

# **GPS – Good Practice in Secondary Data Analysis: Revision after Fundamental Reworking**

Working Group for the Survey and Utilization of Secondary Data (AGENS)<sup>1</sup> with  
representatives from the German Society for Social Medicine and Prevention  
(DGSMP) and the German Society for Epidemiology (DGEpi)

and

Working Group for Epidemiological Methods<sup>2</sup> with representatives from the  
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German Society for Medical Informatics, Biometry and Epidemiology  
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German Society for Social Medicine and Prevention (DGSMP)

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## Overall aim and responsibility

In recent years, the utilization of secondary data in connection with health services research has increased steadily. Secondary data in this context are defined as routine data obtained from the statutory health, pension and accident insurance funds (social data) or data from (population-based) disease registers. There is currently intense discussion about the potential and also the limitations of utilizing this kind of data, which were collected primarily for other purposes, in epidemiological studies and health services research. The increasing importance of secondary data is also demonstrated by the fact that § 303a-f, which deals with data transparency, has been added to the German social security code to highlight a new legal framework for utilizing data of this kind.

In 2005, the AGENS Working Group for the Survey and Utilization of Secondary Data, established under the German Society for Social Medicine and Prevention (DGSMP), published "Good Practice in Secondary Data Analysis" (GPS) for the first time. GPS drew substantially on "Good Epidemiological Practice" (GEP), which has been available since 2000 and was introduced by the Epidemiological Methods Working Group, whose members came from the German Society for Epidemiology (DGEpi; formerly the DAE), the German Society for Medical Informatics, Biometry and Epidemiology (GMDS) and the German Society for Social Medicine and Prevention (DGSMP) in collaboration with the German Region of the International Biometric Society (DR-IBS).

**Aims of GPS:** The aim was to establish a standard for performing secondary data analyses. It can also be used as the basis for contracts between data owners (primary users) and secondary users (see Glossary).

As well as the data owners, the **GPS target group** is secondary users involved in social medicine, epidemiology and health services research and those who use their research results. This includes not only members of tertiary institutions but all those who apply scientific methods to secondary data and its analysis from a scientific perspective. As is normally the case in the health sciences, this includes members of different professional groups; as well as epidemiologists, it is intended for clinicians, statisticians, social scientists, health economists etc.

**Methodology / revision procedure:** The response to the publication of GPS was consistently positive. Since publication, data owners and epidemiologists have submitted proposals for improvement. These refer, on the one hand, to individual statements in GPS, which their critics maintain are oriented too strongly towards the social data in the German statutory health insurance system (GKV) and should therefore be formulated in more general terms. On the other hand, there was a general desire for a stronger and more formal link with GEP to emphasize that secondary data analysis, as a special form of epidemiological study, should always be planned and performed in accordance with GEP.

GPS was revised for the first time in response to this feedback by a cross-sectional working group made up of members of AGENS and the Epidemiological Methods Working Group and including other epidemiological experts. A revised draft was produced over several working sessions, which was subsequently submitted for discussion to the members of the working groups involved. This revised version of GPS was produced compiled by the cross-sectional working group from the proposed revisions received.

The second version of Good Practice in Secondary Data Analysis was completely re-structured in comparison with the first version. The guidelines are now numbered in the same order as the GEP guidelines. By the same token, their wording has been taken literally from GEP. With the exception of Guideline 4 (subject sample biobank), the more general term “epidemiological study” was replaced by the specific term “secondary data analysis”. In GPS, the specific parameters and requirements of secondary data analysis are addressed in the explanations given in the guidelines and the recommendations derived from them. Central terms are defined in a glossary at the end of GPS, which has been extended by comparison with the first edition.

In its current form, GPS has been kept general to address the users of various kinds of secondary data. Actual study conditions and the specific nature of certain data may make it necessary to deviate from the GPS recommendations. A primary aim of those collaborating to produce GPS was to develop a Good Practice in Secondary Data Analysis that is generally applicable.

GPS is not to be understood, therefore, in terms of a binding quality standard which permits no deviation. It is intended more as guiding principle for planning, conducting and analysing studies on the basis of secondary data. It is important to consider, against the background of the aims of the study in question and the available data, whether it is reasonable to follow the guidelines and recommendations. Deviation is possible at any time but should be soundly based on reasons that stand scrutiny. We need to state explicitly that Good Practice in Secondary Data Analysis can be understood in its own right, despite its drawing substantially on GEP, and thus represents an independent guideline. Users of an existing data body need to provide reasons that third parties can understand as to whether the analysis they intend to conduct is a secondary data analysis in terms of GPS or whether the guidelines and recommendations that primarily obtain are those of GEP.

