Opportunities for student nurses to collect empirical data in the Capital Region

Approved by the Clinical Committee of the Capital Region,
29 February 2016

Contents

Introduction

The Bachelor's Degree Programme of Nursing alternates between theoretical teaching and clinical training. Both forms of learning involve the students writing assignments and projects that include various forms of empirical material.

This material may include data from patients and their medical records, data about the patient from relatives and other healthcare professionals, and data collected via observation studies and other methods. The different forms of data collection require different types of permission, as this document attempts to explain.

As part of the clinical training, students will write assignments in three areas within the parameters of the Danish Health Act: somatics, psychiatry and primary. The following is therefore based on the Danish Health Act. The term "patient" is used irrespective of which of the three areas is being referred to.

Collecting empirical data as part of own practical work, where consent is implied by the patient's consent to the treatment

Under the terms of the Ministerial Order on the Danish Health Act (Consolidated Act no. 1202 of 14/11/2014) section 15[(1)], no form of treatment can be initiated or continued without the patient's informed consent. Informed consent may be written, oral or implied. The patient is entitled to withdraw consent at any time.

Under the terms of the Ministerial Order on the Danish Health Act (Consolidated Act no. 1202 of 14/11/2014), section 41(2), (1) and (7), healthcare professionals may, with the patient's consent, disclose information about the patient's health, other purely private matters and other confidential information to other healthcare professionals, including student nurses:

1. when it helps provide care in cases/situation where the student acts as an assistant[2]

[1] In the case of minors or patients who permanently lack the ability to grant informed consent. In these situations, parents or guardians must consent to the treatment.

[2] *A professional authorised under the Danish Act on Authorisation of Health Service staff and Healthcare Companies (the Authorisation Act) can delegate all forms of healthcare, cf. the Authorisation Act 1(3) to an assistant. A licensed healthcare professional may decide that no further delegation of responsibility may take place. The authorised healthcare professional must ensure that the assistant is qualified for the work concerned and has received instruction in how to carry it out (Section 3).*
In hospitals, clinics, nursing homes and other similar institutions, the management is responsible for ensuring that instructions are available for professionally acceptable delegation of responsibilities, including that assistants receive instruction and training in delegation. (Ministerial Order on Authorised Healthcare Professionals' Use of Assistants, Order no. 1219 of 11/12/2009).
The clinical supervisor/nurse who delegates the work to the nursing student is responsible for selecting the

assignment, providing instructions and supervising the work.

2. when it is necessary for the student's understanding of the treatment situation without acting as an assistant, or for the evaluation of the student's participation in the treatment situation.

If the student takes part in a care and treatment situation as an assistant/observer[3] , they may as part of their training process data that has been observed and collected in order to understand the situation and assess the care (reference).

Students who are affiliated to a clinical training site, i.e. registered via civil registration number and study data, can collect data and/or obtain data relating to the patients/the group of patients with whom they work as assistants/observers without obtaining further consent.

If the student's studies focus on a particular area of nursing, e.g. oral hygiene, their work may involve selected patients across the department/area. As such, they may play a part in the patients' care as assistants/observers, and therefore also have access to the patients' journals.

Written presentations for internal exams based on care situations/cases where the student act as an assistant/observer do not require additional consent, cf. the Health Act Section 41(2) 7.

Students have a duty of confidentiality, regardless of whether they take part in a course of treatment as assistants or as
observers. The data must always be anonymised and all legal guidelines must be complied with .

Collecting empirical data that requires (additional) informed consent, where the student is affiliated to the clinical training site

In some cases, additional consent may be needed even if the student is affiliated to the clinical training site.

Collecting own empirical data as part of the clinical training, using interviews/questionnaires

Where it is relevant and justified to collect data via interviews/questionnaires, consent must be obtained in the following situations (see the appendix on obtaining consent):

- Interviewing patients, where the student acts as an assistant/not as an assistant, and where the collection of data does not affect the actual treatment situation
- Interviewing patients in the ward/area, where the student does not participate as an assistant/observer
- Interviewing nurses or other healthcare professionals
- Interviewing relatives.

[3] Observer: The student is present but does not play an active role in the situation.

Collecting own empirical data as part of the clinical training, using participant observations

Observations by nurses and other healthcare professionals included as empirical data require informed consent (see the appendix on obtaining consent).

Collecting empirical data as part of clinical practice, via nurses at the clinical training site

Nurses with responsibility for care have the option to supply generalised data on patients under their care where it is relevant to the nursing problem the student is researching as part of the internal exam.

