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The first wave of the German Health Interview and Examination Survey for Adults (DEGS1)

Recruitment of participants, fieldwork, and quality assurance

Background and purpose

The German Health Interview and Examination Survey for Adults (DEGS) is part of the health monitoring carried out by the Robert Koch Institute (RKI) [1, 2]. Its purpose is to obtain repeated nationwide representative health data for adults aged 18–79 years living in Germany, and it also obtains longitudinal data by repeated examination of the same participants. Each wave of data gathering consists of interviews, and particular waves also include measurements and tests carried out in local study centres. The rationale of DEGS is described in detail elsewhere [3, 4].

The RKI carried out the first wave of data collection (DEGS1) in the form of an examination and interview survey between November 2008 and December 2011 [5]. The study used a mixed design, and was based on a new sample from the population registration office and on participants of the 1998 German National Health Interview and Examination Survey (GNHIES98), a previous cross-sectional health study by the RKI [6]. In order to obtain new data from as many GNHIES98 participants as possible, re-invited individuals who were unable or unwilling to attend a study centre during DEGS1 (particularly those who had moved to other locations) were given the chance to take part in an interview-only programme.

Recruitment of participants and data gathering requires high standards of study management and comprehensive quality assurance. This paper describes how DEGS1 was managed, how participants were recruited, and the instruments and procedures used to obtain the data. It also details the full onsite examination and interview programme, the interview-only programme, and the quality assurance measures used to ensure a high standard of data quality.

Full examination and interview programme

Route planning

The examinations and interviews were carried out by two mobile study teams from the RKI at 180 local study centres. The duration of data collection at each local study centres was limited to 1 week and the sequence of places visited by the study teams at any given time was laid down beforehand in a random touring schedule, in order to avoid a systematic bias of study results by seasonal or time trends.

Recruitment of participants

Invitation and reminder

The study administration office sent invitation letters to potential participants 5 weeks before the beginning of the 1-week survey period at each study location (**Fig. 1**).

The one-page letter briefly described the purpose of the study, the examination location, and when the study team would be onsite. It was accompanied by a comprehensive brochure with details of how the examinations, interviews and laboratory analysis would be carried out, how personal data would be protected, and other information. A list of questions and answers was placed on the information section of the RKI's website, and potential participants could also telephone the toll-free study line with any queries. All this information was designed to give participants a full picture of the study and help them decide whether to take part.

The invitation also included a prepaid reply postcard so that individuals who were willing to participate could inform the study administration office of their telephone numbers and the best times to call.

About 1 week before the invitations were mailed, press releases were sent to local and national newspapers, radio and television stations, and city websites. The purpose of this public relations project was to ensure that as many people as possible knew about the study before they received their invitations. Local media coverage also promoted a positive image of the study and won people's trust.

Invitees who had not replied within 10 days of the invitation being sent received a reminder briefly explaining the purpose of the study again and asking them to take part.

