The Danish National Indicator Project

for Monitoring and Improving Core Healthcare Services

Manual for the Development of Disease-specific Quality Indicators, Standards and Prognostic Factors under The Danish National Indicator Project

Version 3.0
The DNIP secretariat, June 2009

The Danish National Indicator Project for monitoring and improving core healthcare services is a cooperation between the Danish Regions, a number of healthcare professional associations for doctors, nurses, physiotherapists and occupational therapists (Dansk Medicinsk Selskab, De faglige sammenslutninger på sygeplejeområdet, Danske Fysioterapeuter, Ergoterapeutforeningen) and the Danish National Board of Health.

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PREFACE

This is the third version of "Manual for the Work Process of the Indicator Groups" for The Danish National Indicator Project (DNIP), renamed "Manual for Development of Disease-specific Quality Indicators, Standards and Prognostic Factors under The Danish National Indicator Project".

The manual describes the part of DNIP involving the development phase in relation to establishing disease-specific indicators, standards and prognostic factors (indicator sets), focusing on core healthcare services. It also describes the stages in the development phase, including the requirements that the content of the indicator sets has to meet. The manual starts with a short description of the objectives, organisation and activities of DNIP, e.g. feedback on data, auditing and public disclosure.

The manual has been revised on the basis of the experience gained by DNIP since 2004 through its involvement in development of indicators, standards and prognostic factors:

- Development of indicator sets for eight diseases/conditions
- Test phases
- Hearing phases
- Implementation phases.

This edition also includes national and international experiences relating to development and evaluation of indicators (1,2,3).

The manual is intended as a means to make sure that the development of indicator sets rests on the most recent research-based evidence, through a transparent and systematic process, ensuring that the indicators, standards and prognostic factors established are truly well-defined and specific.

The manual's primary target audience is clinicians and healthcare professionals appointed members of an indicator group and who are to participate actively in the development process. In addition, the manual hopes to provide clinicians, healthcare professionals, managers and other stakeholders in the healthcare system with an insight into the foundations of the indicator development process, e.g. in case they are involved in a hearing phase.

The DNIP secretariat
June 2009

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1. INTRODUCTION

The Danish National Indicator Project (DNIP) was established in 1999 as a national quality monitoring and development project, aiming to measure and improve core healthcare services by means of indicators (indicator monitoring). DNIP was initiated as part of a budget agreement between the government, the regional authorities (then counties) and the health authority of the capital area (H:S) and officially adopted at an inter-county meeting in March 2000. After the Danish Local Government Reform in 2006/07, DNIP continued as a national project under the new regional councils.

The period 2000–2008 saw the development and implementation of disease-specific, evidence-based indicator sets for eight diseases/conditions (strokes, acute upper gastrointestinal bleeding/perforation, diabetes, heart failure, hip fractures, chronic obstructive pulmonary disease, lung cancer and schizophrenia), and outcomes have been subjected to national and regional clinical auditing. Since early 2004, quality outcomes for the diseases/conditions mentioned at the national and regional level and for the relevant hospital unit have been disclosed every year on the Danish common public eHealth Portal, "sundhed.dk". Outcomes are disclosed along with health professional interpretations and recommendations for improvement of quality.

So far, the DNIP has completed all phases (development of indicator sets, implementation, auditing and Public disclosure) for eight diseases/conditions, and has performed a systematic review of the original indicator sets in order to incorporate new evidence (e.g. in connection with updates of national reference programmes).

In spring 2009, work to develop indicator sets for two new areas - births and depression - was initiated.

1.1 Objective

The objective of The Danish National Indicator Project is to establish and secure a common foundation and methodology for monitoring and improving the quality of healthcare in the Danish healthcare system, in order to document and further develop the quality of the services provided by the healthcare system, for the benefit of patients.

1.2 Overall goals

The overall goals for DNIP are to

- Document and develop the quality of healthcare by means of disease-specific indicators and standards for core healthcare services
- Provide a qualified basis for dialogue on setting priorities at the professional, management and political level
- Give citizens more insight into the quality of healthcare.

1.3 Focus

The DNIP has its focus on the documentation, monitoring and improvement of core healthcare services. The elements included are:

Development and implementation of indicators

- Selection and definition of diseases/conditions
- Description of patient courses
- Establishment of indicators, standards and prognostic factors (indicator sets)
- Test and hearing phases
- Implementation.

Indicator monitoring

- Data collection, data analysis and feedback
- Clinical auditing and measures to improve quality
- Public disclosure.

Review and update of indicator sets

- Specific updates if required after national audit
- Formalised review and revision every second or third year.

Below the activities relating to the ongoing indicator monitoring will be described briefly; activities related to development and implementation, and to review and updating of the indicator sets will be described in chapters 2, 3 and 4 of this manual.

1.4 Indicator types and indicator requirements

Disease-specific indicators are measurable variables that can be used to monitor and evaluate healthcare quality. The indicators relate to structure, process or outcomes within a given disease/condition (4). The DNIP primarily uses process and outcome indicators, and indicator results are stated quantitatively as ratios. Adjustment variables may be selected as structural variables, just as structural changes may be suggested when national or regional clinical audits need to identify ways of improvement in case of unsatisfactory audit results – please see the DNIP Handbook, chapters 6 and 7 (5).

For any indicator to successfully meet its objective, i.e. indicate the quality of healthcare, it needs to meet a number of formal quality requirements within the following three dimensions:

- Relevance – indicators must measure important aspects of the services provided by the healthcare system
- Research-based – indicators must be based on the best evidence available and be both valid and reliable
- Applicability – indicators must be easy to understand for clinical staff and data must be accessible.

In the process of developing indicators, indicators may be rated within the three dimensions mentioned above by using the rating instrument ”Rating of indicators in The Danish National Indicator Project”. This rating process is described below in 4.1.4 and the rating instrument itself is enclosed as Appendix 4, page 27.

1.5 Indicator monitoring

1.5.1 Data collection, data analysis and feedback

Data related to patient treatment is registered and reported by all clinical units treating patients suffering from the disease/condition in question, and then analysed by clinical epidemiologists at the three competence centres attached: Competence Centre North, Competence Centre South and Competence Centre East . The clinical units receive feedback in the form of real time monthly and quarterly standard reports including unadjusted results that may be used for the unit’s own internal monitoring and development of quality. This feedback also includes an overview of the extent to which the clinical unit meets the standards set for the indicator domain in question, thus enabling the unit to monitor development in their own results over time.

In addition to the continuous feedback to the individual clinical units, there will be an annual report, including an analysis of the data used, for all units. This annual report gives the results when outcome indicators have been adjusted, e.g. for differences in case mix based on prognostic factors. This means that the results can also be used for comparison across units, hospitals and regions.

Increasingly, the data is used also in management information systems at clinical unit, hospital and regional level.

1.5.2 Clinical audit and quality improvement

On the basis of the annual report mentioned above, a clinical audit will be performed at the national and regional/local level, as part of the evaluation and interpretation of the data. The purpose of a clinical audit is to explain and concretise the results in relation to the disease-specific standards and indicators, and to interpret the statistical data in the specific professional setting. The audit process is described in detail in the DNIP Handbook (5).

1.5.3 Public disclosure

When the healthcare professional analysis, interpretation and evaluation process has been completed, the results will be disclosed at the national, regional and clinical unit level. Public disclosure is web-based and is accessed via the eHealth Portal, sundhed.dk. The results will be accompanied by comments made by professionals at the clinical audit and disclosed in two versions: a healthcare professional audit report targeting professionals, and a citizens' version adapted for patients, relatives and citizens in general.

1.6 The DNIP organisation

The DNIP organisation includes a steering committee, indicator groups and a documentalist for each disease/condition, clinical epidemiologists and the DNIP secretariat. In addition, to oversee specific local implementation and operational tasks, there are a number of locally and regionally appointed contact persons in the five regions, as well as DNIP key person in the clinical units involved and at hospital level. The responsibilities and tasks of the regional/local organisation are described in the DNIP Handbook (5). Figure 1, page 8, is an illustration of the DNIP organisation.

The Steering Committee is made up of the regional healthcare directors of the five regions.