Collecting empirical data when the student is not affiliated to the clinical training site

If the student is not affiliated to the clinical training site concerned, then all forms of data collection will require informed consent, except in the following situations:

- If the student is appointed to act as an assistant to collect data on behalf of a development and quality-assurance coordinator. It is up to the member of staff responsible to ensure that the student has the relevant permissions to the gather data.[4]
- If the student is appointed to act as an assistant to collect data on behalf of a PhD student.

It is up to the individual responsible to ensure that the student has the relevant permissions to the gather data.4

Collecting empirical data that does not require consent

Consent is not required to use empirical data in PhD dissertations, scientific articles, nursing databases, clinical guidelines, other guidelines, instructions, policies, vision statements, strategies and objectives for nursing care, patient guidance, leaflets, posters or charts.

The procedure for obtaining informed consent from patients and healthcare professionals in connection with empirical data collection

The reasons for collecting the data must be discussed with the supervisor, who must approve and sign the plan.

[4] In the Capital Region of Denmark, the declaration of consent must clearly state that the patient gives

permission to pass on health information for quality-assurance activities in the region.

The student will then request permission in writing from the manager or the person responsible for healthcare at the clinical training site. The manager's approval must be attached to the subsequent information material supplied to the target group (patients, relatives, nurses, or other healthcare professionals).

The student is responsible for drawing up the information material, which must cover the following:

- A description of the purpose of the assignment/project and preliminary problem statement
- The voluntary nature of participation and the options for withdrawing without consequences
- Anonymity and confidentiality
- How data will be used (e.g. in quotes) and archived
- Any risks or potential discomfort associated with participation
- Who to contact with any questions or problems.

Before collecting the empirical data, the student must go through the information material with the informant, who must sign a consent form (Appendix xx).

The consent form must be kept in the department and shredded once the assignment has been assessed.

Anonymity and confidentiality

The Nursing Programme Management Network (2013) wrote about anonymity and confidentiality:

"Health and other personal information concerning patients and relatives of patients is confidential and must be treated accordingly.

Students are responsible for processing and storing the collected data in such a way that confidentiality and anonymity are maintained. As e-mail is considered an open form of communication, it must not include personal data or information on patients, relatives, departments or healthcare professionals.

Both during the writing process and in the final assignment/project report, students are responsible for ensuring that information about health and treatment, as well as other personal information, is anonymised.

Anonymisation involves removing names, civil registration numbers, occupations, addresses, hospital names, names of local authorities, etc. Other information may be sufficiently specific that it has to be removed or altered in order to avoid identification of the patient. In other words, it must always be impossible for others to identify the patient.

The student is covered by the Danish Public Administration Act's rules on professional secrecy (the Danish Public Administration Act, part 8, section 27, Ministerial Order no. 988 of 09/10/2012). The anonymised "patient information" is considered as anonymous health and treatment data. This means that the

information can be used for teaching purposes without infringing the duty of confidentiality.

The students are responsible for shredding the data material (e.g. interview printouts, medical records, etc.) three weeks after they complete/pass the assignment or exam. This means that interview printouts must not be attached in appendices to submitted assignments, exams, etc.

Assignments and projects that are covered by the legal guidelines are based on anonymised information, and can therefore be published or made public (Kristensen 2011, p.136)" (The Nursing Programme Management Network, 26 February 2013).

The Danish Act on Processing of Personal Data

The Danish Act on Processing of Personal Data (Act no. 429 of 31/05/2000) is the main piece of legislation governing how and when personal data may be processed.

The Danish Act on Processing of Personal Data applies to private companies, associations and organisations, and to all public sector bodies.

As a general rule, the Act applies to all forms of electronic processing of personal data. It also applies to manual processing of personal data in registers or any other structured set of personal data, i.e. any type of information about an identified or identifiable individual.

Any data processed must be relevant, adequate and not comprise more than is necessary to fulfil the purposes for which it was collected and the purposes for which it will subsequently be processed.