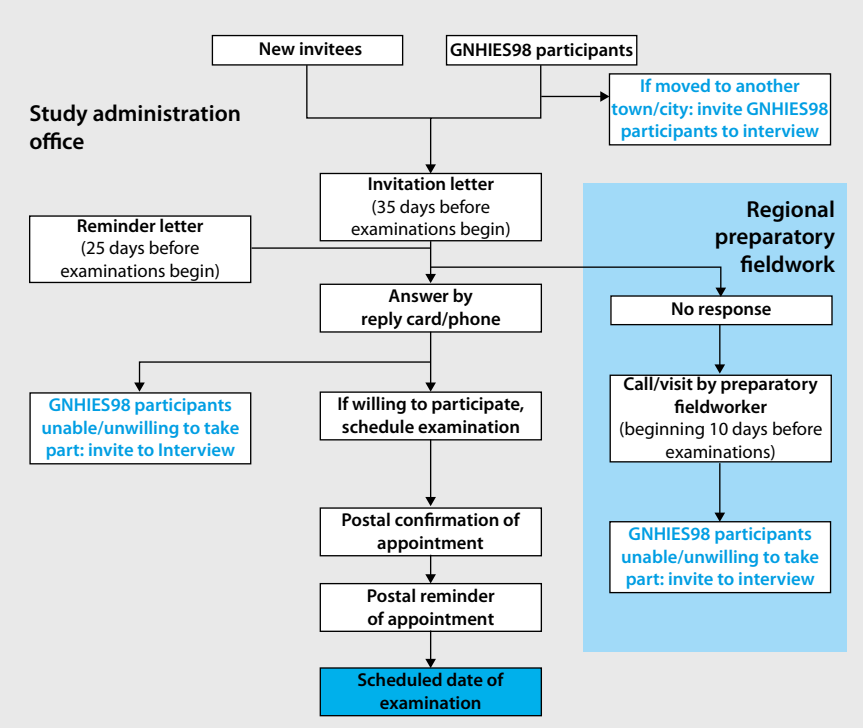

Fig. 1 ▲ Recruitment of participants

Preparatory fieldwork

As outlined in the reminder letter, individuals who did not reply to the reminder were contacted and asked to take part by a regional preparatory fieldworker 1–2 weeks before the 1-week examination period began. They were first contacted by telephone, with at least five attempts being made at different times of the day, and if their telephone numbers were not known, or they could not be contacted, they were visited by the preparatory fieldworker, who made at least three attempts at different times of the day. This procedure was shown to be successful in the German Health Interview and Examination Survey for Children and Adolescents (KiGGS) carried out by the RKI in 2003–2006, and helped to increase the response rate [7]. This approach helped to reach particularly those individuals who did not receive or read the invitation letter, did not understand the purpose of the study but were reluctant to call the information line for further information, or were willing to take part but had not yet replied.

Appointments

Individuals who were willing to take part were contacted by the study administration office as soon as possible after receiving their reply cards, at the times it would be most convenient for them. In many cases, an appointment was made when an individual telephoned with a query.

There were usually two examination days with morning and afternoon appointments, and two with afternoon and evening appointments. Appointments were also available until the early afternoon on Saturdays to make it easier for working people to participate. As a rule, a maximum of 47 appointments were made each week, although this number could be increased if a very large number of people were willing to take part, and more staff could be made available if necessary. Individuals for whom no suitable appointments could be found were placed on a waiting list and contacted as soon as any date became available. This minimised the number of appointments not taken up, and improved the degree of utilisation of the study centre.

The examination programme included a fasting blood sugar test, and therefore when participants made their appointments they were asked, if possible, not to eat or drink anything but water for 4 h before afternoon and evening appointments or 10 h before morning appointments. Diabetics and others who were unable or unwilling to fast for any reason were not asked to do so.

Appointment confirmation and reminders

A few days after the appointment was made, participants were sent a written confirmation and a dietary questionnaire to be completed at home and be brought to the examination site. The letter also enclosed an information sheet with the address of the study centre and details of how to get there.

The study administration office then sent out a reminder a few days before the appointment, asking participants to bring their completed diet questionnaires, vaccination and allergy certificates, packages of any medications taken in the 7 days before the appointment, comfortable clothing for the cycle ergometer test, and reading glasses if necessary. Participants were also reminded of the fasting requirements, if necessary.

Fieldwork

Examination rooms and logistics

The data collection was performed within 1 week in each study location, using short-term rented premises. The process of obtaining suitable venues was often time-consuming, and therefore began around 12 weeks before the data gathering. Letters were sent to local authorities and health departments asking them to help with finding facilities and, failing this, to other local institutions such as hospitals, churches and welfare organisations. In just over two thirds of study locations, rooms were provided either by the public health service or by local authority bodies such as the town hall or fire service, and another quarter were rented from churches and welfare bodies. The remaining approx. 20% was rented from private owners, and the time load involved in finding these properties was considerable. Finding premises was particularly time-consuming in larger cit-

ies. All premises offered were checked for suitability by RKI employees. Criteria for the acceptability of premises were centrally located, easily accessible and wheelchair-friendly, ideally with four to six separate rooms in good condition and adequate bathroom facilities.

The study teams used small vans to carry all the equipment required for the examinations and interviews. These included measuring instruments such as bicycle ergometers, blood pressure monitors, laboratory equipment, refrigerators, notebooks, furniture, office equipment, and single-use sampling and storage equipment. The vehicles were loaded at the RKI before the data collection phase began, with sufficient equipment for either 1 or 2 weeks, and then driven to the study location by a member of the field team. The teams decided onsite how to make best use of the premises, and prepared the necessary equipment and materials. After each study week ended, they reloaded the vans and drove either to the next study location or back to the RKI in Berlin.