The DNIP secretariat is in charge of the day-to-day management of the DNIP. Its organisation and functions are described in more detail in 1.7.

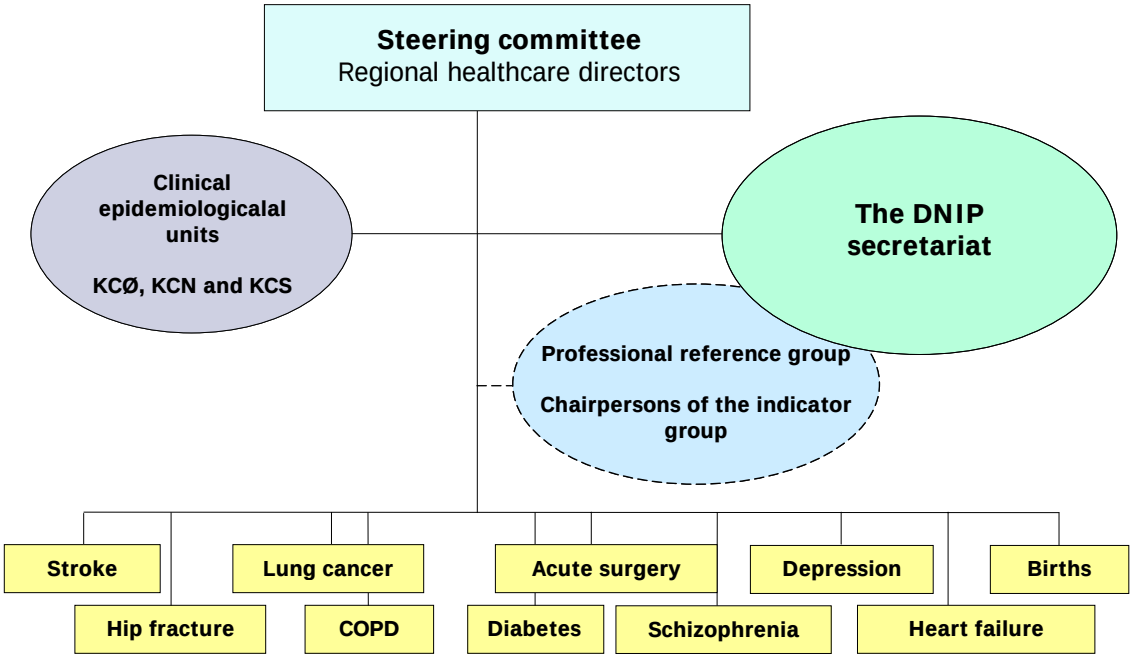
The main task of *the indicator groups* is to prepare the healthcare professional indicators and standards for the core services of the healthcare system within specific diseases/conditions. Furthermore the indicator groups, together with the clinical epidemiologists, describe patient populations and establish data definitions for collection and registration of the data required, and finally they carry out the analysis, interpretation and evaluation of national results (clinical audit). The composition of the indicator groups is described in chapter 3.

Documentalists are specialists with extensive clinical and research experience within the specific disease/condition who are responsible for finding and giving a critical review of the relevant research literature, including rating evidence in cooperation with the members of the indicator groups. The documentalist guarantees the methodological stringency of evidence grading (see also 4.1.3 on the preparation of a documentalist report, and 4.2 on the requirements and contents of the documentalist reports), and the members of the indicator group are responsible for the professional basis and content of the indicators and standards. Documentalists are appointed by the chairpersons and the project management jointly.

The clinical epidemiologist is responsible for clinical epidemiologicalal guidance, data processing and analysis as well as epidemiologicalal interpretation of data. The clinical epidemiologist is attached to one of the three competence centres for clinical quality databases.

Professional reference group
Collectively, the chairpersons of the indicator groups function as a professional reference group in all general, overall professional matters.

Figure 1. The DNIP organisation



1.7 The DNIP secretariat

The DNIP secretariat is in charge of The Danish National Indicator Project on a day-to-day basis; i.e. overall planning, coordination and execution of activities related to the different phases of DNIP (development, implementation, auditing and Public disclosure). The DNIP secretariat consists of a medical director, a project manager, a number of healthcare consultants, an IT officer, a data manager and a secretary.

In cooperation with the professional associations, among others, the DNIP secretariat appoints the members of the indicator groups. Each indicator group is assisted on an ad hoc basis by staff from the DNIP secretariat: a project manager and a healthcare consultant, and, as described in 1.6, a documentalist and a clinical epidemiologist.

The medical director has the overall responsibility for DNIP.

The project manager has the overall responsibility for the organisational and methodological processes in the indicator groups.

The healthcare consultants function as the facilitators of the indicator groups' work and as their academic secretaries. The healthcare consultants also call and plan meetings, draft the minutes etc.

The project manager and the healthcare consultants furthermore oversee that work is carried out in the group in a methodologically stringent way, to ensure that the group's work is evidence-based and reproducible.

The IT officer and data manager of the DNIP secretariat are in charge of user administration, software maintenance and development, developing web-based tools for reporting, and they are responsible for the databases, including use of data for research and statistical analysis.

In addition, the IT officer is responsible for all service agreements for servers and networks, and the data manager is responsible for quality assurance of data, ad hoc analysis and Public disclosure of results and outcomes at sundhed.dk.

2. SELECTION AND PRIORITISING OF DISEASES/CONDITIONS

New diseases/conditions are selected and prioritised for quality monitoring by DNIP based on demand and healthcare professional decisions. When receiving a recommendation from the regional healthcare directors, the DNIP secretariat together with the clinical epidemiologists draws up hearing material describing potential new diseases/conditions for quality monitoring.

The DNIP secretariat then initiates a hearing phase lasting approximately 2 months, during which all relevant organisations and professional associations are consulted about which diseases/conditions to select, based on the following overall criteria:

- Prevalence and severity of the disease/condition
- Any unexplained variation in treatment and/or use of resources
- Suitability for quality monitoring
- Any other national quality initiatives launched in the field.

At the end of the hearing phase, the DNIP secretariat goes through the hearing statements received, prioritises the diseases/conditions suggested for quality monitoring, and submits its draft recommendations to the regional healthcare directors for their final decision.

3. THE MEMBERS OF THE INDICATOR GROUP

After prioritising and selection of a new disease/condition, a cross-disciplinary indicator group will be set up. The composition of members takes place during a dialogue with the relevant professional associations of e.g. doctors, nurses, physiotherapists, occupational therapists, midwives and any other relevant professions, including at times relevant patient organisations.

The idea is that all relevant healthcare professions should be represented in the indicator group for a given disease/condition. Together, the group should reflect all the staff involved in a standardised patient course in the disease/condition in question, at the clinical and research level as well as at the levels of both regional and university hospitals, and at different management levels. Preferably, there should also be a geographic representation of all five regions. The optimal number of members of an indicator group is between 12 and 15, including the chairpersons.

Besides the appointed members of the indicator group, various healthcare professional or research experts may be attached to the group on an ad hoc basis.

3.1 Chairpersons

An indicator group will have two chairpersons: a chairperson with a medical background and a chairperson with a different healthcare professional background, e.g. a nurse or therapist.

The chairpersons are appointed by DNIP's project management (the medical director and the project manager) after hearing with research and professional associations, who will suggest candidates for the positions in the indicator group. Selection of chairpersons will be based on their CVs.

The chairpersons have two overall main functions: 1) An external function involving contact with the external professional and research environment, and 2) An internal function involving healthcare professional aspects within the indicator group.

The duties of the chairpersons include:

- Aiding DNIP's project management in considerations regarding the appointment of the various members of the indicator group
- Maintaining ongoing contact with the research and professional associations involved, to keep them informed and updated on the progress of the process, to secure their co-ownership of DNIP
- Aiding the DNIP secretariat (project manager and healthcare consultant) in
    - Setting up time schedules and project plans
    - Helping to ensure that work is carried out in accordance with the relevant manuals, observing the time and project plans
- Acting as contact persons for the press, answering questions on professional aspects of the group's work.

The chairpersons of the indicator groups perform their duties jointly and in close cooperation with the project manager. The project manager, the chairpersons and the healthcare consultant together act as facilitators at the meetings of the indicator group.

