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Schupp, Jürgen; Behrens, Johann; Kröger, Hannes

Veröffentlichungsversion / Published Version
Arbeitspapier / working paper

Kröger, Hannes; Schupp, Jürgen; Behrens, Johann

Working Paper

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RatSWD Working Paper, No. 237

Provided in Cooperation with:
German Data Forum (RatSWD)

Suggested Citation: Kröger, Hannes; Schupp, Jürgen; Behrens, Johann (2014) : Unlocking further potential in the National Cohort study (NaKo) through comparability with the German Socio-Economic Panel, RatSWD Working Paper, No. 237, Rat für Sozial- und Wirtschaftsdaten (RatSWD), Berlin

This Version is available at:
http://hdl.handle.net/10419/96504

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237

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Hannes Kröger, Jürgen Schupp, and Johann Behrens

April 2014

Federal Ministry of Education and Research

Working Paper Series of the German Data Forum (RatSWD)

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Unlocking further potential in the National Cohort study (NaKo) through comparability with the German Socio-Economic Panel

Hannes Kröger[1,2], Jürgen Schupp[2,3], and Johann Behrens[4]

[1] *European University Institute, Florence*

[2] *Socio-Economic Panel Study (SOEP) in the German Institute for Economic Research (DIW), Berlin*

[3] *Institute for Sociology, Freie Universität Berlin (FUB), Berlin*

[4] *Medical Faculty, Martin-Luther-University, Halle*

***Corresponding author**:*
Hannes Kröger
Department of Political and Social Sciences
European University Institute
Via Giovanni Boccacio 121/111
50014 San Domenico di Fiesole / Italy
Tel. [+39] 055 4685 475

Acknowledgements:
We would like to thank Andreas Stang and Deborah Anne Bowen for valuable comments on previous drafts of this paper.

Abstract

Background: The National Cohort (Nationale Kohorte = NaKo) will be one of the largest cohort studies in Europe to include intensive physical examinations and extensive information about the socio-demographic background and behavior of the subjects. However, regional selectivity of the study and potential learning effects due to the panel structure of the data present challenges for researchers using it.
Methods: We discuss the two problems and show how they might lead to potential biases when trying to obtain results from the National Cohort that are representative for the total population of Germany. We suggest that the long-running German Socio-Economic Panel Study (SOEP) should be used as a reference data set for population means and as a control sample for detection of learning effects ("panel effects") induced by information about the results of individual medical examinations.
Results: We present a wide range of topics and indicators which are available in both the German Socio-Economic Panel Study (SOEP) and the National Cohort (NaKo). These items can be harmonized to make the datasets comparable. The range of topics that overlap between SOEP and NaKo include socio-demographic variables, general indicators, socio-psychological environment, and to a limited extent biomarkers.
Conclusion: Harmonizing certain survey item batteries from the NaKo to the SOEP standard can yield a great deal of additional research potential. This holds true both for researchers mainly interested in the NaKo data and for those mainly interested in the SOEP.

Key points

- Regional selectivity and learning effects in the National Cohort can be analyzed by using a reference data set: the Socio-Economic Panel (SOEP) Study
- Conclusions for healthy policy based on the National Cohort can more easily be generalized to the total population of Germany living in private households
- Harmonizing survey items between SOEP and NaKo would make it possible to validate and improve health-related survey questions in the SOEP

Keywords

National Cohort, NaKo, German Socio-Economic Panel Study, SOEP, survey, study design, health surveys

Introduction

Large-scale cohort studies on health have a long tradition and are important sources of data for epidemiological and public health research. In Germany, a new ambitious project is about to be launched in this area. The National Cohort (*Nationale Kohorte*, NaKo) will be the largest cohort study in Germany to have intensive physical examination, blood and urine examinations, and extensive information about the socio-demographic background and behavior of the subjects. The study will encompass 200,000 men and women aged 20-69 years. Every 5 year, there will be a follow-up study in which participants will be examined again. Additional postal follow-ups are planned every 2-3 years after the first examination. The intensive medical examinations require the subjects to be interviewed and screened in one of 18 medical study centers, which take part in the NaKo.[1]

However, two challenges arise due to the complex study design. The first challenge is the regional selectivity of the NaKo, meaning that only residents who live fairly close to a study center are eligible to participate. The sampling process is therefore not a random sample of the total population of Germany. However, the sampling design enables at least representativeness for the 18 regions of the study centers. The second challenge are the potential learning effects arising from the panel design, meaning that some results of the intensive medical examinations, which are available to the participants, could influence their subsequent health behavior. This might have a more than marginal influence on the results of the follow-up studies. Thus the NaKo could be characterized as an intervention study without a control group (such as BASE II).

