

**Scientific basis for clinical indicators:
concepts, terminology, public
accountability**

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**Scientific basis for clinical
indicators**

Key messages:

- Monitoring health care quality is impossible without the use of clinical indicators
- they create the basis for quality improvement, prioritization and transparency in the health care system
- It is imperative that clinical indicators are meaningful, scientifically sound, generalizable and interpretable
- To achieve this, clinical indicators must be developed, tested and implemented with scientific rigor

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DEFINITIONS

Clinical indicators are:

- Measures that assesses a particular health care process or outcome
- Quantitative measures that can be used to monitor and evaluate the quality of important governance, management, clinical and support functions that affect patient outcomes.
- measurement tools or flags that are used as guides to monitor, evaluate and improve the quality of patient care, clinical support services and organizational functions that affect patient outcomes.

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**Indicator measurement have
different purposes:**

- Document the quality of care
- Make comparisons (benchmarking)
- Make judgments and priorities
- Support accountability
- Support quality improvement
- Provide transparency

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CHARACTERISTICS

The use of indicators should follow scientific principles.

They should be:

- Based on agreed definitions
- Specific and sensitive
- Valid and reliable
- Have discrimination ability
- Relate to identifiable events (relevant to clinical practice)
- Permit useful comparisons
- Be evidence based

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Development of clinical indicators I

Planning phase	<p>1. Choose the clinical area to evaluate:</p> <ul style="list-style-type: none"> • Importance (high volume, cost, variation) • Opportunities for clinical intervention <p>2. Organize the measurement team</p> <ul style="list-style-type: none"> • Select group participants • Organize and divide tasks
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Development of clinical indicators II

Development phase	3. Provide an overview of existing evidence and practice <ul style="list-style-type: none"> • Presentation of documentation and knowledge from the scientific literature for potential indicators • Consensus about existing knowledge and practice
	4. Select clinical indicators and standards <ul style="list-style-type: none"> • Process indicators • Outcome indicators • Identify prognostic factors (risk adjustment) • Consensus and rating procedures

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Development of clinical indicators III

Development phase	5. Design measure specification <ul style="list-style-type: none"> • Define indicators and standards • Identify target population • Inclusion and exclusion criteria • Risk adjustment strategy • Identify data sources • Describe data collection procedures • Develop a analytical plan
	6. Perform pilot testing

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Development of clinical indicators IV

Implementation phase	7. Data collection <ul style="list-style-type: none"> • Data from medical records, questionnaires, clinical databases and registers
	9. Provide data analysis
	10. Interpretation of findings <ol style="list-style-type: none"> a. Analysis, evaluation, interpretation b. Professional discussions of data results
Monitoring phase	11. Implementation of improvements
Revision phase	12. Continuous evaluation of performance
	13. Revision of clinical indicators

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Scientific basis for clinical indicators

PROVIDE AN OVERVIEW OF EXISTING EVIDENCE AND PRACTICE

- Clinical indicators should be based on research evidence rather than on expert opinions or clinical experience alone
- The level of evidence should be transparent before prioritization of indicators
- this makes it possible for the measurement team to take into account the strength of evidence when they prioritize between clinical indicators in the selection process

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Categories of evidence

Ia – Evidence from meta-analysis of randomized controlled trials	A
Ib – Evidence from at least one randomized controlled trial	
IIa – Evidence from at least one controlled study without randomization	B
IIb – Evidence from at least one other type of quasi-experimental study	
III – Evidence from descriptive studies, such as comparative studies, correlation studies and case-control studies	C
IV – Evidence from expert committee reports or opinions or clinical experience of respected authorities, or both	D

1. Eccles M. et al, *BMJ* 1998;316:1232-1235
2. West S et al, *AHRQ No. 02-Eo 16, 2002*

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Indicator concept	Indicator	Type	Standard	Time	Evidence
Organization of treatment (stroke)	Proportion of patients treated/rehabilitated in stroke units	Process	More than 90% of patients with acute stroke should be treated and rehabilitated in a stroke unit	<24 hours after admission	A

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SELECT INDICATORS AND STANDARDS Process or outcome indicators? I

