

English version of "Externe Qualitätssicherung der ersten Welle der Studie zur Gesundheit Erwachsener in Deutschland (DEGS1)"
 Bundesgesundheitsbl 2013 · 56:637–642
 DOI 10.1007/s00103-013-1685-6
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External quality assurance of the first wave of the German Health Interview and Examination Survey for Adults (DEGS1)

Introduction

In accordance with the management concept of the Robert Koch Institute (RKI), the quality assurance (QA) strategy for the first wave of the German Health Interview and Examination Survey for Adults ("Studie zur Gesundheit Erwachsener in Deutschland", DEGS1) comprised two pillars, namely an international QA and an external QA. Following a restricted tender process, the Leibniz-Institute for Prevention Research and Epidemiology–BIPS in Bremen was commissioned to perform the external QA.

The German Health Interview and Examination Survey for Adults (DEGS) is part of the health monitoring programme at the Robert Koch Institute (RKI). The concept and design of DEGS are described in detail elsewhere [1, 2, 3, 4, 5]. The first wave (DEGS1) was conducted from 2008–2011 and comprised interviews, examinations and tests [6, 7]. The target group was persons aged 18–79 years residing in Germany. DEGS1 has a mixed design which permits cross-sectional and longitudinal analysis at the same time. For this purpose, a random sample from the population registration office was supplemented by former participants from the 1998 German National Health Interview and Examination Survey (GNHIES98). A total of 8,152 persons, including 4,193 first-time participants (response rate 42%) and 3,959 former participants in GNHIES98 (response rate 62%), participated in the survey. In all 7,238 persons attended one of the 180 study centres, and 914 were surveyed by means of interview only. The

net random sample [5] permits representative cross-sectional analyses and trend statements for the age group 18–79 years based on comparison with GNHIES98 (n=7,988, including 7,116 in study centres).

External quality assurance

According to Guideline 5 (Quality Assurance) of the Guidelines and Recommendations of the German Society for Epidemiology (DGEpi) to Ensure Good Epidemiological Practice (GEP), quality assurance of all relevant instruments and processes in epidemiological studies should be guaranteed. In addition, it is also recommended that a review be conducted to determine whether quality assurance should be performed by an external person or institution, particularly in the case of large-scale long-term studies [8].

The remit of external quality control for DEGS1 was to conduct an independent review of the internal quality assurance measures and to ensure compliance with the quality requirements for the study through systematic observation and random checks. External quality assurance was considered an integral part of the study, and the findings of the quality control were incorporated in the survey process to improve overall quality.

In line with the terms of its contract, external QA reviewed the training of study personnel, fieldwork, measurements and questionnaire data, random sampling and utilisation as well as the databases. In practice, this involved the com-

pilation of checklists and inspection plans for the above areas. The process entailed assessment not only of measurable criteria but also of subjective factors, such as appearance of the study personnel and the support provided to the participants at the study centre. The criteria for assessment were derived from the procedures and processes outlined in the operation manual.

Procedures for the quality assurance of staff training and examination routines

First, the operation manual was checked for compliance with ethical principles and adherence to the DGEpi guidelines for good epidemiological practice (GEP). Particular attention was paid to ensuring that the survey procedures (e.g. recruitment of study personnel, training measures, conducting of interviews and taking of measurements, internal quality assurance measures and data management) were described in sufficient detail.

Quality control by external QA during the training measures for survey personnel was designed to promote procedural optimisation of internal quality assurance. To this end, the programmes, concepts and manuals for training of survey personnel were evaluated. The same applied for follow-up training and other measures which were supposed to minimise inter- and intra-staff variations and avoid observer trends. External QA also assessed the criteria used by the RKI with regard to selection, support and task-based assessment solutions for the survey person-

Tab. 1 Example of inspection plan: workplace of study centre interviewer

Greeting/collection of urine/support questionnaire		
	Ok	Not ok, see comment
Friendly atmosphere, centre interviewer shows an interest	o	o
Interviewer can adequately answer participants' questions	o	o
Workplace well arranged, interviewer has prepared documents	o	o
Explanation of study procedure: explained in sufficient detail, not too complicated	o	o
Interviewer asks for vaccination/allergy card, copies it or hands over SAE and asks participant to copy it	o	o
Sample container labelled with issue number	o	o
Explanation of how to provide midstream urine sample	o	o
Explanation of how to handle sample container	o	o
Interviewer can provide adequate assistance in completing the questionnaire	o	o
Interviewer complies with editing instructions when correcting the questionnaire	o	o
Data protection: participant documents are not visible to third parties	o	o

