



## Instruction for coding of variables in the pilots in Renewing Health

This document describes how the different variables (e.g. information on age, sex, number of bed days for each patient) in the pilots in Renewing Health should be coded in the local data bases. Thus, the purpose is to make sure that data are coded similarly in order to make analysis of data from several pilots or clusters possible.

Overall, it is the responsibility of the local pilot teams to secure that all data are recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification. At the same time the pilot teams must secure that the confidentiality of data that can identify the patients are protected, respecting the privacy and confidentiality rules in accordance with the regulatory requirements.

### General rules for coding of variables

All pilots must comply with the following general rule for coding of the variables:

- Yes-No questions are coded: Yes = 1, No = 2
- If a respondent refuse to answer a question: Enter 8 or, 88 or 888 etc.
- If a questions has not been asked: Enter 9 or 99 or 999 etc.
- Always use numbers in coding of answers: 1, 2, 3,... (even when the answers are not naturally ordered)
- Always begin coding of answers with: 1
- If questions are scaled: Generally, sign the lowest value to “not agree” (or similar) and highest value to “agree”
- Remember to include a variable with identification number of the patient

These rules are generally in accordance with the coding of the minimum demographic data set described in the appendix. Most of the questions and the coding of the responses are based on similar questions in the questionnaire from a WHO project “Step approach to chronic disease risk factor surveillance (STEPS), see [www.who.int/chp/steps](http://www.who.int/chp/steps)

## SF-36

With regard to coding of the patients answers to the questions in SF-36, the pilots must use the coding described in the SF-36 v2 questionnaire.

### Patient acceptability questionnaire

The coding of the questions in the patient acceptability questionnaire (from the NHS England Whole System Demonstrators programme) is the following:

- 6 = Strongly agree
- 5 = Moderately agree
- 4 = Mildly agree
- 3 = Mildly disagree
- 2 = Moderately disagree
- 1 = Strongly disagree
- 88 = Refused
- 99 = missing answer

The coding of the answers is made easy by use of the same coding for all questions in the acceptability questionnaire. However, in the analysis of the data and the estimation of the Likert Scale it should be noticed that most statements in the questionnaire are positive, but a few (no. 2, 5, 8, 9, 12, 18, 20 and 21) are negative. For these questions new variables should be produced were the coding should opposite (e.g. 1 = strongly agree) and these new variables should be used in the calculation of the additive Likert scale.

### Economic aspects

Description of how the economic aspects of the telemedicine applications should be assessed in each pilot can be found in the guideline “Six important steps in the estimation of the economic aspects of telemedicine applications in Renewing Health” (submitted to the pilot teams in October 2010) and the document “Definition of minimum data set for all pilots in Renewing Health” (submitted in November 2011).

As these documents describes each pilot must collect information about each patient’s use of a number of resources (at patient level) in order to be able to carry out statistical analysis of differences between the intervention and control group.

When entering the economic data into a data base each pilot team must remember to have separate variables for the use of resources (e.g. number of minutes used by nurses, number of utensils used, number of admissions, bed days, GP visits, visits to emergency departments) and the costs of the resources (e.g. the costs of use of staff or the costs of admissions).

## Organisational aspects

In the document “Definition of minimum data set for all pilots in Renewing Health” (submitted in November 2011) it is described how the perception of the health care professionals of the telemedicine application can be assessed by answering ten questions.

These ten questions are open ended because the telemedicine applications and the role of the health care professionals vary from cluster to cluster. Generally, qualitative methods are expected to be used to collect the answers to the questions and often the number of respondents will be quite low, because the number of health care professions using the telemedicine applications in the pilots is limited.

As an example, the collection and analysis of qualitative data on the perception of the health care professionals in cluster 4 is described here:

- Comparison of the common outcomes from the three randomised trials that are qualitative will be done by using the case-study comparative method, which means identifying common themes that are described in focus group interviews with health care professionals.
- The interviewees will be all members of staff that have been participating in delivering the telemedicine services. The interviews will be semi structured and thus follow a set of predetermined subjects (the ten questions) and recorded on tape. The interview guides will be similar in the three trials. Completed sentences will be transcribed, common themes identified and used for coding and coded categories will be included. The final choice of categories will be compared for the three trials in order to identify similarities and differences.
- The methods is described further in Neuman, WL (2004). *Social research methods. Qualitative and quantitative approaches*. Fifth ed. Allyn and Bacon: USA.

It should be noticed that data on use of resources, e.g. the use of time by nurses and medical doctors in the intervention and control group, also can be used to describe the organisational aspects. Instructions for coding of these variables are described above in the section about economic aspects.