3.2 The duties of the members of the indicator group

Attendance at indicator group meetings is compulsory, and members are expected to prepare before and sometimes after meetings. A binding cooperation agreement will be signed by all members attached to the indicator group. This agreement outlines what is expected of members, and it also ensures that members are allowed time off for meetings. It is the workplace of the indicator group member that receives the financial compensation for members' participation in the group's work, at standard rates for time off for similar activities. If a member of the indicator group is not attached to a workplace, remuneration at standard rates may be paid out the member as a private person.

The mix of the indicator group will be reviewed from time to time, and on such occasions the members will be asked to reaffirm their membership of the group.

4. DEVELOPMENT OF INDICATORS, STANDARDS AND PROGNOSTIC FACTORS

Development of indicators and indicator monitoring in DNIP rest on two fundamental principles:

- Healthcare professionals develop indicators and standards along with the accompanying prognostic factors (indicator set) on the basis of evidence, including any existing reference programmes or national clinical guidelines within the disease/condition in question
- Healthcare professionals interpret and evaluate results before public disclosure (clinical audit).

When a new disease/condition is to be monitored, some 8 - 10 disease-specific indicators related to processes or outcomes will be defined. For each indicator, a standard (quality target) for good clinical practice and good clinical outcomes will be established, along with any prognostic factors needed to adjust for potential differences in case mix.

The starting point for this work is a "standardised patient course" for the specific disease/condition in question. This should include and describe all activities and processes involved in the patient course: diagnostics, treatment, care, rehabilitation and prevention.

The following documents are used for each indicator set:

- Indicator form
- Documentalist report
- Data definitions with list of variables
- Calculation rules (indicator algorithms)
- Registration form or checklist.

The requirements and content of the above documents are described in 4.2.

4.1 Phases and activities of the development process

The work process for development of indicator sets in DNIP comprises the following phases:

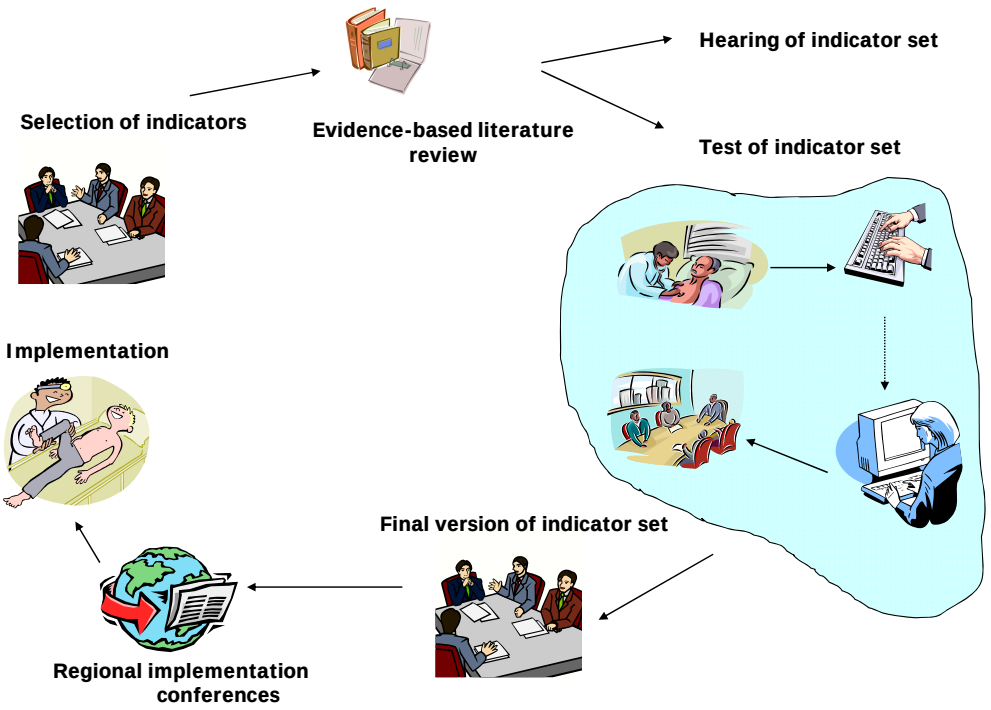
Phase 0: Itroductory chairpersons´ meeting
Phase 1: Preparatory chairpersons´meeting
Phase 2: First meeting of the indicator group
Phase 3: The documentalist's review and evidence grading of indicators
Phase 4: Second meeting of the indicator group
Phase 5: Finalising of documents to be used
Phase 6: Testing of indicator set and logistics of data collection and data quality audit
Phase 7: Indicator set sent for hearing with external stakeholders
Phase 8: Third meeting of the indicator group
Phase 9: National implementation.

The activities and specific tasks related to the individual phases will be described in 4.1.0 – 4.1.9 below. All activities in the development process are continuously documented in the DNIP secretariat.

An illustration of the total development process can be seen in Figure 2, page 12.

Time schedule
The time schedule for the development process depends on the disease/condition to be investigated, any quality initiatives already initiated in the field, and of the previous experience of the members of the indicator group. A "standard process" is outlined in Appendix 1, page 24, and going through phases 0-9 typically lasts approx 43 weeks.

Figure 2. The development process for quality indicators in DNIP



4.1.0 Introductory chairpersons´ meeting (Phase 0)

Participants
The chairpersons of the indicator group, the project management and the healthcare consultant.

Specific tasks for the meeting
- Introduction of DNIP to the chairpersons
- Discussion of the mix and members of the indicator group.

Duration
½ workday.

Tasks arising from meeting
Before their preparatory meeting, the chairpersons will consult the professional associations in preparation of the mix and members of the indicator group.

Duration
4 – 5 weeks.

4.1.1 Preparatory chairpersons' meeting (Phase 1)

Participants
The chairpersons of the indicator group, the documentalist, the clinical epidemiologist, the project management and the healthcare consultant.

Preparation for the meeting
The project manager calls the preparatory planning meeting at which the specific work process and time schedule will be established.

Together with the chairpersons, the healthcare consultant and the documentalist will make an initial overall screening to identify possible sources for indicator development. The screening will be performed within national and international reference programmes and indicator libraries such as AHRQ (6), NHS Scotland (7), RAND (8), National Institute for Health and Clinical Excellence (NICE) (9), The Australian Council on Healthcare Standards (ACHS)(10), Institute for Healthcare Improvement (IHI) (11), Joint Commission (12), Bundesgeschäftstelle Qualitätssicherung (BQS) (13), National Committee for Quality Assurance (NCQA) (14), WHO (15), OECD (16), European Union Network for Patient Safety (EUNetPas) (17) and Danish quality databases (18).

An overview of potential sources will be sent to the participants as an appendix to the agenda of the meeting.

Specific tasks for the meeting

- Go through
  - The tasks and responsibilities of the chairpersons
  - The functions of the documentalist
  - The functions of the clinical epidemiologist
- Finalise the mix of the indicator group on the basis of the suggestions of the chairpersons
- Preliminarily define
  - Disease/condition
  - Inclusion criteria in relation to disease/condition
- Preliminarily describe a standardised patient course within the disease/condition, including a flow diagram (Appendix 3, page 25)
- Identify potential indicator domains on the basis of the standardised patient course
- Clarify
  - Potential sources for indicator development in the disease/condition in question
  - Indicators, standards and prognostic factors on the basis of suggestions from the chairpersons
- Preliminarily describe the wards/clinical units (type of wards and clinical units and perhaps general practitioners) to be included in the indicator monitoring
- Plan the future work in the indicator group, specifying task responsibilities and competences in the group
- Establish a time schedule for the work of the indicator group.

Duration
1 workday.

4.1.2 First meeting of the indicator group (Phase 2)

Participants
The indicator group, the documentalist, the clinical epidemiologist, the project manager and the healthcare consultant.

Preparation for the meeting
At a date agreed with the chairpersons, the project manager convenes the members of the indicator group for their first meeting, attaching the agenda for the meeting.

The chairpersons prepare an introduction for:

- Definition of disease/condition, patient course and inclusion criteria.

The documentalist prepares an introduction for:

- A gross indicator set, including an overall evidence grading
- Potential prognostic factors.