Tab. 2 Example of inspection plan: measurement of participant height

Measurement of height		
	Ok	Not ok, see comment
Easy-to-understand explanation for participants	o	o
Equipment number documented	o	o
Staff number documented	o	o
Participants undressed down to underwear, in socks (disposable socks if required)	o	o
Hairbands hairclips etc. that can influence measurement removed beforehand	o	o
Participants stand up straight, heels touching, feet slightly apart, arms hanging loosely at their side	o	o
Heels, buttocks and shoulder blades lightly touching the measuring bar	o	o
"Frankfort plane" position maintained	o	o
Precise measurement, noted with 0.1 cm accuracy in the measurement sheet	o	o
Documentation of special circumstances in the measurement sheet	o	o
Comments: _____		

nel. Two initial training courses, including certification of the survey personnel, and three follow-up training courses were assessed.

Monitoring of fieldwork was in the form of visits to the sample points and data processing and management sites. After observing survey routines in the study teams, external QA provided feedback to internal QA. The concept provided for two unannounced visits a year per study team at different times of the year as well as visits to the data and sample storage sites. The visited sample points were selected to allow observation of study teams in different regions and sizes of communities under comparable conditions. All in

all, visits were made to 12 sample points during which the room layout, technical processes and the time-based sequence and scope of the individual elements were reviewed.

During the one to two-day visits to the sample points, the work routines were observed and assessed using an inspection plan (■ **Tab. 1** and ■ **Tab. 2** show excerpts from the inspection plan).

The inspection plan covered the following areas:

- greeting/urine sample collection/support/instructions on completing questionnaires,
- measurement of blood pressure/pulse,
- blood sample collection,

- measurement of bodyweight/height,
- measurement of waist/hip circumference,
- medical interview,
- thyroid volume ultrasound,
- cycle ergometry,
- functional tests for participants aged 65 and over,
- medication interview,
- final medical consultation,
- blood and urine processing/urine analysis using test strip,
- bidding farewell,
- study centre check (servicing of equipment, emergency exit and rescue plan etc.) and
- day centre sheet check (opening hours, team composition, room conditions).

The checks and inspections covered the condition of examination rooms, the appearance of staff, communication with participants, measures to rule out mistaken participant identity, final checking of the self-administered questionnaires, monitoring of physical examinations and measurements, the review of documentation sheets and measurement records for completeness, the taking, processing and storage of biosamples, compliance with data protection guidelines, adherence to stipulated standards and time schedules during data collection, documentation of equipment checks, room temperature, data and material transfer and the handover of this documentation to the management team at the RKI. This process culminated in the compilation of an inspection report and where necessary included an outline of recommendations for improvements of study processes which were forwarded to internal QA in a timely manner.

Training courses and site visits

External QA supervised the initial training and certification of the survey teams and submitted a written report to the RKI with its comments. The three follow-up training courses were also observed and monitored. External QA was performed by two employees of BIPS with longstanding experience in the organisation and implementation of sur-

veys and quality assurance in the field of data collection.

Quality assurance for sampling and response

As part of the external QA, the RKI regularly forwarded details of the percentage of non-responders and the number of quality-neutral sample losses to BIPS; for assessment purposes, a distinction was made between first-time invitees (11,008) and participants who had already been part of the GNHIES98 sample (7,124).

Quality-neutral sample losses

Quality-neutral sample losses are generally defined as non-contacts for which the interviewers or respondents are not responsible (deceased, moved abroad or no longer traceable) and which therefore do not have any distorting effect on the representativeness of the random sample. Occasionally—and this was also the case with DEGS1—inadequate language skills are also assigned to this category of losses [9].

Before invitations were sent out, 569 former GNHIES98 participants had been identified as having died or moved abroad or as being no longer traceable. Of the remaining 6,555 potential participants, a further 197 were assigned to the quality-neutral loss category, resulting in a total quality-neutral loss percentage of 10.8% for former GNHIES98 participants. The corresponding figure for the group of first-time invitees was 9.6%. A specific breakdown of quality-neutral sample losses in DEGS1 can be found in Kamtsiuris et al. [5]. Compared to the German Health Interview and Examination Survey for Children and Adolescents (KIGGS; sample loss: 4.7%), the Nixdorf Recall Study (4.8%), the Study of Health in Pomerania, SHIP (10.8%) or GNHIES98 (12.3%), the percentage of quality-neutral sample losses in DEGS1 was as expected; see also [10].