Study teams

The two study teams each consisted of a doctor, a nurse or doctor's assistant, a medical technology assistant, and a study assistant, who were recruited specifically to carry out the fieldwork. They underwent intensive training and certification based on an operations manual before starting work, and their performance was systematically reviewed during the fieldwork as part of the quality assurance process (see below). They were also cross-trained so that, with the exception of the doctors, they could stand in for one another if necessary. Teambuilding events were held at the beginning of the field phase, and specialist advice was offered during the course of the study to prevent team conflict and other psychosocial problems caused by the large amount of travel involved. The field managers remained in close contact with the teams throughout the study, carried out regular site visits, and could be contacted at any time to resolve any problem regarding study procedures or logistics. They also issued regular written progress and organisational reports to the teams.

Abstract · Zusammenfassung

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The first wave of the German Health Interview and Examination Survey for Adults (DEGS1). Participant recruitment, fieldwork, and quality assurance

Abstract

The purpose of the German Health Interview and Examination Survey for Adults (DEGS) is to repeatedly obtain representative nationwide health data for adults aged 18–79 years living in Germany. The first wave (DEGS1) was carried out by the Robert Koch Institute (RKI) from November 2008 to December 2011. The study has a mixed design, which permits both cross-sectional and longitudinal analysis. It was carried out on an up-to-date sample from the population registration office and on participants from the 1998 German National Health Interview and Examination Survey (GNHIES98), who were invited to take part again. All newly selected individuals, and those GNHIES98 participants living in the same locations as in 1998, were asked to undergo an interview and examination. GNHIES98 participants who had moved to a different location were asked to take part in a survey based on self-completion questionnaires and telephone interviews. This article describes the practicalities of recruiting participants, planning and carrying out fieldwork, managing data, and taking measures to ensure the quality of the process and data.

Keywords

Health monitoring · Health survey · Adults · Recruitment · Quality assurance

Die erste Welle der Studie zur Gesundheit Erwachsener in Deutschland (DEGS1). Gewinnung von Studienteilnehmenden, Durchführung der Feldarbeit und Qualitätsmanagement

Zusammenfassung

Ziel der „Studie zur Gesundheit Erwachsener" (DEGS) ist es, wiederholt bundesweit repräsentative Gesundheitsdaten für die in Deutschland lebenden Erwachsenen im Alter von 18 bis 79 Jahren bereitzustellen. Außerdem werden Daten für längsschnittliche Analysen erhoben. Die erste Erhebungswelle (DEGS1) führte das Robert Koch-Institut (RKI) von November 2008 bis Dezember 2011 durch. Das Mischdesign der Studie sah eine aktuell gezogene Einwohnermeldeamtsstichprobe vor, die durch wiedereingeladene Teilnehmende des Bundes-Gesundheitssurveys 1998 (BGS98) ergänzt wurde. Alle neu gezogenen Personen und die Teilnehmenden des BGS98, die noch am selben Ort wohnten wie 1998, wurden zur Teilnahme am Befragungs- und Untersuchungssurvey eingeladen. Teilnehmende des BGS98, die von ihrem damaligen Wohnort verzogen waren, wurden gebeten, sich an einer schriftlichen und telefonischen Befragung zu beteiligen. Der vorliegende Beitrag beschreibt praxisnah den Prozess der Gewinnung der Teilnehmenden, die Organisation und die Durchführung der Feldarbeit, das Datenmanagement sowie Maßnahmen zur Sicherung der Prozess- und Datenqualität.

Schlüsselwörter

Gesundheitsmonitoring · Gesundheitssurvey · Erwachsene · Teilnehmergewinnung · Qualitätssicherung

Data collection procedures

The study protocol was designed differently for two age groups, those aged 18–64 years and those aged 65 years and older [3]. Information was obtained using questionnaires and computer-assisted personal interviews (CAPI). The physician-administered interview, carried out using CAPI, included questions on illnesses, diagnostics, therapy, diagnosis-specific use of health services, vaccinations, and screening examinations.

