

General provisions regarding the Danish Working Hour Database (DAD) - a research database on working hours, well-being and health

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Background

Shift work, including night work, can contribute to work-life imbalance, fatigue and sleep problems, gastrointestinal problems and irritability, among other things. There is also research showing that certain types of shift work is associated with increased risk of reproductive problems and chronic diseases such as cardiovascular disease, cancer, neurological diseases and diabetes. It is therefore important to confirm or refute these associations in new high-quality studies. If there is a link between certain types of working hour schedules and disease, it is also important to investigate how working hours are most appropriately organized and whether there are specific types of working hour schedules without an impact on health and well-being.

Previous studies of the relationship between working hours and illness have a number of limitations related to the operationalization of working hours:

- 1) Often the studies include relatively few individuals with working hours outside of normal daytime work. This limits the statistical power of the studies.
- 2) The time resolution is small. Working hours are often assessed only once or a few times over a working life, and there is rarely information about the changes in exposure that often occur when following individuals over a longer period.
- 3) The description of working hours often lacks details, e.g. a single question about the person's working hours, such as day, evening, night or shift work is used to characterize a lifetime.
- 4) In studies where information about working hours is collected from e.g. questionnaires, there is a possibility of reporting bias.

Finally, low participation in research projects is a problem when collecting individual data in e.g. questionnaire surveys.

Therefore, we are establishing a prospective research database on working hours based on existing registration of working hours in the Danish regions. The name of the database is "Dansk ArbejdstidsDatabase" (DAD). In English, the database is called "The Danish Working Hour Database" (DAD or DWHD).

Purpose of the database

The overall purpose is to establish and maintain a national prospective database with valid and accurate registration of individual working hours. The secondary purpose is to provide the opportunity to describe and investigate possible associations between work environment including working hours, well-being and health and labor market-related outcomes, such as labor market participation and retention. Research that uses DAD for purposes other than this requires explicit

approval from the respective regions. In practice, this is done through the establishment and operation of a database based on existing registers. The database can be supplemented with individual information about well-being and illness, e.g. by linkage to other Danish national registers (e.g. the Central Personal Register, the National Patient Register, the Cause of Death Register or the Cancer Register) or by collecting questionnaire or interview data from the individuals in the database.

Steering committee

A steering committee is established for the research database consisting of senior researcher Johnni Hansen, Danish Cancer Society Research Center, professor Henrik Kolstad, Department of Clinical Medicine, Occupational Medicine, Aarhus University Hospital, professor Åse Marie Hansen, Department of Public Health, University of Copenhagen, and professor Anne Helene Garde, National Research Center for the Working Environment (NFA).

The members of the steering committee can remain in the steering committee as long as they are active in the research field and can resign at will. If necessary, the steering committee can be supplemented with other researchers who are active in the research field. The steering committee appoints a secretary among its members. The secretary role and tasks can rotate among the members of the steering committee. The secretary is responsible for convening meetings and presenting project proposals for approval.

The purpose of the steering committee is to ensure that data from the database are developed and utilized for research with the aim of improving and developing the knowledgebase on working hours and to ensure resources for updating the database.

The steering committee must be presented with project descriptions that describe the background, purpose and method according to usual standards, as well as how applicable rules for the safe handling of personal data are complied with before access to data can be granted.

The steering committee must ensure that the research plans comply with the Declaration of Helsinki and, if necessary, are approved by research ethics committees and relevant bodies for the safe handling of personal data.

The steering committee must coordinate the use of the database so that the projects involve the least possible burden on the participants or their relatives in terms of frequency, scope and content of inquiries, and that it is avoided that several research groups investigate the same research questions.

The steering committee must consider the scientific quality and originality of all new projects and make any proposals for changes to the research plans.

The steering committee shall work towards its purpose and shall strive for consensus in its decisions. The decisions of the steering committee must be supported by a majority of its members. In the event of a member's resignation or indisposition due to illness or otherwise, the remainder of the steering committee shall decide whether to appoint a new member and propose suitable candidates by consensus. The members of the steering committee meet as needed, but at least once

a year, to discuss matters relating to data collection, finances and to process applications for the use of data. Minutes of the group's meetings are taken and subsequently approved by the members.

Advisory board

An advisory board is established with representatives from the regions that provide data to DAD. One or more representatives are invited from each region. "Danish Regions" (an interest organization for the Danish Regions) is also invited to have one or more representatives in the advisory board. The members of the advisory board act as the steering committee's contact person in the regions. The advisory board is informed annually about the status of the research database and associated projects, as well as plans for the coming year. In addition to having access to the latest knowledge, the advisory board also has the opportunity to propose new projects.

In connection with applications for specific projects on data, other advisory board(s) can be established consisting of relevant participants, e.g. from relevant employer and employee organizations.

The data

Data are transferred to NFA, which after cleaning and documentation transfers all data to Statistics Denmark's research service. Data in DAD is, thus, used exclusively for research, cf. the Danish Data Protection Act. Data can be accessed by other researchers via Statistics Denmark's research service after approval by the steering committee.

NFA delivers data to the Danish National Archives (Rigsarkivet). NFA ensures continued availability of the full dataset, and it is possible to hand over the full dataset to other institutions represented in the steering committee at a later date. If it turns out to be relevant to hand over the full dataset to other institutions, a supplement to the cooperation agreement can be made at the given time.