The clinical epidemiologist prepares an introduction for:

- Potential clinical epidemiological analyses within the field.

Specific tasks for the meeting
At its first meeting, the indicator group should:

- Be given an introduction to DNIP
- Define the disease/condition
- Describe the patient course in relation to the disease/condition
- Describe the clinical units to be included (types of wards and clinical units, and general practitioners if relevant)
- Characterise the relevant patient population together with the clinical epidemiologicalal expertise (prevalence, incidence)
- Define inclusion and exclusion criteria in relation to the disease/condition
- Select preliminary indicators, standards and prognostic factors
- Describe potential clinical epidemiological analyses on the basis of the preliminary indicator set
- Select 4 - 5 test units among the members of the indicator group (distributed on regional and university hospitals and the five regions). For diseases/conditions in which the patient course includes the primary sector, 2 – 3 test general practices should be selected as well.

Finally, the future tasks of the indicator group must be organised and delegated, in accordance with the time schedule agreed upon.

If members of the indicator group are to be in charge of specific indicators, this should be arranged at the meeting in preparation for the cooperation with the documentalist.

Duration
1 workday.

4.1.3 The documentalist's review and evidence grading of indicators (Phase 3)

Participants
Primarily the documentalist – cooperating with the members of the indicator group, the clinical epidemiologist and the DNIP secretariat.

Preparation
The documentalist, in cooperation with the DNIP secretariat (project manager and healthcare consultant), assembles the literature relevant for the task in hand on the basis of the decisions made at the first meeting of the indicator group.

The specific tasks
In close cooperation with the members of the indicator group, the documentalist will:

- Go through the relevant literature
- Prepare a review of original literature, identifying indicators
- Grade the evidence of the indicators chosen.

Together with the clinical epidemiologist, the documentalist will:

- Prepare a written evidence graded literature review of potential prognostic factors.

Evidence grading of indicators and prognostic factors must be performed on the basis of the criteria described in Appendix 2, page 25 (19).

Furthermore, an account of the sources and search strategy used for original literature must be prepared. References are continuously registered in a reference management database kept at the DNIP secretariat. Articles not available electronically must be kept in paper version.

A detailed description of requirements and contents of the documentalist report can be seen in 4.2, page 24.

Duration
5 - 6 weeks.

4.1.4 Second meeting of the indicator group (Phase 4)

Participants
The indicator group, the documentalist, the clinical epidemiologist, the project manager, the healthcare consultant and the IT officer of the DNIP secretariat.

Preparation for the meeting
The documentalist:

- Prepares an introduction concerning the draft documentalist report, including:
  - The evidence found for indicators, standards and prognostic factors.

The epidemiologist

- Prepares an introduction concerning calculation rules (indicator algorithm) and data definitions.

The healthcare consultant

- If the data collection is to be based on reports to the DNPR:
  - Map variables with any existing SKS codes (diagnostic, procedure and value codes)
  - Contact the DNPR to discuss new codes for indicators without existing SKS codes
  - Prepare draft for test phase checklist and registration forms for indicators for which data collection is to take place via SKS codes reported to the DNPR
- If the data collection is to take place via KMS (clinical measurement system):
  - Prepare draft for registration form for indicators.

The IT officer

- Prepares draft for electronic registration form for data entry into KMS for diseases/conditions for which data is collected ad hoc.

Specific tasks for the meeting
On the basis of the documentalist's introduction:

- Go through draft for the documentalist report
- Evaluate and prioritise preliminary indicators and standards on the basis of the evidence presented
- Go through opportunities and limitations in the collection of prognostic factors
- Choose prognostic factors for the final indicator set.

In case of doubt or disagreement, the rating instrument "Rating of indicators in The Danish National Indicator Project" (Appendix 4, page 27) can be used to identify strengths, weaknesses and any shortcomings of the indicators. No weighting of the indicators will be made in the final indicator set.

On the basis of the clinical epidemiologist's introduction:

- Specify "numerator/denominator" for the individual indicators (indicator algorithm)
- Clarify draft for data definitions in relation to the indicator set (indicators, prognostic factors and any other relevant variables to be included in the data collection).

On the basis of the IT officer's and healthcare consultant's introduction:

- Go through and clarify draft for registration form and checklist.

Duration
1 workday.

4.1.5 Finalising the data definitions, calculation rules etc. (Phase 5)

Participants
The documentalist, the clinical epidemiologist, the healthcare consultant, DNIP's IT officer and the chairpersons of the indicator group.

The specific tasks
On the basis of the indicator group's second meeting:

The documentalist will finalise
- The documentalist report.

The epidemiologist will finalise
- Specific data definitions for each of the variables of the data set
- Calculation rules (indicator algorithm) for each indicator.

The IT officer will finalise
- Database and electronic registration form including field validations and threshold values
- IT guidelines for data extraction.

The healthcare consultant will
- Contact the DNPR to establish new SKS codes (in case of data collection via the DNPR)
- Draw up registration form in paper edition and checklist.

The documents mentioned above are to be approved by the chairpersons of the indicator group and the DNIP secretariat.

Duration
4 – 5 weeks.

4.1.6 The test phase (Phase 6)

The test phase comprises the following activities:
- Practical testing of the indicator set and logistics of registration and reporting of data
- Rescoring of medical records in order to assess the degree of inter-observer variation when registering data
- Perhaps recoding of diagnostic codes to assess the degree of misclassification of diagnoses (if patients are included on the basis of SKS diagnostic codes reported to the DNPR).

At the end of the test phase, a joint meeting will be held between the participating test units, the clinical epidemiologist and the DNIP secretariat to perform a data quality audit of the rescored medical records and any recoded diagnostic codes. Another purpose of the meeting is to discuss the experience gained during the test phase.

4.1.6.1 Testing of indicator set and logistics in connection with data collection

Participants
The test units, and general practitioners, if any, selected among the members of the indicator group, and the DNIP secretariat.

Preparation for the test phase
During phase 5, the healthcare consultant and the IT officer of the DNIP secretariat will hold introduction meetings at the test units involved, or a joint meeting for all participants. The test units will be given an overview and introduction to the test period, including specific guidance on patient identification, data collection/SKS coding and reporting.

In addition to the members of the indicator group, 1 - 2 DNIP key persons in the test units will be selected to act as coordinators of the specific tasks to be performed.

The specific tasks during the test phase
The test units are to

- Test:
  - Logistics and organisation
  - Patient identification on the basis of the inclusion criteria established
  - Data collection
  - Data reporting to KMS (for diseases/conditions with KMS-based data collection)
  - Coding and reporting of SKS codes (for diseases/conditions with DNPR-based data collection)
- Provide and anonymise patient medical records to be sent to the DNIP secretariat for rescoring – see the DNIP Handbook (5)
- Rescore medical records to assess the degree of inter-observer variation (two units exchange and rescore each other's medical records)
- Perhaps recode diagnoses to asses the degree of misclassification (if patients are included via SKS diagnostic codes in the DNPR) – see "Manual for Data quality audit of DNPR-reported diagnostic codes" (20)
- Perhaps test evaluation of completeness of the database (for diseases/conditions with reporting of data to KMS).

The DNIP secretariat is to

- Prepare a memo for each test unit on the introduction meetings, describing any particular organisational characteristics of the unit, and any spontaneous remarks on the indicator set and registration forms
- Provide support throughout the test period via mail and phone
- Document questions and suggestions received
- Together with the clinical epidemiologist pick random samples of patients for rescoring of their medical records – see the DNIP Handbook (5)
- Copy and forward copies of medical records for rescoring
- Go through and account for the rescoring of medical records
- When necessary, key in data from registration forms from the test units and recode diagnostic codes and forward data to the epidemiologist (for diseases/conditions with DNPR-based data collection).

The clinical epidemiologist is to

- Prepare a draft for reporting (standard report) based on the indicator results from the test phase.

This report will form the basis for the subsequent data quality audit, together with the results of the rescoring of medical records, any recoding of diagnostic codes and the experiences of the test units.

Together with the clinical epidemiologist, it will be discussed and decided whether any statistical calculations of the rescoring of medical records and recoding of diagnostic codes are needed.

Duration
8 – 10 weeks, including a joint meeting to audit data quality and discuss experience gained, and any follow-up work needed.