With the computer-assisted assessment of medication, participants were asked about medications and dietary supplements they had taken during the last 7 days. For each product, they were asked for details of the indication, whether the item was obtained on prescription or over the counter, how long they had been using it, and the dosage and frequency of use.

Separate self-completed questionnaires were administered to the 18-to-64

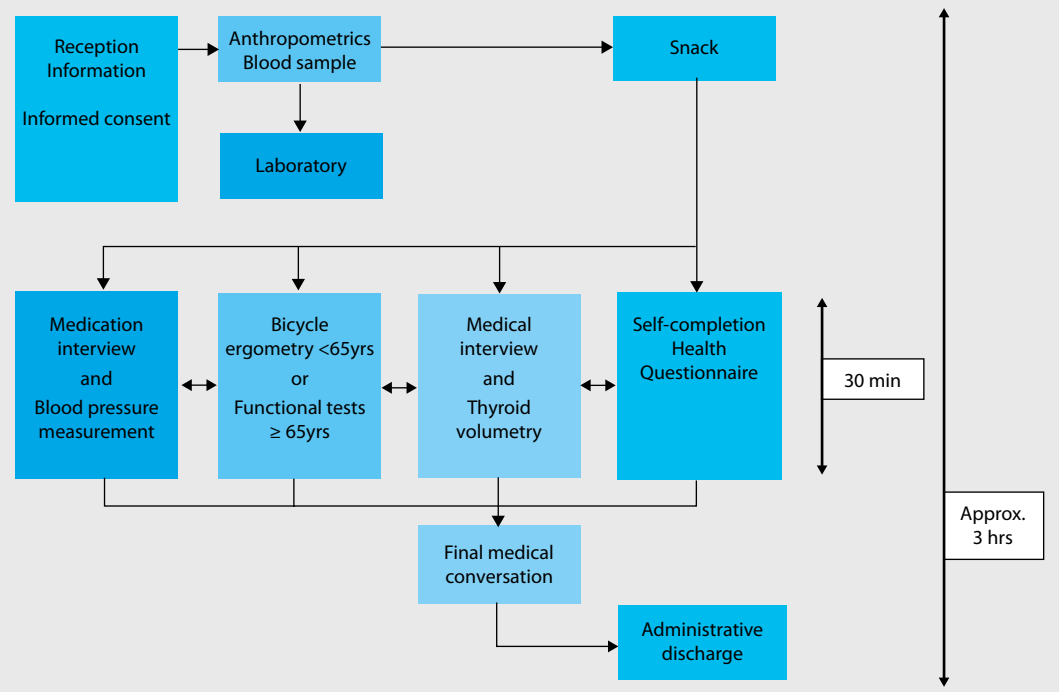

Fig. 2 ◀ Examination procedure

and 65-and-over groups, to obtain details of physical, psychological and social aspects of their health. Participants unable to complete the detailed questionnaires for health reasons were asked to complete a short version giving key indicators. The questionnaires were also available in Russian, Turkish, Serbo-Croat and English.

Dietary information was obtained using a food frequency questionnaire developed and validated by the RKI and related to food intake over the past 4 weeks [8]. Participants normally completed this at home and brought it with them to the study centre.

The examination programme consisted of the following tests and measurements:

- Anthropometrics (height, weight, hip and waist circumference) [9]
- Resting blood pressure [10]
- Bicycle ergometry (for participants aged 18–64 years) [11]
- Testing of physical and cognitive capabilities in participants over 64: timed "up & go" test, chair-rise test, balance tests, measurement of hand grip strength, and digit symbol substitution test [12]
- Thyroid volume ultrasound
- Blood and urine diagnostics [3]

Examination procedure

The study assistant welcomed participants arriving at the study centre and obtained confirmation of their identity. He or she then explained the nature and purpose of the study and the legal requirements concerning data protection, and asked participants to give their written informed consent to take part: first for the study as a whole, and then for specific aspects such as blood sampling, long-term storage of biological samples, genetic testing and, if appropriate, viewing the confidential section of a death certificate. Participants had the possibility to refuse consent to individual aspects even if they gave overall consent.

Each subject was allocated a unique identification number, and all documents and sample containers were barcoded accordingly. Diet questionnaires filled in at home were checked for completeness, and vaccination and allergy certificates were copied and labelled. The study assistant then explained the test procedure and handed out the health questionnaire.