In this article, we propose a means of transforming these two challenges into great research opportunities. NaKo has several areas that overlap with research areas in the well-known Socio-Economic Panel Study (SOEP), a multi-cohort longitudinal study with a strong reputation in the social and behavioral sciences. Systematic comparisons between the two studies would be possible if the shared concepts were measured with the same survey items. This would allow researchers to estimate potential selectivity of the regional sampling of the NCS and, at the same time, test the reliability of a wide range of self-reported health indicators in the SOEP using the results of the medical examinations. A second major advantage of making NaKo and SOEP comparable is that it would be possible to measure the impact of the medical screening “intervention” on health and health behavior using the SOEP population as a control group.

The rest of the article is structured in the following way. First, we describe the two challenges of the NaKo research design. In a second step, we show that using comparable survey items is an effective means of addressing these challenges and stimulating additional research. Third, we present the overlapping concepts between the two studies and discuss which indicators should be measured using SOEP survey items. The last section concludes.

Methods - Two challenges and an elegant solution

Looking at the scope and the immense investment of the NaKo, it stands to reason that the research community, policy makers, and the broader public all want to (and might) draw conclusions from the NaKo that can be generalized to the whole population of Germany. Generalizable results are much easier to interpret, especially for those who are unfamiliar with issues of sampling and statistical inference. Further, high external validity is an important argument for a cohort study like the NaKo compared to a series of clinical trials.[2,3]

Unfortunately, without a random sample of the total population of Germany, or – at least – a close approximation of a random sample (which is usually the reality), this generalization to the German population is not possible. The sample of the NaKo is not a random sample of the German population. It consists of an age- and sex-stratified sample within certain areas, which are close to the 18 medical research facilities where the screening is conducted. For instance, residents from the federal state of Hesse are not part of the NaKo because there is no study center nearby. Another factor that may have an influence on the representativeness is the fact that invited people who are willing to participate have to come to the study center. This approach has been undertaken in all population-based cohort studies in Germany (RECALL, DGS, SHIP, KORA, CARLA, GHS).

Within the KORA cohort study, a comparison of participants and non-participants who were willing to undergo at least a short questionnaire repeatedly showed that people with comorbidities are less likely to participate.[4] Within the Heinz Nixdorf Recall Study, a comparison between participants and nonparticipants revealed that nonparticipants were more often current smokers than participants and less often belonged to the highest social class. Living in a regular relationship with a partner was more often reported among participants than nonparticipants.[5] In addition, consent to medical examinations within surveys has been shown to be higher among the more highly educated and those who display better health behavior.[6]

The questions we want to raise are: Does the sampling method used in the NaKo make the study population systematically different from the total population of Germany? What influence does the sampling design have on prevalence estimates of risk factors and diseases at baseline examination? What influence does the sampling design have on effect measures estimates for exposure-outcome relations during follow-up? Does this constitute a problem, and what can we do about it? Without an independent reference study, there is no way to address this issue empirically. Researchers would remain stuck in survey methodological debates without data to support any of the various positions. To address these issues, we suggest using the SOEP as a reference data set.

The SOEP is one of the largest and longest-running ongoing annual household panel studies in the world.[7] As a household panel, the SOEP is a multi-cohort study. It started in 1984 and covers topics ranging from economic and working conditions and household characteristics to physical and mental health.

The SOEP survey includes both the original household members in households that are selected in a two-stage random sampling process and new household members (children, move in, etc.). New household members and splitting of households are traced and reflected in the SOEP weights.[8,9] The SOEP also provides cross-sectional and longitudinal weights that account for survey- and specific group-related dropout rates. These weights follow an inverse selection probability weighting scheme. The selection probability is estimated using extensive demographic and regional data provided by the German Federal Statistical Office. Applying these weights allows researchers to make statements based on the SOEP data that are representative for the general population of Germany living in private households.[10,11] At the moment over 12,000 households and more than 20,000 individuals participate in the SOEP. Several important studies have already used the SOEP as reference data set for methodological purposes[12] or to compare specific populations to the general population with respect to a certain characteristic – for example, comparing risk attitudes[13] in members of parliament and the broader population, or comparing social and educational outcomes in twins in the multi-cohort-study TwinLife. A study evaluating the representativeness of the Berlin Aging Study II (BASE-II) shares many similarities with our proposal in this article.[14]

The SOEP team actively encourages the use of its core questionnaire as base for other surveys. Almost none of the SOEP questions fall under any kind of copyright restrictions.[12] The long tradition and high quality of the SOEP, the sizable literature in survey methodology

based on the SOEP, together with the successful comparison studies already conducted should facilitate the construction of similar questions in NaKo.

