects
- Cost-effectiveness
- Total costs to the NIA
- Control of (inappropriate) use of the drug (and expenses)
- Administrative constraints
- Seriousness of the condition
- Equity

There was rarely an explicit written evaluation for any of the factors and it is not clear to what extent most of the factors were considered for most of the applications

Factors considered by the Australian Pharmaceutical Benefits Scheme 1994-2004

Statistically significant influences included:

- **Severity of disease**
 - a life threatening condition increased probability of approval by 38%
- **Clinical importance of the treatment effect**
 - increased probability of approval by 21% compared to the average
- **Cost-effectiveness**
 - increase of \$A10,000 from \$A46,400 average reduced probability of approval by 6%
- **Cost to government**
 - increase of \$A5 million from \$A17 million average reduced probability of approval by 3%
- **Interactions**
 - e.g. a life threatening condition and a clinically important treatment effect

Factors that can influence coverage decisions

- **Cost-effectiveness** -- the lower the cost per unit of benefit (e.g. QALY), the more likely it is that insurance should pay for something
 - **Seriousness** -- the more serious a problem is, the more likely it is that insurance should pay for something
 - **Benefits** -- the larger the benefit, the more likely it is that insurance should pay for something
 - **Adverse effects** -- the greater the risk of undesirable effects, the less likely it is that insurance should pay for something
 - **Resource use (costs)** -- the greater the cost, the less likely it is that insurance should pay for something
- **Quality of evidence** -- the lower the quality of evidence, the less likely it is that insurance should pay for something
- **Equity** -- the greater the reduction in inequities, the more likely it is that insurance should pay for something
- **Appropriate use** -- the more likely inappropriate use is to be a problem, the less likely it is that insurance should pay for something

DECIDE frameworks

- Clinical practice guidelines
 - Individual patient perspective
 - Health system perspective
- Coverage decisions
- Health system and public health decisions
- Diagnostic tests

Purpose

To help decision makers move from evidence to a decision

It is intended to

- Inform decision makers' judgements about the pros and cons of each option (intervention) that is considered
- Ensure that important factors that determine a decision (criteria) are considered
- Provide a concise summary of the best available research evidence to inform judgements about each criterion
- Help structure discussion and identify reasons for disagreements
- Make the basis for a decision transparent to those affected

Development of the frameworks

- Part of the DECIDE project
- An iterative process informed by
 - GRADE approach to clinical practice guidelines
 - Review of relevant literature
 - Brain storming
 - Feedback from stakeholders
 - Application of the framework to examples
 - Surveys of (e.g. of policymakers)
 - User testing
 - Trials

CRITERIA	JUDGEMENTS	RESEARCH EVIDENCE	ADDITIONAL INFORMATION
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- ***Criteria*** on which a decision may be based
- ***Judgements*** that the decision makers must make in relation to each criterion
- ***Research evidence*** to inform each of those judgements
- ***Additional information*** to inform or justify each judgement

Conclusions

- The ***balance of consequences*** of the option being considered in relation to the alternative (comparison)
- The ***decision***
- The ***justification*** for the decision, flowing from the judgements in relation to the criteria
- ***Key implementation considerations***

Should health insurance pay for screening mammography for women age 40 to 49?