As most participants had agreed to fast before their appointments, blood samples and anthropometric measurements were always taken first. Participants were then given a healthy snack of fresh bread, cold cuts, fruit, juice, and decaffeinated hot drinks.

In order to keep the participants' stay in the study site as short as possible, the sequence of the subsequent tests was flexible, and any examination was performed as soon as the required team member was available. However, resting blood pressure was always measured before examinations that involved physical exertion (**Fig. 2**). Before each examination, participants' identities were checked using their barcode, sex, and month and year of birth in order to avoid any mistakes.

Participants mainly completed the health questionnaire in a separate waiting room between the different parts of the examination. The study assistants supervised this, answered any queries about the questionnaire, and assisted participants who had difficulties seeing or reading it.

If they had significant problems in understanding the questions, the study assistants provided a shortlist questionnaire focussing on core items.

The medical technology assistant prepared blood and urine samples while participants were undergoing the various tests. The assistant performed complete blood counts onsite, and carried out a urine dip strip test (see below).

At the end of the examination, the study physician informed participants of their first examination results: height,

weight, blood pressure, basic blood test, urine dip strip test, bicycle ergometry and thyroid ultrasound, according to their clinical relevance. Each subject also received a written summary of the findings to discuss with their general practitioner if necessary.

The study assistants discharged the participants, thanked them for taking part, and paid them a cash incentive. Finally, they informed the participants about a modular study focussing on mental health linked to DEGS1 and being carried out by the Clinical Psychology and Psychotherapy Institute of Dresden Technical University. If they were interested in taking part, they were asked for consent to pass on their contact details to the cooperation partner. Detailed explanations of the nature and objectives of the modular study, and invitations to take part, were then subsequently provided by staff of the institute in Dresden.

Laboratory analysis

In DEGS1, selected laboratory parameters were determined from the participants' blood and urine samples. These related primarily to organ function, blood sugar and lipid metabolism, allergies, and antibody seroprevalence. Biological samples were also taken for additional health policy-related issues [3, 5]. Approximately 40 ml of blood and a midstream urine sample were obtained, with the blood, serum and urine samples being divided into small transportable tubes for analysis by different instruments of the RKI central epidemiological laboratory or contract laboratories. They were stored in a deep freezer at the study centre at −40°C, and remained refrigerated while being transported to the RKI.

Only a few laboratory analyses were carried out at the study centre. These included a complete blood count performed by a portable haematology analyser, and a urine dip strip test for all participants. Portable measuring equipment was also used to determine the lactate concentration in capillary blood from the earlobe during the cycle ergometry test [11].

Findings

Participants received a standardised findings report within 6–8 weeks, summarising the clinically relevant results of the examination. These included laboratory parameters (clinical chemistry, infectious diseases, and allergies), anthropometrics, blood pressure, thyroid volume, and a physical fitness assessment. The clinical significance of the findings was evaluated by a physician, and participants were advised to obtain further clarification from their general practitioners if necessary.

Where the laboratory findings indicated that treatment was required as soon as possible, participants were informed as soon as the findings were available and advised to contact their doctor.

Interviewing of GNHIES98 participants

Recruitment of participants

Target group

DEGS1 sought to ensure that as many GNHIES98 participants as possible attended a study centre again so that interview and measurement data were available for evaluation. As expected, not all re-invited participants were able or willing to do so, for example, work commitments, serious illness, or age made it difficult to attend. Furthermore, individuals who were known to have moved away from the original study location were not invited to attend the local study centre for organisational and methodological reasons. In order to obtain interview data from both of these groups, they were invited to take part in an interview programme consisting of a self-administered postal health questionnaire and a computer-assisted medical telephone interview which could be carried out anywhere, regardless of the study location.

Invitations and reminders

Individuals known to have moved from their original GNHIES98 locations were not invited to the study centre. Instead, they were sent written invitations to take part in the interview programme, enclosing a health questionnaire, consent form, two reply-paid envelopes for the questionnaire and consent form, and a brochure informing them of all the factors that might affect their decision to take part.

Individuals invited to a study centre, but unable or unwilling to attend it, were telephoned or visited by the study administration office or a preparatory fieldworker asking them to take part in the interview programme. If they agreed, they were sent or given the necessary consent forms and interview materials.