Using the SOEP as a reference would allow for investigation of whether the NaKo deviates significantly in terms of socio-demographic and health related characteristics from a well-established standard data set in German social (including health) reporting. These deviations might not only be due to sampling but also to other problems in either the SOEP or the NaKo (e.g. survey questions). A comparison of the two presents a great opportunity for validation of the SOEP as well.

In addition to uncertainty about representativeness, there is a second challenge with the research design of NaKo. One important incentive of the NaKo is to provide study participants with some results of the medical investigation they undergo. While this is a sound strategy both from an ethical and from a survey methodological point of view, it might also present a problem. The medical examinations and the information the individuals receive go beyond what is normally given to patients by their doctors. Therefore, we ask whether this constitutes a form of unintended intervention in the National Cohort. If respondents become aware of certain health risks, they might change their health behavior or seek further medical counsel or treatment. It is unclear how this would influence the results of the follow-up studies. Participants of the follow-up studies could become systematically different from persons in the population who do not get feedback on their health status. This “intervention” could have different effects on different groups of respondents. Several results from the literature suggest that more highly educated individuals transfer information about health problems more efficiently into preventive health behavior.[15,16] In the context of the medical screening for the NaKo participants, this might generate a heterogeneous treatment effect of unknown size.

The “intervention” can be investigated using the longitudinal nature of the SOEP, whose participants can be seen as a control group for the NaKo (as SOEP is the control group for BASE II).

The SOEP does not provide medical screening, which means that no external information about respondents’ health is available to them in the SOEP – in contrast to the NaKo. The scale of the NaKo provides an unprecedented test of the effectiveness of medical information in improving health and health behavior. The advantage lies in the exogenous nature of the examination. Study participants do not have to actively search for medical advice and they do

not have to pay for it. A scientific comparison of trajectories of health and health behavior would look at participants of the NaKo as the treatment group and the participants of the SOEP as the control group in an intervention study. Furthermore, sub-groups of the NaKo would undergo even more intensive physical examination, including MRTs. This would yield two different treatments allowing researchers to assess a broader spectrum of medical examinations as type of interventions.

In the follow-up studies to the NaKo, changes in health and health behavior of NaKo participants could then be compared to changes in health and health behavior of participants of the SOEP using a classical difference-in-difference approach.[17]

Finally, comparisons of NaKo and SOEP require the questionnaire of SOEP and NaKo to be as similar as possible in those areas that are included in both studies. Items that could be harmonized between SOEP and NaKo are listed in Table 1.

Results - Indicators in NaKo and SOEP

In this section, we describe the set of constructs from the SOEP that will be part of the NaKo as well. Our suggestion is that the survey items should reflect the overlap in content between the SOEP and the NaKo by using the same wording and response categories.

For each set of variables, we explain how the SOEP has implemented it in the questionnaire and point out how the NaKo questionnaire can incorporate the identical questions to make the two data sets as similar as possible. We give short examples of how the comparison can be carried out for each item set.

Table 1 has a list of constructs that are part of the SOEP and that will be part of the NaKo as well. In addition, the appendix includes the exact formulation of the items in the SOEP as they should appear in the NaKo.

Socio-demographic variables

As planned in the NaKo, the SOEP has information on migration background. Here, the SOEP asks subjects where they and their parents were born (Germany or abroad), so that first- and second-generation immigrants can be identified as well as ethnic Germans who immigrated to Germany from the former USSR or Poland. Regarding family status, both surveys will have items on marital status, number of children, number of siblings, and partnership status. Information on socio-economic background is available for the respondents (education, occupation, wealth, and income) and their parents (education and occupation). To obtain a more detailed view of the labor market situation, respondents answer an open question providing precise classification of occupations and industries (e.g., ISCO-88/08 or KLDB92/2010, NACE Rev. 1.1).

Health

The SOEP includes screeners (all self-reported) for chronic diseases including diabetes, coronary heart disease, cancer, respiratory illness, stroke, migraine, arthritis, rheumatism, depression, and dementia. The SOEP does not offer detailed information beyond these self-reports. Therefore it is important to make sure the starting question in NaKo is identical to the SOEP so that the prevalence of different health conditions can be compared. Detailed results from the NaKo make it possible to test the reliability of self-reports and to estimate the degree of measurement error compared to intensive medical screening. Researchers in different

disciplines who have to rely on self-reports could use the results to assess reliability. Survey questions could also be altered if they were found to be too unreliable.

