



DESCRIPTION OF DANISH REGISTERS

Danish clinical databases: An overview

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Abstract

Introduction: Clinical databases contain data related to diagnostic procedures, treatments and outcomes. In 2001, a scheme was introduced for the approval, supervision and support to clinical databases in Denmark. **Content:** Clinical databases may cover disease entities, specific interventions, or specific activities. **Validity and coverage:** As of January 2011, 59 clinical databases (51 nationwide) are registered as approved by the National Board of Health. The National Indicator Project currently covers eight disease areas, with two more under implementation. **Conclusion: Current challenges for clinical databases in Denmark are outlined.**

Key Words: *Clinical databases, epidemiology, healthcare research, quality of care*

Introduction

Clinical databases contain systematically collected data related to clinical observations, diagnostic procedures, treatments, and outcomes. Occasionally, it may be difficult to distinguish between clinical databases and health registers. However, whereas health registers include routinely submitted data for the purpose of accounting for activities and contacts, clinical databases typically contain supplementary clinical data obtained within the context of patient pathways of specific diseases or health-related interventions.

Many clinical databases have originally been founded and operated by clinicians who have felt a need to know the clinical profile of their patients and the types of interventions and care offered, with associated clinical outcomes. From the perspective of healthcare management, there is an increasing recognition of the need to proper information of the services offered by the healthcare organisations, particularly in relation to aspects related to the quality and clinical outcomes of the services. Simultaneously, the development in information technology has made it increasingly easy to manage

and even exchange person-specific health data without proper safeguards rather than operating the database with the approval and supervision of the central authorities.

By 2001, these trends had prompted the association of the Danish counties (now regions), together with the National Board of Health to introduce a scheme with guidelines for the establishment, management and support to Danish national clinical databases devoted to the monitoring and continuous development of quality of care.

Content

Clinical databases may cover specific disease entities. A clinical database for a chronic disease like diabetes, for example, should contain key information about the lifetime course with diabetes for the patient population covered. This information include: how and when the diagnosis of diabetes was established; at which dates relevant pharmaceutical interventions were commenced (and terminated, as relevant); at which dates relevant signs of specified complications to diabetes were observed for the first time; at which

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dates any interventions against diabetes complications were initiated; any relevant personal and demographic information, including changes in address and date of death, of the registrants.

Other clinical databases concern specific interventions. A clinical database addressing interventions in acute stroke should contain information on all relevant clinical information (including symptoms and manifestations, comorbidity, and severity) as well as data on further diagnostic evaluations, treatments, and measures of rehabilitation, in addition to the clinical outcomes (including recovery or death) within a given follow-up period.

A third group represents clinical databases containing information on the provision of specific activities (like data on all transfusions and all anaesthetic procedures): such databases serve as resources for linkage to databases that cover the underlying diseases and interventions of relevance.

In order to support the operation of approved nationwide clinical databases, about 20 million DKK has been allocated annually. A smaller additional amount of funds have been allocated to the upgrading of databases to up-to-date technology platforms.

The infrastructure of support to the clinical databases also comprises the establishment of a network of three Competence Centers located in relation to the university hospitals in Copenhagen, Aarhus, and Odense, respectively. In order to receive support from the funding scheme, each database is associated with one of the centres which, on a contractual basis, shall provide services in epidemiology, biostatistics, and advice in information technology.

To assist the national and regional health authorities in decisions related to clinical databases, various advisory committees and boards have been formed with representation from the health authorities, including the Danish Regions, the centres of competence and major national scientific associations. Subsequently, steps were taken to establish a formal framework for the clinical databases including a circular issued in 2006 by the National Board of Health with regulations relevant for approving and operating a regional or national clinical database.

The approval of a clinical database is granted on a temporary basis, usually for a 3-year period. Very importantly, for an approved clinical database it is mandatory by law for all relevant clinical units to submit data to the clinical database. Furthermore, the approval implies that informed consent from the patients is not required before submitting their data to the clinical databases.

Table I shows the major authorities and institutions involved with the clinical databases in Denmark with

links to the relevant websites. In parallel, the National Indicator Project (NIP) has been established with the particular purpose of monitoring the quality of treatment and care of selected diseases and conditions of high priority, like lung cancer. While NIP shares the features of clinical databases concerning the collection, management and reporting of data, NIP is characterised by a formal auditing process of the results, with the involvement of regional and hospital-based quality staff and all clinical units of relevance.

It is important to stress that the funding scheme and the formal regulations for the clinical databases concern exclusively the explicit purpose of monitoring aspects related to the quality of care. Thus, a clinical database or any part of a database that might be devoted to research without also serving the purpose of monitoring quality of care will not obtain approval according to the circular of the National Board of Health and will not qualify for support from the general funding scheme established by the Danish Regions.