4.1.6.2 Data quality audit and discussion of experience gained

To round off the test phase, there will be a joint meeting between the test units, the clinical epidemiologist and the DNIP secretariat to audit data quality and discuss the experience gained from the test phase.

Participants
Representatives from the test units and any general practitioners involved, possibly the chairpersons, the clinical epidemiologist and the DNIP secretariat.

Preparation for the meeting
The project manager calls the meeting.

Den clinical epidemiologist
- Prepares a draft for the report (standard report) based on the indicator results from the test phase.

The healthcare consultant
- Describes the results from:
  - The rescoring of medical records
  - The recoding of diagnostic codes (for diseases/conditions with DNPR-based data collection)
  - The statement of the completeness of the database (for diseases/conditions with data reporting to KMS)
- Writes a memo about the introduction meetings.

Specific tasks for the meeting
- Present preliminary results from the test phase (the epidemiologist)
- Go through the results of the rescoring of medical records to assess the degree of inter-observer variation
- Go through the recoding of diagnoses to assess the degree of misclassification (if the patients are included via SKS diagnostic codes in the DNPR) – see "Manual for data quality assurance audit of DNPR-reported diagnostic codes" (20)
- Go through and discuss the experience gained concerning:
  - Patient identification and data collection
  - Coding and reporting SKS codes (for diseases/conditions with DNPR-based data collection)
  - Statement of completeness of the database (for diseases/conditions with data reporting to KMS)
  - Any comments on the indicators from the test units on clinical applicability and relevance.

Duration
½ - 1 workday.

Follow-up tasks
The DNIP secretariat after the meeting
- Prepares the final report of the experiences and recommendations, which together with the hearing statements will form the basis of subsequent adjustments of the indicator set (Phase 9).

4.1.7 Hearing on indicator sets with external stakeholders (Phase 7)

Concurrently with Phase 6, hearings on the indicator set will be held in all relevant forums, including healthcare professional and research associations, The Danish National Health Board, any patient organisations and other relevant stakeholders.

The DNIP secretariat is in charge of the hearing process and makes sure that all external stakeholders get an opportunity to suggest adjustments and specifications before the national implementation.

The specific tasks
The DNIP secretariat
- Forwards copies of the indicator set established to all parties to be consulted
- Processes and edits hearing statements, which will form part of basis for the indicator group's decisions on adjustments of the indicator set.

Duration
8 – 10 weeks, concurrently with the test phase.

4.1.8 Third meeting of the indicator group (Phase 8)

Participants
The indicator group, the documentalist, the clinical epidemiologist, the project manager, the healthcare consultant and the IT officer of the DNIP secretariat.

Preparation for the meeting
The clinical epidemiologist
- Prepares a presentation of the draft final report.

The DNIP secretariat
- Forwards hearing statements and report from the test units to the members of the indicator group.

Specific tasks for the meeting
The indicator group
- Finalises the complete indicator set
- Specifies
  - Inclusion criteria and inclusion diagnoses
  - Any exclusion criteria
  - Data definitions and calculation rules (indicator algorithms)
  - The form of the final report
- Adjusts IT registration form/checklist
- Sets date for start of national implementation
- Plans the overall national implementation phase.

Duration
1 workday.

4.1.9 National implementation (Phase 9)

Once the final indicator set has been developed, preparations for the national implementation starts. The objective is to make sure that work with the indicator set is integrated in the most appropriate way into the daily routines of the practical clinical setting, and that the indicator set is presented to the clinical units in such a way that the background for the choice of indicators is fully understood. In the implementation phase, the primary focus should be on patient identification, coding and registration practices and data quality.

During the implementation phase, the database of DNIP for the new disease/condition, like all other national clinical databases, needs to be approved in accordance with the rules laid down in the Act on Processing of Personal Data and by The Danish National Board of Health (21). The IT officer sees to the necessary application procedures.

4.1.9.1 Identification of the clinical units included

Together with the regional contact persons, the DNIP secretariat identifies the clinical units included for implementation of the indicator monitoring of the disease/condition. A list is made of the exact names used for the units in questions by the hospitals and wards, along with their SKS codes, and it is decided which units are to receive indicator results. Lastly, a number of DNIP key persons are appointed at each unit to support the process of identifying patients, collecting data etc.

The activities in the operational phase, including the tasks and responsibilities of the DNIP key persons, are described in detail in the DNIP Handbook (5).

4.1.9.2 Regional implementation conferences

Well before the national implementation, regional implementation conferences will be held, in order to introduce the indicator set.

Participants
The chairpersons, the local representatives of the indicator group, the future DNIP key persons in the units included (clinical staff, management representatives, persons in charge of IT and PAS systems, medical secretaries), regional contact persons and general practice coordinators, the project manager, the IT officer and the healthcare consultant from the DNIP secretariat.

Preparation for the conferences
The healthcare consultant is in charge of the practical preparations for the conferences, including drafting a programme, reservation of facilities, catering etc.

The specific tasks at the conferences
- Introducing the DNIP key persons to
  - DNIP (the project manager)
  - The professional aspects and content of the indicator set (the chairpersons)
  - The logistics and tools for data collection and assessment of completeness of the database (the healthcare consultant)
  - The methods selected for follow-up and development of quality (the project manager).

Duration
Implementation conferences: 4 - 5 x ½ workday.

4.2 Documents related to the indicator set

Each indicator set consists of an indicator form, a documentalist report, a set of data definitions, a set of calculation rules (indicator algorithms) and a registration form or a checklist.

Indicator form
The indicator form contains information on:
- Indicator area
- The exact formulation of the indicator (including any time frame)
- Indicator type (process or outcome indicator)
- Standard (quality target).

An example of an indicator form can be seen in Appendix 5, page 28.

The documentalist report
The completed documentalist report comprises:
- An indicator form
- Account of sources/search strategy
- Basis for choosing disease/condition, including:
  - Incidence/prevalence
  - Morbidity/mortality
  - Known variation (quality issues)
  - Intervention possibilities
  - Healthcare political/professional initiatives in the area
  - Estimated resource consumption
- Basis for choosing indicator area, including:
  - Description of standardised patient process in the disease/condition (referral/diagnostics/treatment/rehabilitation), including flow diagram (sectors/wards)
- Description of patient population (based on source studies):
  - In general
  - Sub-populations
- Description of indicators:
  - Rationale/relevance (clinical importance)
  - Evidence of the indicator
  - Applicability, including practical availability of data
  - Reasons for choosing indicators with evidence grading
  - Consensus and recommendations
  - Standard (target for quality)
- Prognostic factors:
  - Description of evidence foundation, including evidence grading

- A short description of indicators not included in the final prioritising, including reasons for not including.

The documentalist report must have a preface and a list of the members of the indicator group.

Data definitions
The data definitions include:
- Detailed descriptions and definitions of the clinical units involved
- Diagnosis and inclusion criteria for the patient population
- Definitions of variables
- List of all variables included in the data set.

Calculation rules (indicator algorithms)
The calculation rules for each indicator include a detailed description of:
- The numerator of the indicator
- The denominator of the indicator
- Groups excluded
- Assessment of data completeness.

Finally, the calculation rules (indicator algorithms) must include diagrams of the algorithms (see Appendix 6, page 29).

Registration form and/or checklist
For each disease/condition, a data registration form (paper/electronic version) or a checklist for data collection must be prepared. The content and specific design of these documents will depend on whether data is collected manually or partly or entirely via the DNPR or other existing data sources.

The documentalist reports, data definitions, calculation rules and any registration forms or checklists for existing diseases/conditions can be found at DNIP's home page www.nip.dk.

4.3 Revision and updating of the indicator sets

Every year in connection with the national clinical audit, there may be isolated updates of the indicator sets, e.g. addition of new indicators or new supplementary variables. Every second or third year, there will a more formalised review with a proper revision of the indicator set, which will also includes a complete update of both documentalist report and other documents related to the indicator set.