- **Process** denotes what is actually done in giving and receiving care
- **Outcome** denotes the effects of care on the health status of patients and populations
- A good process increases the likelihood of a good outcome
- The process of care do not signify quality until their relationship to desirable outcomes have been established

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SELECT INDICATORS AND STANDARDS Process or outcome indicators? II

- It is necessary to have established a relationship between a particular process and outcome
- The scientific literature can establish the linkage between process and outcome
- Clinical indicators should be evidence based to confirm this linkage

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Examples of indicators related to structure, process and outcome

- **Structure**
 1. Proportion of specialists compared to other doctors.
 2. Access to specific technologies (e.g. MR scan).
 3. Access of specific units (e.g. Stroke units).
 4. Clinical guidelines revised every 2nd year.
 5. Physiotherapists associated to specific units.
- **Process**
 1. Proportion of patients with diabetes given regular foot care.
 2. Proportion of patients with MI who received thrombolyses.
 3. Proportion of patients assessed by a doctor within 24 hours of referral.
 4. Door to needle time for patients with MI.
 5. Proportion of patients treated according to clinical guidelines.
- **Outcome**
 - **Intermediate**
 1. HbA1C for diabetics.
 2. Lipid profile for patients with hyperlipidemia.
 3. Blood pressure for hypertensive patients.
 - **End result (should be specified for diseases)**
 1. Mortality.
 2. Morbidity.
 3. Functional status.
 4. Health status measurement.
 5. Work status.
 6. Quality of life.
 7. Patient satisfaction.

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PROCESS AND OUTCOME INDICATORS?

Process data are useful when:

- The goal is improving delivery of care
- Explaining why specific providers achieve particular outcomes
- Short time frames are necessary
- The processes of interest affect long-term outcomes
- Performance of low volume providers is of interest
- Tools to adjust or stratify compared in a competitive/coercive situation

Quality Healthcare, 1998

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PROCESS AND OUTCOME INDICATORS? OUTCOME data are useful when:

- Areas for quality improvement should be identified
- If specific processes are known to yield specific gains in outcomes
- Long time frames are possible
- Performance of whole systems should be studied
- High volume cases are available

Palmer, Int J Quality Healthcare, 1998

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Examples of outcome indicators

Indicator concept	Indicator	Type	Standard	Time	Evidence	Prognostic factors
Blood glucose control	Proportion of diabetics	Intermediate outcome	90% or more should have a HbA1C < 7.0 mmol/l	Every third month	A	
Mortality (stroke)	30 days and 3, 6, 12 months mortality	Outcome	30 days mortality < 20%	30 days after stroke	B	Age, sex, previous stroke, social status

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RISK ADJUSTMENT Process indicators

- For some process indicators risk adjustment plays a smaller role
- For other process measures risk adjustment may reveal that patient factors are influencing a measure
- The more closely an indicator measures the actual process of care delivered rather than patient adherence or other factors the less risk adjustment will be needed

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RISK ADJUSTMENT Outcome indicators

- Multiple factors contribute to health care outcomes
- The adequacy of controls for differences in case mix and other covariates are important when using outcome indicators
- Prognostic factors should be identified from the scientific literature

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- **The patient**
 - Demographic factors (age, sex, height)
 - Lifestyle factors (smoking, alcohol, weight, diet, physical exercise)
 - Psychosocial factors (social status, education)
 - Compliance
 - +
 - **The illness**
 - Severity, prognosis
 - Comorbidity
 - +
 - **The treatment (prevention, diagnostics, care, rehabilitation, therapy and control)**
 - Competence
 - Technical equipment
 - Evidence based clinical practice
 - Efficacy, accuracy
 - +
 - **The organization**
 - Use of clinical guidelines
 - Cooperation
 - Delay
- == OUTCOME

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STANDARD SETTING

- A standard of care embodies acceptability of a performance or outcome rate
- If a desired attribute of care falls below the standard or an undesired attribute of care rises above this level, further evaluation or action is triggered
- The strength of evidence for both the clinical indicator and the related standard should ideally be evidence
- BUT: It is difficult
- The scientific literature does seldom report specific standard
- Clinician should interpret the scientific literature in order to set appropriate standards of care