A second important set of health items deals with health behavior. Smoking and alcohol consumption (wine, beer, spirits, and mixed drinks) are surveyed in the SOEP by asking respondents how often they consume alcohol and whether and how many cigarettes they smoke per day. The same items can be used in the NaKo. The SOEP questionnaire also asks how often the interviewees went to the doctor in the previous 3 months. Even if more detailed questions are used in the NaKo, a similar starting question should be used. This would enable the reliability of standard survey items to be tested against the results of the NaKo, which is especially important in this area, where effects of social desirability on response are possible [18]. SOEP respondents also state how many days they were on sick leave or hospitalized in the previous year. While a question about hospitalization will also be asked in the NaKo, sick leave has not been mentioned explicitly in the NaKo's scientific concept. However, this is an important link between the individual's health, health behavior, and labor market situation and is of special interest to all social epidemiologists. It should therefore be included in the NaKo given its ease of implementation.

The NaKo will collect information about birth weight and breastfeeding retrospectively, because the respondents have already reached adulthood. The SOEP contains questions about these two indicators of child health in the mother-child questionnaire. Here, it would seem that the SOEP might be especially useful as a reference data set, because rather than surveying respondents retrospectively in adulthood, it collects this information a few months after the child's birth, thereby avoiding recollection bias. In addition, mothers are asked to provide the child's height and weight, allowing derivatives such as BMI to be calculated in both data sets.

Finally, subjective evaluations of health are included in both data sets. Satisfaction with health is captured with an 11-point scale in the SOEP as is satisfaction with sleep. In the NaKo, satisfaction with health will be one item from the WHOQOL-BREF instrument, measured on a five-point scale. In this case, it makes sense to deviate from the SOEP reference, as it would break up the WHOQOL-BREF instrument, which relies mostly on five-point Likert scales. The SOEP question can be reduced to a comparable five-point scale. The same is true for satisfaction with sleep.

The number of hours a person usually sleeps is part of the SOEP and will also be part of the NaKo in the form of a single item from the Pittsburgh Sleep Quality Index (PSQI).

Psychosocial and environmental factors

A great strength of the NaKo and SOEP is the wide range of variables they contain in addition to standard socio-demographic variables and explicit health instruments. These include psychosocial instruments for the measurement of work-related stress, effort-reward imbalance (ERI)[19], and personality traits – the Big Five.[20] Both are standardized items and are therefore easy to compare across the samples.

Additionally, there is information about pollution in the areas where the residents live. It is collected using geo-referenced remote sensing of the household address. A comparison of the two studies provides a basis for assessing the question of whether the NaKo is systematically different with regard to pollution. This is important because the NaKo does not cover all parts of Germany equally and this could systematically correlate with reduced or increased environmental strain on the subjects.

Biomarkers

The number of bio-markers in the SOEP is limited but exists in subsamples. Besides the non-invasive method of grip strength measurement, a saliva sample has been taken from respondents in a pretest sample. For the collection, a new method combining buccal swap and mouthwash was developed, which yielded very good results with regard to high concentration of DNA with a high degree of purity.[21] Analysis of similarity between the NaKo and the SOEP would provide precious evidence about generalizability, reliability, and comparability of biomarker information in surveys. This is a very new field of research, which bears significant potential for the future.[22,23]

Discussion

The NaKo has immense potential for health service research, clinical epidemiology, nursing science, medical cohort analysis, and public health analysis. Yet doubts remain as to whether the sample will be representative of the German population. Therefore, a reference data set should be used to evaluate whether age- and sex-standardized prevalences of risk factors and diseases in the NaKo are similar to prevalences in the SOEP. In this article, we showed on the one hand that the longitudinal nature, the large degree of overlapping content, and past experiences make the SOEP the best choice for a reference data set because it combines a high-quality sample and no-copyright questionnaire suitable to test sampling or indicator-related irregularities in the NaKo. On the other hand, the medical screening in the NaKo allows assessing the reliability of comparable SOEP items.

In addition, and equally important, using SOEP survey items in the NaKo allows researchers to evaluate in the NaKo follow-up studies whether there is an intervention effect of the medical screening on their subjects.

We therefore welcome the effort of the NaKo, to implement at least some items of the SOEP core questionnaire so that comparisons of prevalences between NaKo and SOEP will become possible.

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Table 1 – Concepts in NaKo which should be measured comparable to SOEP

Socio-demographic Characteristics
Migration background
Place of birth (Germany or abroad)
Marital status
Partnership
Number of children
Education (own, partner, parents)
Occupation (own, parents)
Income
Number of siblings
Occupational classifications
Industry of the employer

Health indicators
Diabetes
Coronary heart disease
Cancer
Respiratory illness
Stroke
Migraine
Musculoskeletal system disease
Depression
Dementia
Hospitalization
Doctor visits
Weight/Height
Birth weight, breast feeding, adoption
Subjective well-being (Satisfaction with life and areas of life)
Satisfaction with health
Satisfaction with sleep
Hours of sleep
Smoking
Alcohol consumption
SF-12

Psychosocial & Environmental Factors
Effort-Reward Imbalance
Big Five
Regional air pollution

Biomarkers
Grip strength
Saliva sample