Response

The response rates were 62% among the former GNHIES98 participants and 42% for first-time invitees. The RKI took a number of measures to promote accep-

Bundesgesundheitsbl 2013 · DOI 10.1007/s00103-013-1685-6
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Abstract

The quality management concept for the first wave of the German Health Interview and Examination Survey for Adults (DEGS1) included in addition to conducting internal quality assurance (QS) also the supervision by an external independent institute. After a restricted tendering procedure, the Leibniz Institute for Prevention Research and Epidemiology–BIPS was commissioned to conduct the external quality assurance. The external quality control included the review of the operation manuals, the training of the field staff, the execution of field work (including mea-

surements), and the monitoring of sampling, response and data management. For the realization of the controls in these areas, test criteria were developed to reveal shortcomings early and to give recommendations for the internal quality assurance. This paper briefly describes the concept and the execution of the accompanying external quality assurance with regard to the above mentioned areas.

Keywords

Health survey · Fieldwork · Response · Data management · Quality assurance

Externe Qualitätssicherung der ersten Welle der Studie zur Gesundheit Erwachsener in Deutschland (DEGS1)

Zusammenfassung

Das Qualitätsmanagementkonzept für die erste Welle der Studie zur Gesundheit Erwachsener in Deutschland (DEGS1) umfasste neben einer internen Qualitätssicherung (QS) durch das RKI auch eine externe Qualitätssicherung (QS) durch ein externes unabhängiges Institut. Zur Durchführung der externen Qualitätssicherung wurde das Leibniz-Institut für Präventionsforschung und Epidemiologie – BIPS GmbH nach einem beschränkten Ausschreibungsverfahren beauftragt. Die externe QS beinhaltete die Prüfung des Operationshandbuchs, die Schulung des Untersuchungspersonals, die Supervision der Feldarbeit (einschließlich der Untersu-

chungsabläufe), die Beobachtung der Stichprobenziehung und Ausschöpfung sowie die Kontrolle des Datenmanagements. Seitens der externen QS wurden Prüfpläne erarbeitet, um frühzeitig Fehlentwicklungen aufdecken zu können und Empfehlungen für die interne Qualitätssicherung auszusprechen. Im vorliegenden Beitrag werden das Konzept und die Ausführung der begleitenden externen Qualitätssicherung hinsichtlich der oben genannten Bereiche beschrieben.

Schlüsselwörter

Gesundheitssurvey · Feldarbeit · Response · Datenmanagement · Qualitätskontrolle

tance among study participants which were also geared towards promoting support from the scientific community: these measures included targeted press and PR activities in the local media, radio interviews, the deployment of preparatory fieldworkers responsible for recruitment, as well as the creation of a project website and publication of articles in special-interest journals. Through these measures, what had been a modest response in the first few months was successfully boosted by the end of the first year of the study and thereafter maintained at a relative constant level. A further slight increase in response rates was achieved towards the end of the study by staging targeted training courses for preparatory fieldworkers

and increasing remuneration for participants from 30 to 40 €.

Stratified analyses were performed in order to assess the influence of factors like age, sex, size of community on response. No differences were found between men and women or between eastern and western Germany (■ Fig. 1).

In contrast, there were minor to moderate deviations with regard to willingness to participate based on size of community (the bigger the community, the poorer the response) and age, with below-average response rates in the age group of 30–39 year olds and among people aged 80 and above [5]. Moreover, considerably lower response rates for non-Germans were observed among first-time invitees