Under the Act, personal data must, as a general rule, be reported to the Danish Data Protection Agency. However, the Act specifies several exceptions to the obligation to notify.
From 15/05/12, student projects and theses, etc. written as part of professional bachelor programmes are exempted when the data subject expressly grants their consent.
Additional information is found in Ministerial Order no. 410 of 9 May 2012:
http://www.datatilsynet.dk/blanketter/privat-sektor/forskning-og-statistik/forskning-og-statistik-vejledning

Forms used to provide patients with information and for obtaining consent

The forms below are designed specifically for providing information and granting consent:

- Procedure when collecting empirical data (from the patient, relatives and the nurses concerned) (Appendix 1)
- Application to the clinical training site regarding data collection for assignments and projects (Appendix 2)

- Information in connection with participation in assignments/projects (Appendix 3)
- Declaration of consent – assignments and projects (Appendix 4)

References

Ministerial order on Authorised Healthcare Professionals' Use of Assistants, no. 1219 of 11/12/2009, the Ministerial Order on Professional Bachelor Programmes in Nursing, no. 29 of 24/01/2008 Ministerial order amending the Order on the Exemption to the Notification Obligation, no. 410 of 09/05/2012
Ministerial Order no. 1202 of 14/11/2014. The Ministerial Order on the
Danish Health Act (Consolidated Act no. 988 of 09/10/2012). The Public
Administration Act (Consolidated Act no. 429 of 31/05/2000). The Danish Act
on Processing of Personal Data
Guidelines no. 161 of 16/09/1988 on Information, Consent and Disclosure of Health Information, etc. (the Nursing Programme Management Network, 26/02/2013). Legal guidelines for the collection of patient data for use in assignments and projects
Kristensen, Kent, 2011. *Sundhedsjura. Gads Forlag:* (4th edition).

Appendices

Appendix 1

Procedure for collecting empirical data

Source: *Juridiske retningslinjer for indsamling af patientdata til brug i opgaver og projekter* (Legal guidelines for the collection of patient data for use in assignments and projects) (http://kurh.dk/Retningslinjer/Juridiske+retningslinjer+for+udveksling+af+patientdata). Written by Ulla Gars and Anne V. Schmidt, 30 January 2013

If the informant is a patient

1. Discuss empirical data collection with the supervisor, who must sign and approve the plan	Appendix 2
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2. Submit a written request to your manager or the healthcare professional responsible at the clinical training site (subsequent approval must be enclosed with the information material provided to the patient)	Appendix 2
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3. The manager or the individual responsible obtains the patient's oral permission for the student to approach the patient	
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4. Draw up information material for the patient, including a description of: a. the purpose of the project and a preliminary problem formulation b. The voluntary nature of participation and the options for withdrawing without consequences c. Anonymity and confidentiality d. how data will be used (e.g. in quotes) and stored e. potential risks and discomfort associated with participation f. who to contact with any questions or problems.	Appendix 3
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5. The student informs the patient and the information material is reviewed	
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6. The patient signs the informed consent form, which must be kept in the department and shredded once the assignment has been assessed (after the exam)	Appendix 4

If the informant is a relative

1. Discuss empirical data collection with the supervisor, who must sign and approve the plan	Appendix 2

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2. Written request to manager or the healthcare professional responsible at the clinical training site (approval must be enclosed with subsequent information material)	Appendix 2

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3. The manager or individual responsible obtains oral permission from relatives (as well as the patient) for the student to approach them

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4. Preparation of Information material for the patient and relatives, including a description of: a. the purpose of the project and a preliminary problem formulation b. The voluntary nature of participation and the options for withdrawing without consequences c. Anonymity and confidentiality d. how data will be used (e.g. in quotes) and stored e. potential risks and discomfort associated with participation f. who to contact with any questions or problems.	Appendix 3

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5. The student informs both parties and the information material is reviewed

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6. The relatives and patient sign the informed consent form, which must be kept in the department and shredded once the assignment has been assessed (after the exam)	Appendix 4

If the informant is a nurse or other member of staff

These guidelines are more stringent than the official guidelines, which do not require informed consent when the informant is a health-service employee. The Department of Nursing at Metropolitan University College wishes to offer employees the same opportunities for protection as are afforded to patients and their relatives.

1. Discuss empirical data collection with the supervisor, who must sign and approve the plan	Appendix 2

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2. Written request to manager or the healthcare professional responsible at the clinical training site (subsequent approval must be enclosed with the information material to the informant)	Appendix 2

↓

3. Preparation of information material for the informant, including a description of: a. The purpose of the project and a preliminary problem statement b. The voluntary nature of participation and the options for withdrawing without consequences c. Anonymity and confidentiality d. How data will be used (e.g. in quotes) and stored e. Potential risks and discomfort associated with participation f. Who to contact with any questions or problems.	Appendix 3

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4. Discuss the information material with the informant

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5. If the informant is required to comment on specific patients, each patient must give informed consent by signing a consent form, which is stored in the department and must be shredded once the assignment has been assessed (after the exam)	Appendix 4

Appendix 2.