## More information on data management

More information on data management in accordance with the Good Clinical Practice (GCP) guidelines can be found in a report from European Clinical Research Infrastructures Network

ECRIN: GCP-compliant data management in multinational clinical trials ([http://www.ecrin.org/fileadmin/user\\_upload/public\\_documents/About\\_ecrin/downloads/ECRIN\\_Report\\_D10\\_Vers1\\_final\\_150908.pdf](http://www.ecrin.org/fileadmin/user_upload/public_documents/About_ecrin/downloads/ECRIN_Report_D10_Vers1_final_150908.pdf)). The document includes a number of recommendations for data management, e.g.:

- Recommendations for data entry:
  - List authorized personnel
  - User training with instruction/guidelines
- Recommendations for data processing:
  - Data only accessible to authorized personnel
  - Data handler familiar with GCP
  - Keep data secure and confidential in accordance with regulatory requirements and the informed consent of the patients

- Data validation and quality:
  - Describe data validation plan
  - Check missing, illogical and inconsistent data
  - Documentation of all data checks
  - If data is transformed it should always be possible to compare the original data with the processed data (e.g. if a variable is grouped, always save the original data)
- Data archiving:
  - Data must be archived securely
  - Patient identifiers should not be archived with clinical and other outcome data
  - Use standard formats for archiving

Generally, the pilot teams should follow guidelines for management of data from clinical trials. However, it should be noticed that even though the pilots in Renewing Health all have the same minimum data set, they are based on different protocols and collect information from patients in different ways. Therefore, a number of the recommendations in the report by ECRIN cannot be met in Renewing Health.

### Appendix. Coding of minimum demographic data set in each pilots

Question	Response and coding
Cluster no.	1 = cluster 1 2 = cluster 2 3 = cluster 3 4 = cluster 4 5 = cluster 5 6 = cluster 6 7 = cluster 7 8 = cluster 8 9 = cluster 9
Country	1 = Austria 2 = Denmark 3 = Germany 4 = Greece 5 = Finland 6 = Italy 7 = Norway 8 = Spain 9 = Sweden
Intervention or control group	1 = Intervention 2 = Control group
Diagnosis of the patients in the cluster	1 = Diabetes 2 = COPD 3 = CHF
Demographic data on each patient	
Date of birth	DD-MM-YYYY
Gender	1 = Male 2 = Female 9 = Missing answer
What is the highest level of education you have completed?	1 = No formal schooling 2 = Less than primary school 3 = Primary school completed 4 = Secondary school completed 5 = High school completed 6 = College/University completed 7 = Post graduate degree 88 = Refused 99 = missing answer
What is your present marital status?	1 = Never married 2 = Currently married 3 = Separated 4 = Divorced 5 = Widowed 6 = Cohabiting 88 = refused 99 = missing answer
Which of the following best describes your <b>main work</b> status over the past 12 months?	1 = Government employee 2 = Non-government employee 3 = Self-employed 4 = Non-paid 5 = Student 6 = Homemaker

	7 = Retired 8 = Unemployed (able to work) 9 = Unemployed (unable to work) 88 = refused 99 = Missing answer
How many people older than 18 years, including yourself, live in your household	Number of people _ _ 88 = Refused 99 = Missing answer
<b>OTHER MEASURES</b>	
Do you currently smoke tobacco products <b>daily</b> ?	1 = yes 2 = No 8 = Refuse 9 = Missing answer
During the past 12 months <b>how frequently</b> have you had at least one alcoholic drink?	1 =Daily 2 = 5-6 days per week 3 = 1-4 days per week 4 = 1-3 days per month 5 = Less than once a months 88 = Refuse 99 = Missing answer
Your height is?	In centimetres (cm) _ _ _ 888 = Refuse 999 = Missing answer
Your weight is?	In kilograms (kg) _ _ _ 888 = Refuse 999 = Missing answer
Have you been diagnosed with other diseases?	1 = Heart diseases 2 = Cerebrovascular disease 3 = Dementia 4 = Chronic pulmonary disease, incl. COPD 5 = Connective tissue disease or rheumatic disease 6 = Ulcer disease 7 = Liver disease 8 = Diabetes 9 = Hemiplegia 10 = Renal disease 11 = Cancer 12 = AIDS 13 = Other 88 = Refuse 99 = Missing answer
Are you familiar with using a personal computer (PC)?	1 = yes 2 = No 8 = Refuse 9 = Missing answer
Are you familiar with using a mobile telephone?	1 = yes 2 = No 8 = Refuse 9 = Missing answer