If they did not reply within 4 weeks of being sent these materials, they received a reminder enclosing further copies.

Appointments

Appointments for medical telephone interviews were made as soon as the participants returned their signed consent forms. In order to provide them with as much flexibility as possible, appointments were available on weekdays, evenings or Saturdays. If they had not completed and returned the health questionnaire, they were reminded to do so when the appointment for interviewing was made.

Fieldwork

Two physicians were trained to carry out medical telephone interviews in accordance with the fieldwork operations manual, taking account of the special requirements applying to telephone conversations. They used headsets to make the computer-assisted interviews as ergonomic as possible, contacted participants at the agreed times, and administered interviews lasting between approximately 15 and 45 min. After they had completed the interview and when the health questionnaire arrived at the study office, participants were sent an incentive.

Data management

All data from the self-administered questionnaires, measurement records and CAPI interviews were converted into a single format by the epidemiological data centre. Non-electronic data, namely, paper questionnaires, measurement records and ultrasound images, were scanned and entered into the central da-

tabase. The data were then matched to the subject based on their identity number, sex, and month and year of birth, and checked for completeness. These measures were carried out for all individual datasets, and the final number of cases was determined. Next, individual case-related formal data corrections were made to such items as input errors, free-form text coding and individual data based on comments by the person recording them.

Correction syntaxes based on SPSS or SAS were developed and implemented as part of the data content evaluation process. The main tasks to be carried out at this stage included analysing missing and extreme values, interviewer and equipment effects, plausibility, and interpretability. Because all data corrections were essentially made using syntax, it was possible to test, document and, if necessary, deactivate them at any time. Each correction was documented in detail for the content evaluator using a quality assurance database to ensure transparency.

Quality assurance

Current quality management principles require that the process of planning an epidemiological study begins by defining the objectives of the work to be carried out, and the criteria used to evaluate it. It should also set out quality control strategies to minimise errors.

The project description of DEGS1 defined the objectives of the study. The operations manual describes the implementation of the different procedural stages in detail, and thus the quality-assurance criteria.

Error-reduction strategies

The following is a discussion of some of the practical aspects for error reduction; further details are available in the project description [3] and other articles in this publication [13].

All employees, including members of the study administration office, regional preparatory fieldworkers, study teams and data entry staff, underwent structured training in accordance with standard operating procedures (SOPs). Their work was repeatedly checked and they received additional training at regular intervals. A shortened, laminated SOP listing the key requirements was also placed on each employee's desk for quick reference, and all teams held regular meetings to discuss any problems.

Care was taken when planning the data-gathering process to prevent incorrect entries, and documentation was designed to be clear and easy to understand. Plausibility checks were carried out during the electronic data gathering to identify any potentially incorrect inputs. For the medication interview, which was carried out using CAPI, databases of product names and other relevant information were integrated in the software in order to identify the products accurately [13]. Participants' identification numbers were encrypted as barcodes and printed on adhesive labels for attachment to documents and sample containers. A barcode scanner was used to check participants' identities as they underwent each test, and all materials carefully allocated to them. This prevented errors caused by transposed digits and unclear handwriting.

Equipment checks and calibration

Measuring equipment was checked daily and calibrated if necessary, and underwent regular accuracy and safety checks in accordance with the medical product user regulations. All laboratory diagnostics (blood, urine stripes and lactates) were carried out onsite in accordance with guidelines laid down by the German Medical Association, regular control measurements were taken and systematically documented and evaluated, and round robin tests were carried out. Samples and substrates were stored and transported in refrigerators monitored using temperature loggers, whose measurements were documented.

Internal and external quality assurance

Accompanying and observational quality controls were carried out during the fieldwork phase. The internal controls were carried out by an employee of the RKI having many years of experience in planning and carrying out examination surveys, and the external controls, following a tendering process, by the Bremen Institute of Preventive Health Research and Social Medicine (BIPS) [14].

The purpose of both the internal and external quality assurance was to ensure that the survey complied with the procedures and standards laid down in the operations manual, and to use any problems to develop error-prevention and -reduction strategies. This required regular quality controls at all stages of the fieldwork. Quality-assurance staff monitored the process independently and regularly shared their experiences to ensure that they were dealing with the study teams in a standardised way. The different levels of quality assurance are described in detail elsewhere in this publication [14].