	CRITERIA	JUDGEMENT	EVIDENCE	COMMENTS																															
SEVERITY	<p>Is the condition severe?</p> <p>No <input type="checkbox"/> Moderately <input type="checkbox"/> Yes* <input type="checkbox"/></p> <p><i>te.g. life threatening or disabling</i></p>		The cumulative risk of breast cancer for women age 40 to 49 without screening is 13 per 1,000 women. The risk of dying from breast cancer without screening is 3 per 1,000.																																
BENEFITS & HARMS	<p>Are the benefits large?</p> <p>No <input type="checkbox"/> Moderately <input type="checkbox"/> Yes <input type="checkbox"/></p>		<p><i>Summary of findings: Screening mammography for women age 40 to 49</i></p> <table border="1"> <thead> <tr> <th>Outcomes (after 11.4 years)</th> <th>No screening (per 10,000)^a</th> <th>Screening (per 10,000)</th> <th>Difference (per 10,000) (95% CI)</th> <th>Certainty of the evidence (GRADE)</th> </tr> </thead> <tbody> <tr> <td>Total deaths</td> <td>181</td> <td>176</td> <td>(16 fewer to 7 more)</td> <td>⊕⊕⊕○ Moderate</td> </tr> <tr> <td>Deaths from breast cancer</td> <td>32</td> <td>27</td> <td>5 fewer (8 to 1 fewer)</td> <td>⊕⊕⊕○ Moderate</td> </tr> <tr> <td>Overdiagnosis of breast cancer^{b,c}</td> <td></td> <td>69</td> <td>69 more (61 to 77 more)</td> <td>⊕⊕○○ Low</td> </tr> <tr> <td>Recalled for at least one biopsy³</td> <td></td> <td>595</td> <td>595 more</td> <td>⊕⊕○○ Low</td> </tr> <tr> <td>Bother</td> <td></td> <td>Biannual screening mammography</td> <td>Bother associated with biannual screening mammography</td> <td></td> </tr> </tbody> </table>		Outcomes (after 11.4 years)	No screening (per 10,000) ^a	Screening (per 10,000)	Difference (per 10,000) (95% CI)	Certainty of the evidence (GRADE)	Total deaths	181	176	(16 fewer to 7 more)	⊕⊕⊕○ Moderate	Deaths from breast cancer	32	27	5 fewer (8 to 1 fewer)	⊕⊕⊕○ Moderate	Overdiagnosis of breast cancer ^{b,c}		69	69 more (61 to 77 more)	⊕⊕○○ Low	Recalled for at least one biopsy ³		595	595 more	⊕⊕○○ Low	Bother		Biannual screening mammography	Bother associated with biannual screening mammography		
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<p>Are the harms small?</p> <p>No <input type="checkbox"/> Moderately <input type="checkbox"/> Yes <input type="checkbox"/></p>																																			
<p>What is the overall certainty of these anticipated effects?</p> <p>Very low <input type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> High <input type="checkbox"/></p>																																			
VALUES	<p>Would well-informed patients feel that the benefits outweigh the harms?</p> <p>No <input type="checkbox"/> Majority would not <input type="checkbox"/> Uncertain <input type="checkbox"/> Majority would <input type="checkbox"/> Yes <input type="checkbox"/></p>		None available																																

Should health insurance pay for screening mammography for women age 40 to 49?

	CRITERIA	JUDGEMENT	EVIDENCE	COMMENTS
RESOURCE USE	Is the total cost (impact on the budget) low?	No <input type="checkbox"/> Probably not <input type="checkbox"/> Uncertain <input type="checkbox"/> Probably <input type="checkbox"/> Yes <input type="checkbox"/>	The median Medicare reimbursement for a mammogram is \$108. For 300,000 women screened biennially the cost would be around \$16,000,000 annually for mammograms. The full cost (including follow-up investigations and costs and savings from treatment) is not available.	
	Is the incremental cost small relative to the net benefits?	No <input type="checkbox"/> Probably not <input type="checkbox"/> Uncertain <input type="checkbox"/> Probably <input type="checkbox"/> Yes <input checked="" type="checkbox"/>	The cost per QALY is \$106,000 for screening every 3 to 4 years and \$223,000 for screening every 2 years. The cost per QALY is less for some high risk groups. For example, biennial mammography costs less than \$50 000 per QALY gained for women aged 40 to 49 years with category 3 or 4 breast density and either a previous breast biopsy or a family history of breast cancer.	
EQUITY	What would be the impact on health inequities?	Increased <input type="checkbox"/> Probably increased <input type="checkbox"/> Uncertain <input type="checkbox"/> Probably reduced <input type="checkbox"/> Reduced <input type="checkbox"/>	None available	Not covering mammograms might increase inequities for low-income women.
APPROPRIATE USE	Is inappropriate use likely to be an important problem?	No <input type="checkbox"/> Probably not <input type="checkbox"/> Uncertain <input type="checkbox"/> Probably <input type="checkbox"/> Yes <input type="checkbox"/>	None available	

Should health insurance pay for screening mammography for women age 40 to 49?