Validity and coverage

Clinical databases may, in terms of coverage, be restricted to a single hospital or an administratively defined healthcare region or may be national. In Denmark it has been decided that in order to qualify for the term “national clinical database”, the database should cover more than 90% of the true national patient population as defined by specified diagnostic criteria fulfilled within a specified period of calendar time.

For each patient and disease pathway covered by a given clinical database, it is required that the deficit in data shall be less than 10%.

As of January 2011 the National Board of Health lists 59 approved clinical quality databases. Of these, 51 databases are classified as being nationwide, three are classified as regional databases and coverage remains unspecified for five databases. In 2009, 32 nationwide clinical quality databases received support to cover operational costs from the funds controlled by the Danish Regions.

Within the framework of NIP currently, eight diseases and interventions have been considered sufficiently important to be covered by clinical quality databases: Acute surgery (bleeding gastro-duodenal ulcer and perforated peptic ulcer); chronic obstructive pulmonary disease; diabetes; heart failure; hip fracture; primary lung cancer; schizophrenia; and stroke. As part of the NIP programme, each of these areas will be closely monitored periodically and

Table I. Sources of information related to clinical databases in Denmark.

Institution/authority	Type of information	Website ^a
The National Board of Health (Sundhedsstyrelsen)	Legal requirements and administrative procedures for the establishment and approval of clinical quality databases	http://www.sst.dk/
Danish Regions (Danske Regioner)	List of currently approved clinical quality databases Management and requirements related to the national clinical quality databases supported by Danish Regions Links to information on support to clinical quality databases	http://www.regioner.dk/
The Danish National Indicator Project (Det Nationale Indikator project, NIP)	Documentation of quality indicators and auditing processes related to the disease and intervention areas covered by NIP Links to annual reports for the disease areas covered by NIP	http://www.nip.dk/
The Danish eHealth Portal (sundhed.dk)	Quality indicators for various disease and intervention areas for health professionals and lay citizens Listing of currently approved clinical quality databases reports, produced for health professionals and lay citizens Links to reports from the databases, produced separately for health professionals and lay citizens	http://www.sundhed.dk/
The Danish Data Protection Agency (Datatilsynet)	Legal requirements and managerial issues related to obtaining permission to establish registers and databases under the Danish Act on Processing Personal Data that controls the protection of individuals with regard to the processing of personal data and on the free movement of such data	http://www.datatilsynet.dk/
Competence Center for National Clinical Databases, East (KCØ)	Information on databases and activities associated with the Competence Center	http://www.kliniskedatabaser.dk/
Competence Center for National Clinical Databases, North (KCN)	Information on databases and activities associated with the Competence Center	http://kea.au.dk/
Competence Center for National Clinical Databases, South (KCS)	Information on databases and activities associated with the Competence Center	http://www.kcsinfo.dk/

^aContent is only available in Danish for a substantial number of the sites.

with annual auditing of the level and trends in the associated indicators of quality of care. Depression and obstetric care are currently being established with NIP.

The number is unknown with respect to currently active clinical databases that have been established for research purposes exclusively with approval obtained from the Danish Data Protection Agency, but outside the joint regulation and approval system by the National Board of Health and Danish Regions.

Conclusion

Until now, the main focus on clinical databases has been the provision of information needed for the

continuous monitoring of indicators relating to the quality of care.

It has been increasingly recognised that improvements in quality of care cannot be isolated from health research. During the last few years, new advisory committees and management structures have been established to encourage the use of clinical quality databases for research purposes, primarily in the area of cancer diseases. To support this, a range of clinical cancer databases have obtained additional funding.

The field of clinical databases in Denmark has, during the last 1–2 decades, matured from a “pioneering state” to a “state of consolidation”. At the same time, the information technology in the health-care sector has developed rapidly while resources for the support to the databases are becoming

increasingly scarce. In this scenario, the Danish clinical databases are facing a series of challenges:

- How to optimise the use of data available from all established health related registers, as presented elsewhere in this supplementum
- How data from the electronic patient record systems may be used as source wholly or partly for a clinical database
- How to further improve the reporting of results and recommendations from the clinical databases to clinicians, healthcare administrators, decision makers, and consumers
- How to integrate the research potential into the formal regulations and funding schemes of the clinical database.

In order to optimise the infrastructure supporting the Danish clinical databases it has been decided,

with effect from the beginning of 2011, to establish a new nationwide secretariat that shall coordinate the activities of the network of Competence Centers at the same time as a stratification scheme is being developed to assist in the allocation of support that is tailored according to individual needs of each database.

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