The study teams were regularly monitored to ensure that they were complying with the standard study requirements. Quality controls were carried out onsite every 3–4 months, and internal and external quality-assurance staff made unannounced visits, albeit by prior agreement with the field manager. All functional areas (participant check-in, laboratory, examinations, medical interview) were reviewed during the control visits, and study procedures were monitored either in their entirety or on a sample basis, with the participants' consent. Checks were carried out to ensure that all procedures were carried out in accordance with the standardised requirements, with particular attention to data protection and ethical issues.

The results of the field visits were documented in writing and discussed with the field manager so that joint measures could be taken to achieve the required standard. Any observed deviations from the requirements were discussed face-to-face with the field workers onsite.

The effectiveness of quality management is greatly dependent on quality controls being carried out in accordance with a plan laying down the assessment criteria, time intervals and documentation requirements. The results of the checks must be evaluated jointly, and adequate measures must be taken to resolve any problems. This eventually leads to a

regular cycle in which the results are repeatedly reviewed and the effectiveness of the measures is assessed.

Conclusions

The design of DEGS1 drew on the RKI's detailed experience gained in carrying out the basic data gathering for the German Health Interview and Examination Survey for Children and Adolescents (KiGGS), and many of the procedures developed for KiGGS were successfully used again in DEGS1 [15]. Some procedures, however, were restructured and refined, taking changing requirements and technological developments into account.

Public relations

This paper includes only a brief discussion of the public relations that formed an important part of the study realisation. This was a time-consuming process, since it involved setting up local distribution lists, contacting editorial staff, and carrying out specialist public relations aimed at relevant groups within the health sector, including general and special-topic contributions to appropriate publications. Radio and television coverage was also organised locally, and the study teams received media training.

These measures created increased public awareness of the study, and are likely to have made potential participants more willing to take part.

Recruitment of participants

Recruiting participants for DEGS1 was a highly complex task. Extensive research was required to locate former GNHIES98 participants, and separate invitations and documents had to be produced for those who had taken part before and those who had not. Additional procedures also had to be developed and implemented for re-invited individuals who were interviewed but not examined onsite. This was done by programming a sophisticated administrative database allowing the study administration office to carry out the different procedures. The complexity of these procedures also required the staff of the study administration office to undergo standardised training and continuous supervision. The use of regional preparatory fieldworkers to contact potential participants by telephone or personal visit once again proved highly effective, and there was a measurable increase in the response [6]

Fieldwork

The fieldwork for a nationwide survey carried out at 180 locations requires a high degree of logistical effort and requires fieldworkers to be mobile and flexible. They must receive standardised training and certification, and be closely supervised if the data are to be of a sufficiently high quality. Regular internal and external quality assurance is essential in order to achieve the quality objectives and maintain these over the 3 years of the study.

Close contact with fieldworkers is also vital in order to develop a process of constructive cooperation and ensure that they are fully involved in the entire study procedure. Regular field visits, written reports, information events and training at RKI all proved successful, and continuous telephone contact was maintained with the field manager and logistics teams so that any practical issues could be resolved quickly.

If the study is to operate efficiently, all of the study equipment and materials must be put in place at the beginning of each week, and this should ideally be done by a team of staff familiar with the fieldwork examination procedures. Checklists can be used to ensure that the checking routines are carried out regularly, materials are reordered in plenty of time, and all the required items are loaded onto the vehicles.

Finding suitable premises was also a time-consuming process. This should be carried out using a list of criteria, beginning around 3 months before the examinations take place, and may require assistance from local bodies and extensive online searches. Talking to potential providers of premises by telephone often proved effective.

Close cooperation with the central laboratory is required in order to maintain a high standard of diagnosis. Logistical planning must be carefully tailored both to pre-analytic requirements of sample handling and storage, and to changing conditions of fieldwork at different examination sites.

The time and effort involved, the need for different approaches to different target groups, and the logistical demands of a representative nationwide epidemiological study all presented a major challenge for the whole project team. It is therefore essential that all the procedures involved during the preparation, implementation and processing phases be carefully organised, with the flow of information between the different areas of the project and on-going quality assurance being particularly important. Combined effort was focused not only on producing high-quality data but also on ensuring that the participants were satisfied and willing to take part again.

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