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## Original Research

# Linking primary study data with administrative and claims data in a German cohort study on work, age, health and work participation: is there a consent bias?

C. Stallmann<sup>\*</sup>, E. Swart<sup>a</sup>, B.-P. Robra<sup>b</sup>, S. March<sup>c</sup>

Institute of Social Medicine and Health Economics, Faculty of Medicine, Otto-von-Guericke-University Magdeburg, Magdeburg, Germany

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## ABSTRACT

**Objectives:** We analysed the degree and impact of consent bias in the prospective study 'leben in der Arbeit (lidA)' after linking primary interview data with claims data from German statutory health insurance funds as well as with administrative data provided by the German Federal Employment Agency.

**Study design:** Prospective cohort study.

**Methods:** Within two study waves (2011, 2014) primary data were collected based on computer-assisted personal interviews. During interview informed consent to data linkage was obtained. We used binary logistic regression analyses with participants' consent for record linkage as the dependent variable calculating odds ratios (ORs) and 95% confidence intervals (95% CIs) for independent variables. Several sociodemographic, socio-economic and work-related factors were modelled as potential determinants of consent.

**Results:** A total of 4244 participants took part in both waves. After excluding invalid consent, 4178 participants were included in the analysis. About 3918 (93.8%) of these participants gave their consent to link their primary data with data from at least one source. Within regression analyses only moderate bias was found due to region of residence, apprenticeship, professional affiliations, income and number of diseases. Participants from former West Germany were less likely to have their study data linked with both data sources (OR 0.63 [95% CI 0.42–0.96]) than those from the former East Germany. Participants with no information on income were more likely to refuse consent to both data sources compared to the reference group (net income: under EUR 1000; OR 0.15 [95% CI 0.08–0.30]). Respondents with two (OR 1.37 [95% CI 1.06–1.77]) or three and more diseases (OR 1.30 [95% CI 1.02–1.66]) diagnosed by a doctor agreed more frequently to linking both data sources than participants without disease. There is just a small proportion of variance in

<sup>\*</sup> Corresponding author. Institute of Social Medicine and Health Economics, Faculty of Medicine, Otto-von-Guericke-University, Leipziger Strasse 44, D-39120, Magdeburg, Germany. Tel.: +49 391 67 24 321.

E-mail addresses: [christoph.stallmann@med.ovgu.de](mailto:christoph.stallmann@med.ovgu.de) (C. Stallmann), [enno.swart@med.ovgu.de](mailto:enno.swart@med.ovgu.de) (E. Swart), [bernt-peter.robra@med.ovgu.de](mailto:bernt-peter.robra@med.ovgu.de) (B.-P. Robra), [stefanie.march@med.ovgu.de](mailto:stefanie.march@med.ovgu.de) (S. March).

<sup>a</sup> Tel.: +49 391 67 24 306.

<sup>b</sup> Tel.: +49 391 67 24 300.

<sup>c</sup> Tel.: +49 391 67 24 323.

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consenting explained by the models ( $R^2$ : 0.063–0.085). Also, only small changes of factors' prevalence were observed in consenters.

**Conclusions:** For the first time in Germany, the lidA-study links primary survey data with health claims and administrative employment data. We conclude that there is only a minor relation between the analysed factors and consent behaviour of the participants. A linked data set may be used in further analyses without substantial biases.

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## Introduction

The option of linking primary data with information from existing data sources within the scope of epidemiological studies is used increasingly in Germany. For example, within the research framework of KORA (Cooperative Health Research in the Region Augsburg) two studies linked administrative data of statutory health insurance funds (SHI) with the primary survey data. The first study evaluated the healthcare costs of allergic diseases, the second the economic efficiency of acute myocardial infarction therapy.<sup>1,2</sup> The Study of Health in Pomerania (SHIP) linked primary survey data with data from clinical patient records, claims data and reports of physicians as well as death certificates in order to compare different stroke outcomes.<sup>3,4</sup> The aim of linking such data is to utilise the synergy of both primary and administrative data (in Germany mostly administrative employment data and claims data from social insurance carriers).

The use of these data implies high data protection requirements, however.<sup>5</sup> Mandatory provision of information for obtaining the participants' written informed consent presents a logistic challenge. If several data sources are to be linked, information must be provided and the participants' written consent obtained for each data source separately. The German cohort study on work, age, health and work participation "leben in der Arbeit" links, for the first time in Germany, study data with (a) statutory health insurance claims data (SHI data) and (b) employment data provided by the Institute for Employment Research (IAB) of the German Federal Employment Agency (IAB data).<sup>6</sup> While the employment data contain information on employment histories, unemployment benefits and participation in labour market programmes,<sup>6,7</sup> the SHI data contain detailed information on inpatient and outpatient care, incapacity to work, pharmaceutical prescriptions as well as prescriptions of non-pharmaceutical therapies and technical aids.<sup>8</sup> Actually there are 113 SHIs in Germany.<sup>9</sup> Beside the written consent of the study participants a cooperation agreement must be concluded with each insurance company separately and the supervisory authority of the SHIs must agree to get access to the SHI data.<sup>8,10</sup>

The lidA-study closes the gap with other countries that have used data linkage for several years.<sup>11</sup> Primary data concerning aspects of work, health and work participation were collected in two study waves (2011 and 2014) based on computer-assisted personal interviews (CAPI). Because of the detailed information about the participants health and their

employment history contained in the SHI and employment data, those aspects have been kept short within the interview. Nevertheless, both administrative data sources have a supplementary nature within lidA. All core questions can be answered using the primary data. From the addition of the administrative data we expect to gain more detailed information on diseases causing incapacity for work and their burden within certain occupations.

As part of the CAPI, three written informed consents were obtained from participants in a multistep process, the consent to participate in a panel, for linkage of the IAB data with the survey data and linkage of SHI data with the survey data. First, the need to consent was explained during the CAPI. The written consent was requested subsequently to the interview in the order participation in a panel, IAB data and SHI data.<sup>6,12,13</sup>

This process may be prone to a consent bias. Previous studies which also used linkage of primary data with data from different other sources, mostly claims data, examined several factors that potentially influence the consenting behaviour, among other factors age and gender,<sup>2,14–23</sup> region of residence,<sup>14,16–22</sup> migrant background/ethnicity,<sup>15–18,20–23</sup> level of education/qualifications,<sup>16–22</sup> family status,<sup>16–20,22</sup> income,<sup>14–18,21,23</sup> (subjective) health status,<sup>17,18,22,23</sup> self-reported health problems<sup>17,18,23</sup> and the utilisation of medical services.<sup>2,16–18,22</sup> As a result, direction and size of effects differ.

Within the framework of this research, the paper aims to identify potential determinants of the willingness to give consent to data linkage within the lidA-study. Also, the analysis provides estimates of consenting bias. First representativity and selectivity analyses found only a minimal bias within the primary data,<sup>13,24</sup> so we expect that only minimal bias within the SHI and IAB data can be traced back to the consent behaviour.

## Methods

The lidA-study focuses on employees born in 1959 and 1965 who were paying mandatory social security contributions as of December 31, 2009. The sample was taken from the IAB's 'Integrated Employment Biographies'.<sup>6</sup> During the first wave, 6585 persons participated in lidA (response rate 27.3%). Of these, 74.7% ( $n = 4921$ ) gave written consent for IAB data. Of 6265 participants who were insured by a SHI, 55.2% ( $n = 3640$ ) gave their written consent for SHI data. While 5618

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