The research database includes:

1. individual information about the employees' daily working hours, including starting and ending times. Furthermore, for each person there is information about job, department, first date of employment and central personal registration number for unique identification of the each individual (see appendix for further details). Working time data are retrieved from relevant sources, e.g. Silkeborg Data and KMD, where it is stored for use when calculating salaries etc. The research database is based on data from 2007-2011, which was available when the database was created in 2012. It can be continuously updated with working time information typical for the past year.
2. individual information obtained by linkage to National health registers. This can be from the Danish Personal Registration System (vital status, marital status, addresses, spouses and children), DREAM (about social transfer income in the case of long-term sick leave and

early retirement), the National Patient Register and the Cancer Register. It can also be information from private companies.

The database can be supplemented with information about well-being and health, for example by linking to other registers or by contacting the individuals in the database using e.g. questionnaires or interviews. Working time data are collected with the permission from each individual region.

All data are stored and processed in accordance with applicable laws and regulations for the secure handling of personal data. DAD is approved by the Danish Data Protection Agency through NFA's general approval from the Danish Data Protection Agency regarding data for research (2015-57-0074) and an internal notification and approval of DAD at NFA (j.nr: 2013-10-11/133).

Access to data

It is possible to apply for the use of data for specific projects. Researchers (including members of the steering committee), who wish to use data, must apply in writing. Researchers can gain access to data when their application has been approved by the steering committee and collaboration agreement has been signed. This is based on the guidelines described below.

How to apply

Persons employed at recognized research institutions who wish to use data must submit an application containing the following:

1. Title of the project
2. Short description of the background for the project (incl. relevant references)
3. The aim of the project
4. Plan for the analysis including which variables and expected number of cases, where relevant.
5. More detailed description of the requested data e.g. variables, year, population
6. Description of collection of new data, where relevant
7. Description of research group incl. CV for project leader and other researchers with central roles.
8. Description of the research collaboration incl. suggestion for steering committee and/or contact person.
9. Time schedule
10. Plan (or status) for funding and any potential conflicts of interest
11. Plan for publications incl. authors if possible

Research sub-projects must comply with the submitted research protocol and new studies based on the provided data may not be initiated without permission from the steering committee.

New sub-projects are presented by the secretary of the steering group for approval. Upon presentation, members of the steering committee can sign up to be active in sub-projects.

General provisions

Other researchers can access DAD via Statistics Denmark's researcher service after permission from NFA.

Use of data must be approved by the DAD steering committee. In collaboration with the leader/PI of each sub-project, the steering committee decides how the sub-project is best implemented within the framework of the overall research plan for the research database.

No new sub-projects may be initiated on data outside the purpose and framework of the applied sub-project without the steering committee's permission. Data may not be disclosed or transferred to third parties without permission from the steering committee.

If a sub-project involves the collection of new data as a result of contact with participants, the steering committee must receive a copy of the necessary approvals before the collection is initiated.

Contact with individuals in the DAD beyond what is described in the protocol must not take place without authorization from the steering committee.

Sub-projects must inform the steering committee annually about the status and progress of the project. In the event of lack of progress or if the sub-project leader/PI is absent, the steering committee, in collaboration with the responsible institution, must initiate measures to complete or terminate the project.

If a sub-project is not progressing satisfactorily scientifically or in terms of collaboration, the steering committee may choose to discontinue the collaboration and possibly refer the dispute to the The Danish Board on Research Misconduct. If the collaboration is terminated, the sub-project manager must delete the data provided as soon as possible.

Completion of sub-projects

When a sub-project is completed, all data provided must be deleted. Any new data are returned to the database.

The sub-project has the right to use data collected in the project throughout the project period and for three years after the project has ended. After this, the data will be handed over to the steering committee so that the data can be made available to other researchers. Exceptions to this rule can be applied for if the sub-project is still active.

The steering committee does not transfer data from a sub-project to other researchers as long as the research project is active and complies with approved schedules.

Economy

If possible, the regions pay for the extraction of their own data from Silkeborg Data/KMD. Alternatively, the costs can be covered by research funding.

It is the responsibility of the steering committee to obtain resources for establishment, operation, linkage to registers and data analysis. It is thus the steering committee's responsibility to ensure that there are sufficient resources to cover expenses in relation to update of data before this is initiated.

The costs of a sub-project are covered by the sub-project. For each sub-project, the steering committee determines an amount for each subproject to help cover the costs of 1) creation and maintenance of DAD and 2) hourly wages for work in connection with a specific sub-project.

Publications and presentations

All publications will be prepared according to the principles of good scientific practice as set forth by the International Epidemiological Association, January 2007 and in full compliance with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Journals, February 2006 (Vancouver Rules) (www.icmje.org).

Publications using data must be submitted to the steering committee and at least one steering committee member must be included as a co-author. For each new sub-project, the steering committee will appoint one or more contact persons from the steering committee. This person(s) must be a member of the project group of the sub-project and be co-author(s) on publications, with the understanding that they will be given the opportunity to fulfill the co-authorship requirements of the Vancouver Rules.

All manuscripts must be approved by at least one contact person from the steering committee before submission to a scientific journal. The contact person(s) is responsible for commenting on manuscripts within an agreed time frame, usually max. 2 weeks. On special occasions, e.g. normal vacation periods, the deadline can be extended to 4 weeks. A copy of manuscripts (including abstracts) that are based on results from a sub-project must always be submitted to the steering committee.

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