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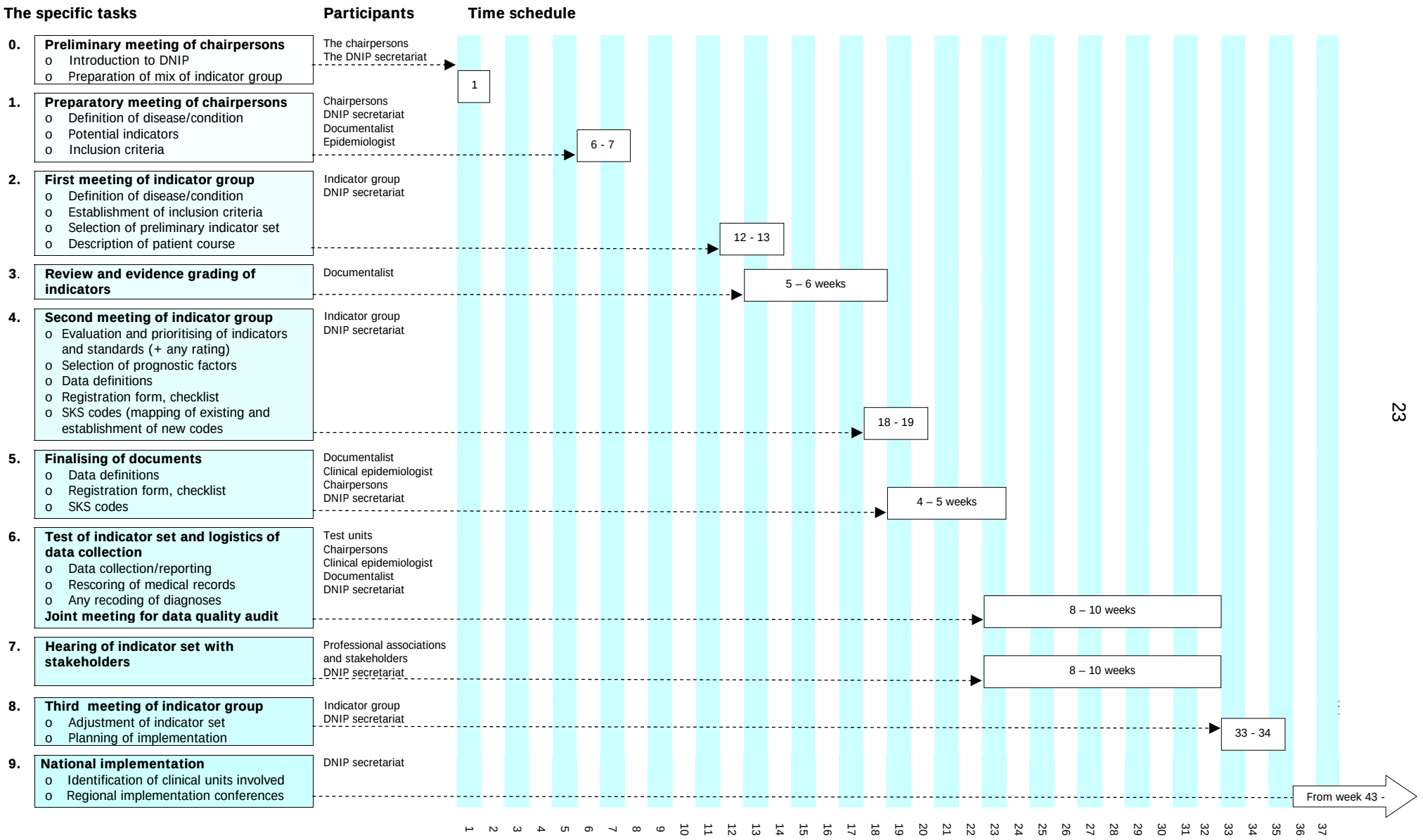
APPENDIX 1. TIME SCHEDULE FOR DEVELOPMENT OF INDICATORS IN DNIP



* The time schedule does not represent actual calendar weeks as allowances must be made for holidays, vacations etc.

APPENDIX 2. LEVELS OF EVIDENCE AND GRADES OF RECOMMANDATION

Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001)

Level	Therapy/Prevention, Aetiology/Harm	Prognosis	Diagnosis	Differential diagnosis/symptom prevalence study	Economic and decision analyses
1a	SR (with homogeneity*) of RCTs	SR (with homogeneity*) of inception cohort studies; CDR† validated in different populations	SR (with homogeneity*) of Level 1 diagnostic studies; CDR† with 1b studies from different clinical centres	SR (with homogeneity*) of prospective cohort studies	SR (with homogeneity*) of Level 1 economic studies
1b	Individual RCT (with narrow Confidence Interval‡)	Individual inception cohort study with ≥ 80% follow-up; CDR† validated in a single population	Validating** cohort study with good††† reference standards; or CDR† tested within one clinical centre	Prospective cohort study with good follow-up****	Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses
1c	All or none§	All or none case-series	Absolute SpPins and SnNouts††	All or none case-series	Absolute better-value or worse-value analyses ††††
2a	SR (with homogeneity*) of cohort studies	SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity*) of Level >2 diagnostic studies	SR (with homogeneity*) of 2b and better studies	SR (with homogeneity*) of Level >2 economic studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR† or validated on split-sample§§§ only	Exploratory** cohort study with good†††reference standards; CDR† after derivation, or validated only on split-sample§§§ or databases	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses
2c	"Outcomes" Research; Ecological studies	"Outcomes" Research		Ecological studies	Audit or outcomes research
3a	SR (with homogeneity*) of case-control studies		SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies
3b	Individual Case-Control Study		Non-consecutive study; or without consistently applied reference standards	Non-consecutive cohort study, or very limited population	Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.
4	Case-series (and poor quality cohort and case-control studies§§)	Case-series (and poor quality prognostic cohort studies***)	Case-control study, poor or non-independent reference standard	Case-series or superseded reference standards	Analysis with no sensitivity analysis
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on economic theory or "first principles"

Produced by Bob Phillips, Chris Ball, Dave Sackett, Doug Badenoch, Sharon Straus, Brian Haynes, Martin Dawes since November 1998.

Notes

Users can add a minus-sign "-" to denote the level of that fails to provide a conclusive answer because of:

- EITHER a single result with a wide Confidence Interval (such that, for example, an ARR in an RCT is not statistically significant but whose confidence intervals fail to exclude clinically important benefit or harm)
- OR a Systematic Review with troublesome (and statistically significant) heterogeneity.
- Such evidence is inconclusive, and therefore can only generate Grade D recommendations.

*	By homogeneity we mean a systematic review that is free of worrisome variations (heterogeneity) in the directions and degrees of results between individual studies. Not all systematic reviews with statistically significant heterogeneity need be worrisome, and not all worrisome heterogeneity need be statistically significant. As noted above, studies displaying worrisome heterogeneity should be tagged with a "-" at the end of their designated level.
†	Clinical Decision Rule. (These are algorithms or scoring systems which lead to a prognostic estimation or a diagnostic category.)
‡	See note #2 for advice on how to understand, rate and use trials or other studies with wide confidence intervals.
§	Met when all patients died before the Rx became available, but some now survive on it; or when some patients died before the Rx became available, but none now die on it.
§§	By poor quality cohort study we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both exposed and non-exposed individuals and/or failed to identify or appropriately control known confounders and/or failed to carry out a sufficiently long and complete follow-up of patients. By poor quality case-control study we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both cases and controls and/or failed to identify or appropriately control known confounders.
§§§	Split-sample validation is achieved by collecting all the information in a single tranche, then artificially dividing this into "derivation" and "validation" samples.
††	An "Absolute SpPin" is a diagnostic finding whose Specificity is so high that a Positive result rules-in the diagnosis. An "Absolute SnNout" is a diagnostic finding whose Sensitivity is so high that a Negative result rules-out the diagnosis.
‡‡	Good, better, bad and worse refer to the comparisons between treatments in terms of their clinical risks and benefits.
†††	Good reference standards are independent of the test, and applied blindly or objectively to applied to all patients. Poor reference standards are haphazardly applied, but still independent of the test. Use of a non-independent reference standard (where the 'test' is included in the 'reference', or where the 'testing' affects the 'reference') implies a level 4 study.
††††	Better-value treatments are clearly as good but cheaper, or better at the same or reduced cost. Worse-value treatments are as good and more expensive, or worse and the equally or more expensive.
**	Validating studies test the quality of a specific diagnostic test, based on prior evidence. An exploratory study collects information and trawls the data (e.g. using a regression analysis) to find which factors are 'significant'.
***	By poor quality prognostic cohort study we mean one in which sampling was biased in favour of patients who already had the target outcome, or the measurement of outcomes was accomplished in <80% of study patients, or outcomes were determined in an unblinded, non-objective way, or there was no correction for confounding factors.
****	Good follow-up in a differential diagnosis study is >80%, with adequate time for alternative diagnoses to emerge (eg 1-6 months acute, 1 - 5 years chronic)