Balance of consequences	<i>Undesirable consequences clearly outweigh desirable consequences</i>	<i>Undesirable consequences probably outweigh desirable consequences</i>	<i>Desirable/undesirable consequences closely balanced or uncertain</i>	<i>Desirable consequences probably outweigh undesirable consequences</i>	<i>Desirable consequences clearly outweigh undesirable consequences</i>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Coverage decision	<i>Do not cover</i>		<input type="checkbox"/> <i>Cover with evidence development</i> <input type="checkbox"/> <i>Restricted coverage</i> <input type="checkbox"/> <i>Cover with price reduction</i>		<i>Implement the option</i>
	<input type="checkbox"/>				<input type="checkbox"/>
Restrictions					
Justification					
Implementation					

Questions or comments about
coverage decisions?

What about public health and health system decisions?

- **Delivery arrangements** (e.g. stroke units, use of lay health workers)
- **Financial arrangements** (e.g. user fees, pay for performance)
- **Governance arrangements** (e.g. decentralisation, mergers)
- **Implementation strategies** (e.g. continuing professional education, mass media campaigns)

What criteria should be used for public health and health system decisions?

- **How serious the problem is**
 - the more serious a problem is, the more likely it is that a policy or programme that addresses the problem will be a priority (e.g. diseases that are fatal or disabling are likely to be a higher priority than diseases that only cause minor distress)
- **The number of people that are affected by the problem**
 - the more people who are affected, the more likely it is that a policy or programme that addresses the problem will be a priority

What criteria should be used for public health and health system decisions?

- **Benefits**
 - the larger the benefit, the more likely it is that a policy or programme will be a priority
- **Adverse effects**
 - the greater the risk of undesirable effects, the less likely it is that a policy or programme will be a priority
- **Resource use (costs)**
 - the greater the cost, the less likely it is that a policy or programme will be a priority
- **Cost-effectiveness**
 - the lower the cost per unit of benefit, the more likely it is that a policy or programme will be a priority

What criteria should be used for public health and health system decisions?

- **Impacts on equity**
 - policies or programmes that reduce inequities may be more of a priority than ones that do not (or ones that increase inequities)
- **Feasibility (easy to implement)**
 - the less feasible (capable of being accomplished or brought about) a policy or programme is, the less likely it is that it will be a priority (i.e. the more barriers there are that would be difficult to overcome)
- **Acceptability**
 - the less acceptable a policy or programme is to key stakeholders, the less likely it is to be a priority. Unacceptability may be due to some stakeholders
 - attaching more value (relative importance) to the undesirable consequences than to the desirable consequences of a policy or programme (either because of how they might be affected personally or because of their perceptions of the relative importance of consequences for others)
 - moral approval or disapproval (i.e. in relationship to ethical principles such as autonomy, nonmaleficence, beneficence or justice)

Should patients with acute stroke be treated in stroke units, stroke units with early discharge or general medical wards?

Problem

- The organisation of treatment and rehabilitation for acute stroke patients can affect patient outcomes and costs.

Options

- **Stroke units** are an option where care is provided by nurses, doctors and therapists who specialise in looking after stroke patients and work as a co-ordinated team in a discrete ward caring exclusively for stroke patients.
- **Early supported discharge** is an option that aims to get patients back to an active life as quickly as possible. It includes acute treatment in a stroke unit followed by early discharge and follow-up by a multidisciplinary team, coordination of care with primary healthcare providers, and patients living so far as possible at home.

Comparison

- Care in an acute medical or neurology ward (general medical wards) without routine multidisciplinary input

Should patients with acute stroke be treated in stroke units, stroke units with early discharge or general medical wards?

	CRITERIA	JUDGEMENTS	RESEARCH EVIDENCE	ADDITIONAL INFORMATION
PROBLEM	Is the problem a priority?	No <input type="checkbox"/> Probably no <input type="checkbox"/> Uncertain <input type="checkbox"/> Probably yes <input type="checkbox"/> Yes <input checked="" type="checkbox"/>	Acute stroke patients cared for in general medical wards have a high risk of death (27%) and dependency (24%). 15% require institutional care following discharge. [1]	
	Are a large number of people affected?	No <input type="checkbox"/> Probably no <input type="checkbox"/> Uncertain <input type="checkbox"/> Probably yes <input type="checkbox"/> Yes <input checked="" type="checkbox"/>	15,000 strokes per year in Norway. 3rd most common cause of death. Most common cause of serious disability. [2]	

Should patients with acute stroke be treated in stroke units, stroke units with early discharge or general medical wards?