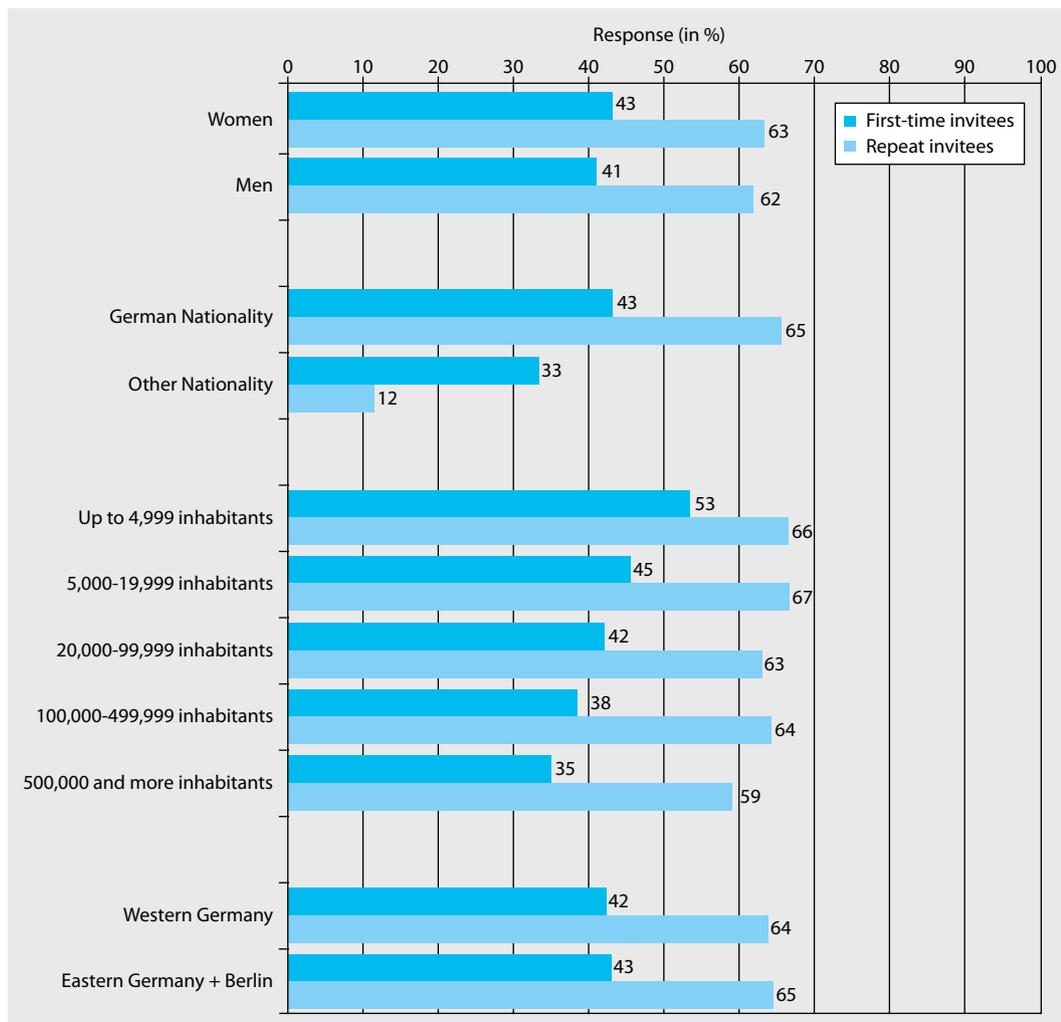


Fig. 1 ◀ Response among first-time and repeat invitees (by sex, nationality, size of home municipality and region of residence)

as well as among former GNHIES98 participants. In order to allow for these effects in the planned evaluations, the letters sent to the population registration offices by the RKI not only described the process for correct random selection from the registers, but also requested tables for the total reference population stratified by sex, age and nationality so that suitable weighting factors could be calculated for each sample point to facilitate subsequent analysis [5].

The willingness to participate in DEGS1 among first-time invitees was far lower than in GNHIES98 with its response rate of over 60% or the Cooperative Health Research in the Augsburg region (KORA) 2000 study with a 65% response rate. More recent studies such as the 2008 German General Social Survey (ALLBUS) however also now report lower participation rates [11]. In recent years

there has been a general increase in scepticism and rejection among the population when it comes to taking part in health surveys [12], resulting in a comparatively low response rate of 42% among first-time DEGS1 invitees. It should be emphasised, however, that, from the point of view of external QA, practically all measures seen as being effective to boost response were taken. Even though these measures were only moderately successful with first-time invitees, the participation rate of 62% among former GNHIES98 participants can be considered satisfactory.

Non-responder analysis

To ensure the representative nature of population-based surveys, it is important to be able to make statements on the composition of the group of non-responders. Hence the RKI tried to obtain select-

ed characteristic sociodemographic and health-related data on non-participants using a short questionnaire—and succeeded in doing so for 2,342 persons (approx. 40%) from the group of first-time invitees who did not take part in the survey. With regard to the indicator “highest educational qualifications”, the data reflect the known effect that participants are better educated than non-responders. At around 40%, the percentage of non-responders who left school with “only” a lower secondary school certificate was roughly ten percentage points higher than the corresponding percentage of persons who took part in the survey among both men and women. The percentage of persons with a university entrance qualification among survey participants is on the other hand correspondingly higher. With regard to selected health-related variables, the data show that survey partici-

pants rate their own state of health as being slightly better and, in particular men, smoke slightly less. In contrast, the prevalence of overweight among non-responders and participants is more or less identical in both men and women. Finally, comparison of various health/health care indicators (recognised severe disability, health insurance) with data from the 2009 microcensus and the official statistics for 2010 also confirm that the data are highly representative [13, 14]. Further detailed information on the representativeness of the surveyed data can be found in [5].