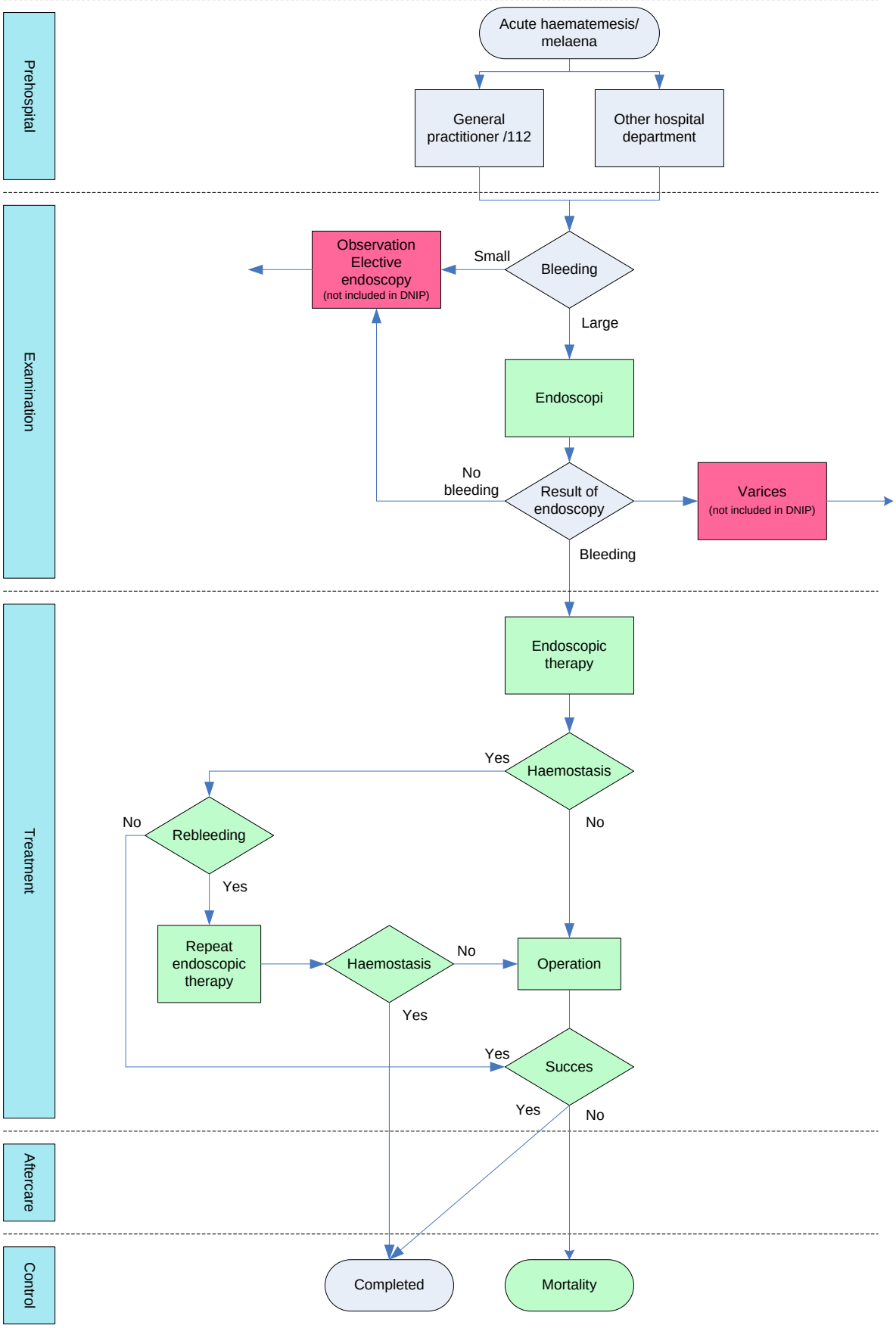
Grades of Recommendation

A	consistent level 1 studies
B	consistent level 2 or 3 studies ***or*** extrapolations from level 1 studies
C	level 4 studies ***or*** extrapolations from level 2 or 3 studies
D	level 5 evidence ***or*** troublingly inconsistent or inconclusive studies of any level

"Extrapolations" are where data is used in a situation which has potentially clinically important differences than the original study situation.

APPENDIX 3. EXAMPLE OF FLOW DIAGRAM OF A STANDARDISED PATIENT COURSE

Patient course for a patient with acute bleeding ulcer



Green boxes = DNIP indicator i the patient course

APPENDIX 4. RATING INSTRUMENT

"Rating of indicators in The Danish National Indicator Project"[1]

Dimension	Criterion	Score	Remarks
Relevance	The indicator captures essential aspects of core healthcare services, patient course, health condition or survival	[ ] 1 = Fully disagree [ ] 2 = Partially agree [ ] 3 = Fully agree [ ] 0 = Abstention	
	The processes or result monitored can be influenced by clinicians	[ ] 1 = Fully disagree [ ] 2 = Partially agree [ ] 3 = Fully agree [ ] 0 = Abstention	
	There are no known undesired consequences from the use of this indicator	[ ] 1 = Fully disagree [ ] 2 = Partially agree [ ] 3 = Fully agree [ ] 0 = Abstention	
Scientific basis	The indicator is based on recommendations from an evidence based guideline or studies published in peer-reviewed scientific journals	[ ] 1 = Fully disagree [ ] 2 = Partially agree [ ] 3 = Fully agree [ ] 0 = Abstention	
	It is fully described and defined which clinical service the indicator is covering	[ ] 1 = Fully disagree [ ] 2 = Partially agree [ ] 3 = Fully agree [ ] 0 = Abstention	
	The organizational context and patient population (including any subpopulations) is fully described and defined	[ ] 1 = Fully disagree [ ] 2 = Partially agree [ ] 3 = Fully agree [ ] 0 = Abstention	
	The indicator measures what it is intended to measure (validity)	[ ] 1 = Fully disagree [ ] 2 = Partially agree [ ] 3 = Fully agree [ ] 0 = Abstention	
	The indicator measures accurately and consistently (reliability)	[ ] 1 = Fully disagree [ ] 2 = Partially agree [ ] 3 = Fully agree [ ] 0 = Abstention	
Feasibility	Results from the indicator can be understood and interpreted by the clinical staff	[ ] 1 = Fully disagree [ ] 2 = Partially agree [ ] 3 = Fully agree [ ] 0 = Abstention	
	Data is routinely documented in the clinical setting or the collection of data only requires a minimum of additional effort	[ ] 1 = Fully disagree [ ] 2 = Partially agree [ ] 3 = Fully agree [ ] 0 = Abstention	
	No other data source already exists (register or laboratory system) that will eliminate manual collection of data	[ ] 1 = Fully disagree [ ] 2 = Partially agree [ ] 3 = Fully agree [ ] 0 = Abstention	

[1] Sources: International literature on development and assessment of clinical quality indicators, among others the assessment instruments Qualify (1), AIRE (2) and indicator development in NCQA (HEDIS Measure Development) (14).