CRITERIA	JUDGEMENTS	RESEARCH EVIDENCE	ADDITIONAL INFORMATION																								
<p>Are the desirable anticipated effects large?</p>	<p>No <input type="checkbox"/> Probably no <input type="checkbox"/> Uncertain <input type="checkbox"/> Probably yes <input type="checkbox"/> Yes <input checked="" type="checkbox"/></p>	<p>Summary of findings: Stroke units vs general medical wards [1]</p> <table border="1"> <thead> <tr> <th>Outcome (1-12 months)</th> <th>General wards (per 1000)*</th> <th>Stroke units (per 1000)</th> <th>Difference (per 1000) (95% CI)</th> <th>Relative effect (RR) (95% CI)</th> <th>Certainty of the evidence (GRADE)</th> </tr> </thead> <tbody> <tr> <td>Death</td> <td>265</td> <td>236</td> <td>29 fewer (from 3 to 53 fewer)</td> <td>RR 0.89 (0.80 to 0.99)</td> <td>⊕⊕⊕○ Moderate</td> </tr> <tr> <td>Dependency</td> <td>235</td> <td>223</td> <td>12 fewer (from 52 fewer to 40 more)</td> <td>RR 0.95 (0.78 to 1.17)</td> <td>⊕⊕⊕○ Moderate</td> </tr> <tr> <td>Institutionalized</td> <td>148</td> <td>117</td> <td>31 fewer (from 58 fewer to 4 more)</td> <td>RR 0.79 (0.61 to 1.03)</td> <td>⊕⊕○○ Low</td> </tr> </tbody> </table>	Outcome (1-12 months)	General wards (per 1000)*	Stroke units (per 1000)	Difference (per 1000) (95% CI)	Relative effect (RR) (95% CI)	Certainty of the evidence (GRADE)	Death	265	236	29 fewer (from 3 to 53 fewer)	RR 0.89 (0.80 to 0.99)	⊕⊕⊕○ Moderate	Dependency	235	223	12 fewer (from 52 fewer to 40 more)	RR 0.95 (0.78 to 1.17)	⊕⊕⊕○ Moderate	Institutionalized	148	117	31 fewer (from 58 fewer to 4 more)	RR 0.79 (0.61 to 1.03)	⊕⊕○○ Low	
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<p>What is the overall certainty of this evidence?</p>	<p>No included studies <input type="checkbox"/> Very low <input type="checkbox"/> Low <input type="checkbox"/> Moderate <input checked="" type="checkbox"/> High <input type="checkbox"/></p>	<p>No adverse effects of stroke units were reported. *Based on findings in the systematic review. Current risks in Norway are uncertain. Link to detailed evidence profile</p> <p>Summary of findings: Early supported discharge vs ordinary discharge [3, 4]</p> <table border="1"> <thead> <tr> <th>Outcome (1-12 months)</th> <th>Ordinary discharge (per 1000)</th> <th>Early Supported discharge (per 1000)</th> <th>Difference (per 1000) (95% CI)</th> <th>Relative effect (RR) (95% CI)</th> <th>Certainty of the evidence (GRADE)</th> </tr> </thead> <tbody> <tr> <td>Death</td> <td>236</td> <td>215</td> <td>21 fewer (from 106 fewer to 120 more)</td> <td>RR 0.91 (0.55 to 1.51)</td> <td>⊕⊕○○ Low</td> </tr> <tr> <td>Dependency</td> <td>223</td> <td>185</td> <td>38 fewer (from 71 fewer to 2 more)</td> <td>RR 0.83 (0.68 to 1.01)</td> <td>⊕⊕⊕○ Moderate</td> </tr> <tr> <td>Institutionalized</td> <td>117</td> <td>85</td> <td>32 fewer (from 62 fewer to 15 more)</td> <td>RR 0.73 (0.47 to 1.13)</td> <td>⊕⊕⊕○ Moderate</td> </tr> </tbody> </table> <p>No adverse effects of stroke units with early discharge were reported. *Based on findings in the systematic review of stroke units. Link to detailed evidence profile</p>	Outcome (1-12 months)	Ordinary discharge (per 1000)	Early Supported discharge (per 1000)	Difference (per 1000) (95% CI)	Relative effect (RR) (95% CI)	Certainty of the evidence (GRADE)	Death	236	215	21 fewer (from 106 fewer to 120 more)	RR 0.91 (0.55 to 1.51)	⊕⊕○○ Low	Dependency	223	185	38 fewer (from 71 fewer to 2 more)	RR 0.83 (0.68 to 1.01)	⊕⊕⊕○ Moderate	Institutionalized	117	85	32 fewer (from 62 fewer to 15 more)	RR 0.73 (0.47 to 1.13)	⊕⊕⊕○ Moderate	
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Death	236	215	21 fewer (from 106 fewer to 120 more)	RR 0.91 (0.55 to 1.51)	⊕⊕○○ Low																						
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Institutionalized	117	85	32 fewer (from 62 fewer to 15 more)	RR 0.73 (0.47 to 1.13)	⊕⊕⊕○ Moderate																						