Application to the clinical training site for permission to collect data in connection with the assignments and projects in/on:

In the period:_____
Assignment/project:_____
Purpose:_____
Problem formulation:_____

Data-collection method: (insert X)

Interviewing individuals	
Group interviews	
Questionnaire	
Observation	
Other	

Participants: (describe types and numbers)

	Which group?	How many?
Professionals		
Patients in a specific ward or with a specific diagnosis		
Others		

Information for participants:

	When?	Who notifies?
Oral information is given		
	When?	Who by?
Written information is given		

Kind regards,

Name and student

number: Educational

institution:

E-mail address and telephone no.:

The above has been approved by

Supervisor (teacher): _____
Educational institution:_____
E-mail address and telephone no.:_____
Supervisor's signature: _____

The manager responsible for clinical training:

I, the undersigned hereby approve the above application:

Date:_____Name:_____

I, the undersigned, cannot approve the above application Date:

_____Name:_____

Appen

Information about participation in assignments and projects on the the Bachelor's Degree Programme of Nursing

Date:_____

I am a student nurse at the University College: _____

As part of my studies, I am in the process of producing an assignment/project that deals with (briefly describe the purpose and problem statement).

For this purpose, I need to make contact with (number of patients), who I will (describe the examination method in brief)

I would like to request that you participate in the assignment/project on the following conditions:

- Your participation would be voluntary, and you may withdraw at any time. If you withdraw, none of the information you have provided will be used.
- All information will be treated as confidential and anonymous.
- Information used as part of the assignment/project will be stored safely until the assignment/project has been completed. All information will then be deleted/destroyed.
- There are no risks associated with participation in the assignment/project.

If you have any questions or problems regarding your participation, please contact: (insert details of contact person).

If you would like to participate, please sign a consent form. This will be kept in your journal at the department.

Kind regards,

_____

(Name of student(s))

The supervisor is:
Name:_____
Signature: _____

Work phone no.: _____

Work e-mail: _____

Appen

Declaration of consent in connection with assignments/projects as part of the Bachelor's Degree Programme of Nursing

In respect of the assignment/project:_____

Written by: _____

The purpose of the assignment/project: _____

The problem formulation:_____

I hereby consent to my participation in the above assignment/project. For these purposes, my information etc. may be used by the student(s) writing the assignment/project.

I have been informed that:

1. Participation is voluntary, and that refusing to participate will not have any consequences
2. I can stop participating at any given point in time
3. No information will be passed on to any other party in a form that allows me to be identified
4. Confidential information will be deleted/destroyed after the exam has been completed
5. No risks are associated with participation in this project.

Date: _____

Name: _____

Signature: _____

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An example of a declaration of consent covering multiple parties.

KØBENHAVNS KOMMUNE
Sundheds- og Omsorgsforvaltningen
Lokalområde Amager
Mobil Studieunit

Declaration of consent

Shorter periods spent in hospital and the greater use of outpatient treatment increase the need to coordinate how people are treated across sectors and units. The City of Copenhagen would like to develop good services for the public in relation to the coordination of interventions and rehabilitation. We will, therefore, be working with Metropolitan University College to study ordinary people's encounters with the healthcare system.

The focus will be on how coherent they find the rehabilitation processes. This may involve collaboration between the training centre, outpatient clinic, social and healthcare workers in the home or GPs. The study will be conducted by students from occupational therapy, physiotherapy and nursing courses on Module 13 at Metropolitan University College.

The purpose is to improve the content of these study programmes so that they are in line with the needs of the citizen in the health service of the future. The data collected will be analysed and then used to develop both the practical and theoretical parts of the programme.

We would like to ask if you would, therefore, be prepared to allow one or two students to visit your home, spend a few hours with you and accompany you to the outpatient treatment or during any other form of contact you have with the health service.

Participation is voluntary and you will always be able to withdraw your consent.

Students and teachers are bound by confidentiality and all personal information will be treated confidentially and securely. All data will be processed in anonymised form, even if it is used when preparing for the final bachelor exam.

If you have any questions in connection with the project, please contact the senior lecturer for occupational therapy [redacted] or the programme co-ordinator [redacted].

Yes, I give my consent for students to visit me in my home in weeks 37, 38 and 39, to accompany me on visits to my GP, outpatient clinic or other health service facility, and to observe and learn about my case.

Date:_____

Name:_____

Civ. reg. no.:_____

Signature:_____

Contact: [redacted], tel.: [redacted], e-mai[redacted]