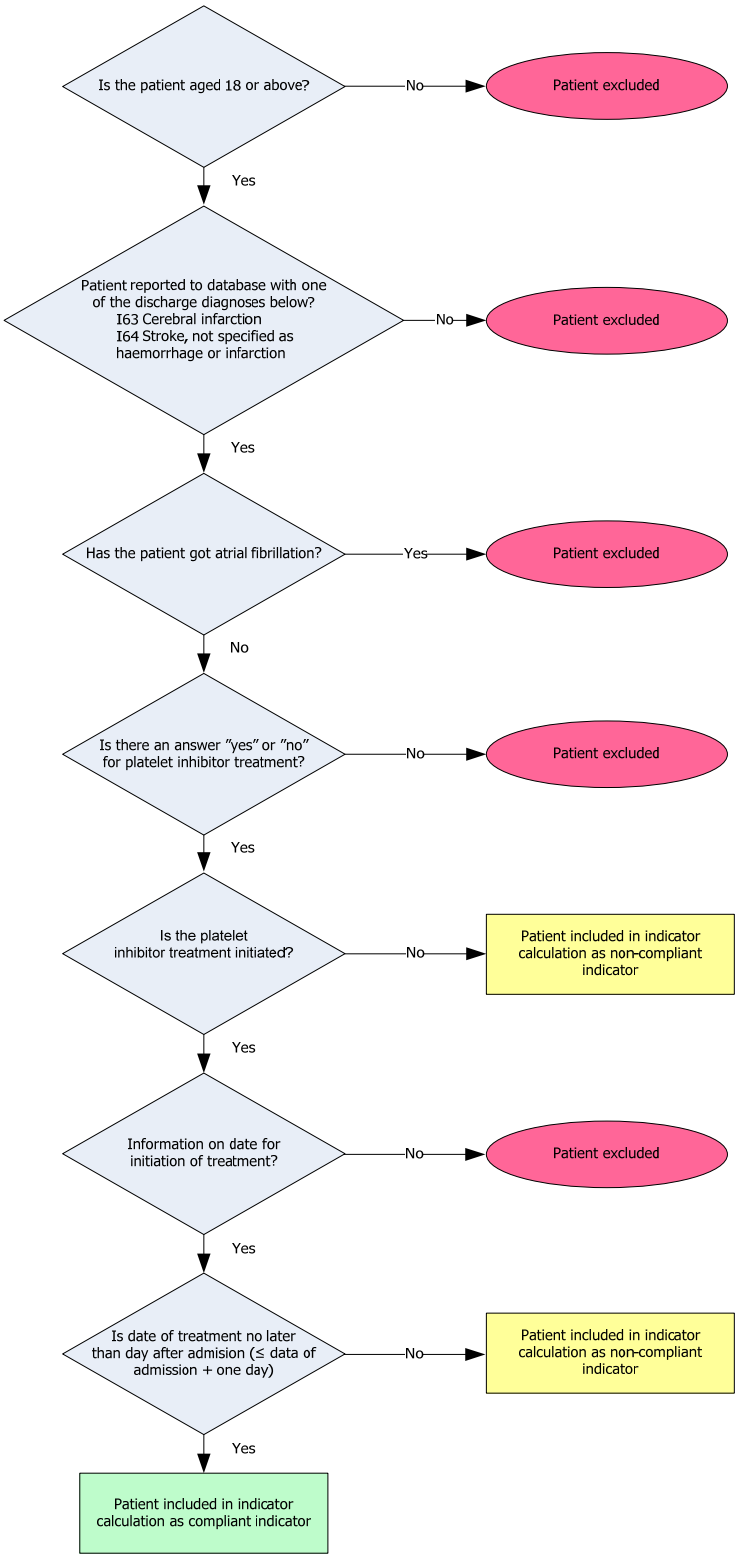
APPENDIX 5. EXAMPLE OF INDICATOR FORM

Standards, indicators and prognostic factors for strokes in The Danish National Indicator Project (May 2008)

Indicator domain	Indicator	Type	Standard
Organisation of treatment and rehabilitation in a stroke unit	Proportion of patients admitted to a stroke unit no later than the day after admission.	Process	Min. 90%
Medical secondary prophylaxis	Proportion of patients with acute ischaemic stroke without atrial fibrillation who get platelet inhibitor treatment no later than the day after admission	Process	Min. 95%
	Proportion of patients with acute ischaemic stroke and atrial fibrillation who get anticoagulant treatment no later than 14 days after admission	Process	Min. 95%
Diagnosis by CT/MR scan	Proportion of patients who have a CT/MR scan on the day of admission	Process	Min. 80%
Assessment by physiotherapist	Proportion of patients seen by physiotherapist no later than the day after admission to assess the scope and type of rehabilitation needed and the date for start of physiotherapy	Process	Min. 90%
Assessment by occupational therapist	Proportion of patients seen by occupational therapist no later than the day after admission to assess the scope and type of rehabilitation needed and the date for start of occupational physiotherapy	Process	Min. 90%
Assessment of dietary risk	Proportion of patients assessed for dietary risks no later than the day after admission	Process	Min. 90%
Water test conducted at admission	Proportion of patients assessed on the day of admission by water test before intake of solid or liquid food to check ability to swallow and aspiration risk	Process	Min. 90%
Ultrasound/CT angiography of neck vessels	Proportion of patients who have ultrasound/CT angiography of neck vessels no later than four days after admission	Process	Min. 90%
Mortality	Proportion of patients who die within 30 days of admission for stroke	Outcome	Max. 15%

[1] When comparing over time across units, adjustments will be made for any differences in distribution of a number of prognostic factors.
[2] The recommended time frame in the reference programme for treatment of patients with stroke is 24 hours. Due to missing registration of exact hour and minute in DNIP Stroke, the indicator value is calculated in terms of the time frames ”On the day of admission” and ”No later than the day after admission”.

APPENDIX 6. EXAMPLE OF AN INDICATOR ALGORITHM[1]



1 Preliminary draft for graphic illustration of indicator algorithm for indicator 2 in NIP Stroke: "Proportion of patients with acute ischaemic stroke without atrial fibrillation, where platelet inhibitor treatment is not contraindicated, who are treated with platelet inhibitor".

APPENDIX 7. LIST OF TERMS ORDLISTE

Algorithm
Set of instructions describing step by step which procedures to carry out to perform a task (22).

Applicability
A clinical quality indicator is applicable if it can be understood and interpreted by the clinical staff, patients and other interested citizens. Applicability also implies that data is available and can be collected without disproportionate use of resources (1).

Audit
Healthcare professionals going through specific processes (patient courses and/or procedures) in order to evaluate the quality of the services provided by the healthcare system. The evaluation is made on the basis of quality targets, and the purpose of the audit is to uncover both satisfactory and unsatisfactory conditions (23).

Feedback
Feedback in this connection refers to reporting results back to the clinical environments and the management of clinical units and hospitals. In the Danish National Indicator Project this reporting takes place both on an ongoing basis through standard reports (monthly or quarterly reports) and annually in national and regional audit reports.

Incidence
The frequency of an incident, e.g. new cases or deaths. May be expressed as incidence rate or cumulated incidence proportion (24).

Indicator
A measurable variable used to monitor and evaluate quality (23). The Danish National Indicator Project uses disease-specific quality indicators, often just referred to as indicators.

Misclassification
Wrong classification of objects, cf. measurement errors (24).

Monitoring (quality monitoring)
Systematic ongoing measuring, documentation and/or evaluation of quality (23).

Patient process
The sum of activities, contacts and events in the health care system experienced by a patient or a defined group of patients in connection with provision of a healthcare professional service (23).

Process
Process refers to activities performed in connection with the healthcare professional services provided to the patient (23).

Prevalence
Population, number of persons characterised by certain properties, e.g. disease at a given time. Often expressed as a proportion: prevalence proportion (24).

Rating
Evaluation, classification (22).

Relevance
A clinical quality indicator is relevant if it catches important aspects of core healthcare professional services, patient courses, health condition or survival (1).

Reliability
An indicator is reliable if the data on which the indicator results are based are reproducible, using a defined measurement method (data collection and analysis) (1).

Outcome
Outcome refers to the patient's achieved health results (23). Standards may be formulated both qualitatively and quantitatively. The Danish National Indicator Project uses quantitative standards.

Standard
The measure for quality that forms the basis of assessment and evaluation of the quality of a service (23).

Structure
Structure refers to the healthcare system's resources and organisation, such as finances, staffing levels, buildings, medical equipment and presence of clinical guidelines (23).

Validity
Here refers to the concept: content validity. If the indicator reflects the theoretical content intended; i.e. if the indicator measures what it set out to measure, then it is valid (1).