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EXAMPLE

Indicator: Proportion of stroke patients treated and rehabilitated in a stroke unit

- Metaanalyses of RCTs have demonstrated the effects of stroke units on outcomes of care
- Treatment in stroke units was associated with lower mortality (odds Ratio = 0,83, 95% confidence interval (0,71 – 0,97) compared to departments of internal medicine
- On this basis all patients with acute stroke should be treated at specialized stroke units
- BUT observational studies suggest that a smaller subgroup of patients (approx 10%) will not benefit for treatment at stroke units because they are declared at admittance etc.
- Clinicians suggest that the standard should be 90%

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DESIGN MEASURE SPECIFICATIONS I

Define the clinical indicator

- Exhaustive and exclusive measure specifications should be described
- Some indicators can be described as a proportion
- Some measures are dichotomous
- Some measures are continuous
- Each component related to the indicator should be described in detail

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DESIGN MEASURE SPECIFICATIONS II

Define the clinical indicator

Example Indicator: Proportion of stroke patients treated in a stroke unit within 24 hours

BUT: What is a stroke unit?

“A stroke unit can be described as a hospital unit or part of a hospital unit which alone or almost alone treats or rehabilitate patients with stroke”

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DEFINITIONS E.G NOSOCOMIAL INFECTIONS

- **Dirty:** Operations in which a perforated viscus or pus is found.
- **Contaminated:** Operations breaching the gastrointestinal, respiratory and genitourinary tracts, or in which a break in aseptic technique occurs and in traumatic wounds.
- **Clean:** All other operations where the criteria set out in 'dirty' and 'contaminated' do not apply.
- **Wound infection:** Any surgical wound from which purulent material drains or is obtained.
- **37,4°C** on blood collected 48h after admission.
- **Hospital-acquired bacteraemia:** A positive blood culture for inpatients who were afebrile on admission (i.e. temperatures less than Reference: ACHS. J. Qual. Clin Practice 1997

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DATA FORMAT E.G NOSOCOMIAL INFECTIONS

- **Clean and contaminated wound infection**
 - A) Numerator: The number of patients who develop wound infection from the fifth post-operative day after (i) clean surgery, (ii) contaminated surgery.
 - B) Denominator: The total number of patients undergoing (i) clean and (ii) contaminated surgery within the time period under study who have a post-operative length of stay of 5 or more days
- **Hospital-acquired bacteraemia**
 - A) Numerator: Total number of patients who acquire bacteraemia as defined above.
 - B) Denominator: Total number of patients in hospital during the study period.

– Reference: ACHS. J. Qual. Clin Practice 1997

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IDENTIFY TARGET POPULATION

- Specific inclusion and exclusion criteria
- Diagnoses or symptoms (signs)?
- Age limits?
- Time period for measurement
- Prevalent or incident cases?

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DATA SOURCES AND DATA COLLECTION

- Identify data sources
 - administrative data
 - clinical data
 - primary data
- Describe data collection procedures
 - registration forms
 - implementation in clinical departments
 - missing data
 - data outside a logical range
- Develop analytical plan
 - how are measures to be analyzed?
 - how should statistical and clinical significance be determined

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TESTING

- **Reliability** expresses the extent to which repeated measurements of a staple phenomenon by different providers, at different times and places get similar results
- Reliability can be tested as interrater reliability, where different clinicians score the same data
- Reliability can also be tested as internal consistency, when items are compared that should provide similar results
- Reliability can be tested as test – retest reliability, where differences related to the same clinicians are compared at two different time points.

Measuring reliability is crucial in order to determine if data is precise enough to provide reproducible results

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TESTING

- **Validity** determines the degree to which an indicator measure what it is intended to measure
- Validity can be tested by confirming that the scores of a measure are linked to specific outcomes and that the measure can reflect good and bad quality

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RESULTS TREATMENT IN STROKE

UNIT

More than 90% should be treated in a stroke unit within 24 hours after admittance

N=892

County	Treatment <24 hours %	Treatment during admittance
County A	66	79
County B	64	71
County C	83	93
County D	46	79

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