BENEFITS & HARMS OF THE OPTIONS

Should patients with acute stroke be treated in stroke units, stroke units with early discharge or general medical wards?

	CRITERIA	JUDGEMENTS	RESEARCH EVIDENCE	ADDITIONAL INFORMATION																								
VALUES	Are the desirable effects large relative to undesirable effects?	No <input type="checkbox"/> Probably no <input type="checkbox"/> Uncertain <input type="checkbox"/> Probably yes <input type="checkbox"/> Yes <input checked="" type="checkbox"/>	<p>Quality of life (utility) values for stroke patients:*</p> <table border="1"> <thead> <tr> <th>Type of stroke</th> <th>Ara 2008 [5]</th> <th>Slot 2009 [6]</th> </tr> </thead> <tbody> <tr> <td>Mild</td> <td>0.78</td> <td>0.93</td> </tr> <tr> <td>Moderate</td> <td>0.61</td> <td>0.78</td> </tr> <tr> <td>Serious</td> <td>0.47</td> <td>0.18</td> </tr> </tbody> </table> <p>*Average values from two studies where 0.00 represents death and 1.00 represents perfect health</p>	Type of stroke	Ara 2008 [5]	Slot 2009 [6]	Mild	0.78	0.93	Moderate	0.61	0.78	Serious	0.47	0.18													
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Moderate	0.61	0.78																										
Serious	0.47	0.18																										
RESOURCE USE	Are the resources required small?	No <input type="checkbox"/> Probably no <input type="checkbox"/> Uncertain <input type="checkbox"/> Probably yes <input type="checkbox"/> Yes <input checked="" type="checkbox"/>	<table border="1"> <thead> <tr> <th rowspan="2">Strategy</th> <th colspan="2">Total cost per year*</th> <th colspan="2">Cost per patient [2]</th> </tr> <tr> <th>NOK</th> <th>Difference</th> <th>NOK</th> <th>Difference</th> </tr> </thead> <tbody> <tr> <td>General ward)</td> <td>19 billion</td> <td></td> <td>1 270 000</td> <td></td> </tr> <tr> <td>Stroke unit</td> <td>14 billion</td> <td>-5 billion</td> <td>933 000</td> <td>-337 000</td> </tr> <tr> <td>Stroke unit with early discharge</td> <td>12 billion</td> <td>-2 billion</td> <td>806 000</td> <td>-127 000</td> </tr> </tbody> </table> <p>*Based on 15000 stroke patients per year</p>	Strategy	Total cost per year*		Cost per patient [2]		NOK	Difference	NOK	Difference	General ward)	19 billion		1 270 000		Stroke unit	14 billion	-5 billion	933 000	-337 000	Stroke unit with early discharge	12 billion	-2 billion	806 000	-127 000	
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	Is the incremental cost small relative to the net benefits?	No <input type="checkbox"/> Probably no <input type="checkbox"/> Uncertain <input type="checkbox"/> Probably yes <input type="checkbox"/> Yes <input checked="" type="checkbox"/>	Cost per QALY = -1 million NOK (i.e. a savings of 1 million kroner with each quality adjusted life year saved) for stroke units compared to general wards and -734 000 NOK for stroke units with early discharge compared to stroke units. Sensitivity analyses showed that care in stroke units followed by early supported discharge is the most cost-effective strategy in 88% of the simulations, while care in ordinary stroke units was the most cost-effective in 12% in urban hospitals. [2]																									

Should patients with acute stroke be treated in stroke units, stroke units with early discharge or general medical wards?