DEGS1 documented the reasons for non-participation in great detail. However, no information whatsoever was available for around 13% of first-time invitees and just under 4% of all repeat invitees, as it was not possible to contact the people in question. If all those who did not turn up at the agreed time, refused to participate without stating reasons or cancelled their appointments due to lack of interest are categorised as “total refusers”, this group accounted for 17% of all first-time invitees (and approx. 7% of repeat invitees). Further details can be found in [5].

Completeness of individual survey elements

Health questionnaires, diet questionnaires and medical interviews are all available for more than 7,000 participants. The same applies to bodyweight and blood pressure measurements as well as samples of biological material (blood, urine). Based on the 7,116 persons between the ages of 18 and 79 who are regarded as having been *interviewed and examined* in DEGS1, the percentages for individual missing survey elements are between 0.3 and 0.7%. With a consistent rate of over 99%, the completeness of individual survey elements can therefore be described as virtually perfect.

Quality assurance of data management

Data management procedures were also reviewed as part of external QA; both the IT systems used and the data processing methods (such as data input) were monitored.

The organisation of the whole data management process was based on methods that have already been used in other RKI studies. The implemented systems, concepts and methods used have been tried and tested and have proven their suitability in terms of security, clarity, low error rate and practical suitability. Data processing and preparation at the RKI takes place in several stages, during which separate data statuses are generated and stored. Using the original data as the starting point, this results in the creation of a raw data status (with correction of recording errors or identification variables), an inspection data status (with encoding of texts and correction of formal errors in the data) and the analysis datasets. All data statuses are permanently available. It is, for example, possible to directly access the original data to check for any identified implausibilities. Data transformation and correction are exclusively program-controlled and can be repeated and reconstructed at any time. The techniques used are transparent; corrections are “hard-coded” in the programs, which means they are simultaneously documented and can be reconstructed at any time. It is possible to trace each value in the analysis datasets back to the original data and therefore to depict the entire process in a transparent manner.

To ensure error-free transfer of data from questionnaires and have the different measuring devices, a number of measures were taken and the data were subjected to various checks. For example, the collected questionnaires were documented and tracked using a tracking system. A record was created for each individual questionnaire to document when it was forwarded to a particular processing stage and when it was moved to a new location. This means that reliable information is available at all times on the current processing and/or storage location. To ensure correct allocation of the individual survey elements to the study participants, the participants were not only requested to provide proof of identification when they arrived at the study centre, but were also asked their name, date of birth and address. The date of birth and sex were once again recorded in each of the individual instruments. The reliability

of data input was ensured by input checks for a part of the questionnaires at different times during the course of the study. Changes to the questionnaires were documented so that it was possible to determine which version of the instrument was used with which participant at all times.

The measures taken in the area of data management included the monitoring of data throughput itself (along the processing chain) as well as correct allocation of data to the respective study participants. These measures ensure that no information is lost during the transfer of data from paper to the database.

The recruitment of participants was supported by a database application designed specifically for the study which controlled contact with study participants, documentation and monitoring of returns through the entire survey process. Electronic storage of events during contact with participants paves the way for problem-free analysis of the fieldwork phase. Events such as the dispatch of letters or the receipt of an answer and the reasons for non-participation were saved with details at each respective point in time. Evaluation of reasons for loss of participants or the number of required contact attempts provide insights into the fieldwork phase and can be used to optimise future surveys.

The organisation of data management in DEGS1 meets the requirements for an epidemiological study as for example outlined in the guidelines on GEP (DGEpi 2004) [8].

Conclusion

In summary, it can be said that the RKI has succeeded in mastering the relatively broad and interdisciplinary remit of DEGS1 through the use of suitably qualified and trained personnel, thereby ensuring consistently high data quality. During the entire survey period, the teams showed a high commitment towards ensuring the quality of data collection. The frequency of quality-neutral sample losses is in keeping with the average figures for other, comparable studies. The response from first-time invitees at 42% is rather low but in line with the

response rate of recent studies. Moreover, the external quality assurance experts can confirm that the DEGS1 team practically took all measures that are considered effective in order to boost the response rate. The completeness of the individual study elements can be described as almost perfect. The processes and methods used for data management are *state of the art*, meticulously planned, well coordinated and outlined in SOPs. External QA rates the cooperation with the RKI, internal QA and the fieldwork management as positive and highly constructive.

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Funding of the study. The study was financed by the Robert Koch Institute and the Federal Ministry of Health.

Conflict of interest. On behalf of all authors, the corresponding author states that there are no conflicts of interest.

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