	CRITERIA	JUDGEMENTS	RESEARCH EVIDENCE	ADDITIONAL INFORMATION										
EQUITY	What would be the impact on health inequities?	<table> <tr> <td>No</td> <td>Probably no</td> <td>Uncertain</td> <td>Probably yes</td> <td>Yes</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input checked="" type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>	No	Probably no	Uncertain	Probably yes	Yes	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Might increase inequities between rural and urban areas
No	Probably no	Uncertain	Probably yes	Yes										
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>										
ACCEPTABILITY	Is the option acceptable to key stakeholders?	<table> <tr> <td>No</td> <td>Probably no</td> <td>Uncertain</td> <td>Probably yes</td> <td>Yes</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input checked="" type="checkbox"/></td> </tr> </table>	No	Probably no	Uncertain	Probably yes	Yes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	From a hospital perspective stroke units may cost more (8000 NOK per admission) [2], while communities (not hospitals) benefit from the savings (which occur after discharge from the hospital)	
No	Probably no	Uncertain	Probably yes	Yes										
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>										
FEASIBILITY	Is the option feasible to implement?	<table> <tr> <td>No</td> <td>Probably no</td> <td>Uncertain</td> <td>Probably yes</td> <td>Yes</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input checked="" type="checkbox"/></td> </tr> </table>	No	Probably no	Uncertain	Probably yes	Yes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		<p>There are stroke units in Norway</p> <p>It requires space, an initial investment, and a leader to establish a unit</p> <p>It might not be clear whose responsibility it is to establish a unit</p>
No	Probably no	Uncertain	Probably yes	Yes										
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>										

Should patients with acute stroke be treated in stroke units, stroke units with early discharge or general medical wards?

Balance of consequences	Undesirable consequences <i>clearly outweigh</i> desirable consequences in most settings <input type="checkbox"/>	Undesirable consequences <i>probably outweigh</i> desirable consequences in most settings <input type="checkbox"/>	The balance between desirable and undesirable consequences <i>is uncertain</i> <input type="checkbox"/>	Desirable consequences <i>probably outweigh</i> undesirable consequences in most settings <input type="checkbox"/>	Desirable consequences <i>clearly outweigh</i> undesirable consequences in most settings <input checked="" type="checkbox"/>
Decision	Do not implement the option <input type="checkbox"/>	Postpone a decision <input type="checkbox"/>	Do a pilot study <input type="checkbox"/>	Implement with an impact evaluation <input type="checkbox"/>	Implement the option <input checked="" type="checkbox"/>
<p>We conclude that patients with acute stroke should be cared for in stroke units with early discharge. All urban hospitals must, therefore, have a stroke unit and communities must have arrangements for early discharge from those units.</p>					
Justification	Stroke units with early supported discharge probably will reduce mortality and dependency and save money. The cost-effectiveness analysis suggests that this conclusion is robust.				
Implementation considerations	Implementing this option requires establishing responsibility and accountability for establishing and maintaining stroke units and early discharge, and aligning financial incentives for hospitals and communities; e.g. by compensating hospitals for the costs of establishing and maintaining a stroke unit.				
Monitoring	The following indicators should be used to monitor the implementation of this decision and inform decisions about the need for further action: establishment of stroke units at all urban hospitals, whether stroke patients are managed in stroke units and discharged early, survival, dependency, institutionalization, hospital costs and costs of community-based health and social services.				
Evaluation	Although further evaluation could increase the certainty of the anticipated effects, this is not likely to change the decision. Therefore evaluation of the impacts of this decision is not considered a priority.				

Questions or comments?