After completion of the revision process described above, GPS was submitted in its current form to the executive committee of the four specialist epidemiological societies, the DGEpi, DGSMP, GMDS (Society for Medical Documentation and Statistics) and IBS-DR (German Region of the International Biometric Society) and formally adopted at the annual general meeting of the four societies held in September 2007 in Augsburg.

GPS is valid until the end of 2010. Any revision after this date can be carried out without simultaneous revision of GEP under the direction of AGENS.

## Good Practice in Secondary Data Analysis

Version 2 valid to 12/2010

### Guideline 1: Ethics

**Secondary data analyses must be conducted in accordance with ethical principles and respect human dignity as well as human rights.**

This requirement applies to secondary data analyses as well as to primary data surveys. Ethical principles are expressed in general human rights and civil liberties. Ethical principles are also to be observed when no legal obligation to do so exists.

The recommendation to consult with an ethics committee need not apply to secondary data analyses, if all the data protection provisions on pseudo-anonymization of all personal data are fulfilled (see also Guideline 8) and no link to primary data is intended.

### Guideline 2: Research question

**Planning each secondary data analysis requires posing explicit questions that can actually be answered. These questions must be worded as specifically and precisely as possible. The population groups to be studied must be selected for reasons that relate to the research question.**

It is important in secondary data analysis as well that the population groups to be studied are selected for reasons relating to the research question.

The research question is an essential starting point for evaluating the potential benefit of secondary data analysis. This applies independently of the type of data. The explicit wording of the research question is an essential prerequisite for the planning and analysis, not just of the study design and data extraction, but also of the time and cost framework of the intended study. It is through the research question that the details of a secondary data analysis can be established (choice of study group, selection of appropriate data body, determination of relevant variables etc.).

In secondary data analyses, a distinction should be drawn between confirmatory and explorative analyses. Hypotheses to be tested using a confirmatory strategy must be formulated before analysis begins.

### Guideline 3: Protocol

**A detailed and binding protocol which sets out the study characteristics in writing is essential to secondary data analysis.**

Producing a protocol before the start of secondary data analysis is an essential methodological condition for quality.

The protocol is composed of the most important information required for submitting applications in relation to the study, for evaluating the study as a research proposal and for conducting it. In the context of secondary data analysis, the protocol should consist of the following:

- The explicit question to be addressed and working hypotheses,
- Type of study,
- Database,
- Scope of the study with reasons for this,
- Inclusion and exclusion criteria applied to define the data body,
- Specifying suitable variables within the data in question,

- Concept for data provision and transfer as well as for archiving raw and analysed data sets,
- Analysis strategy including statistical methods,
- Quality assurance procedures,
- Measures to ensure data protection and ethical principles,
- Timetable setting out responsibilities.

The properties of the specific data body should be taken into account when implementing these requirements.

*Recommendation 3.1 – Study design*

The type of study should be described and the reasons for selecting it provided. Reasons should also be given why the data body in question is considered to be a suitable basis for analyses in terms of the study design.

*Recommendation 3.2 – Study participants / database*

Secondary data analysis should relate to one study population, which is selected on the basis of a critical analysis of the purpose of the data survey and the quality, reliability and validity of the data used as well as the generalizability of the results.

*Recommendation 3.3 – Preventing bias, internal validity*

Any potential bias in the results, which may arise from selection and/or confounding, should be countered as early as the planning stage in the case of studies based on secondary data. In secondary data analysis, this can be achieved by matching individuals or groups or by taking account of information required to control confounding disturbance variables.

*Recommendation 3.4 – Representativity, generalizability, external validity*

Analogously to minimizing the non-participation rate in primary data analyses, the aim in secondary data analyses should be to achieve as high as possible generalizability for the basic population studied.

*Recommendation 3.5 - Variables*

A secondary data analysis must take into account the accuracy and completeness of the features to be studied and any potential disturbance variables in the primary data. This includes the description and analysis of all variables (fields) used and the context in which data was surveyed.

*Recommendation 3.6 – Scope of the study*

The protocol should state the rationale for the scope of the study. In particular, quantitative estimates of statistical validity should be made in analyses of rare events or those involving smaller target populations to define the population sizes required (feasibility analysis).

*Recommendation 3.7 – Operations manual*

To supplement the protocol, all organisational stipulations for preparing for and conducting secondary data analysis and their step-by-step execution should be documented in an operations manual. This includes data provision by the data owners, data transfer to secondary users and data preparation by the latter.

#### Recommendation 3.8 – Resources

Data owners and secondary users should provide sufficient resources in terms of time and personnel for the study. This applies equally to data provision, the preparation, analysis and presentation of the results, as well as to the necessary communication and discussion within and between participating sites.

#### Guideline 4: Sample databases

**In many epidemiological studies, it is essential or useful to set up a biological sample database. The documented consent of all subjects is required for this and for the current and anticipated future utilization of samples.**

At present, biological samples are not the subject of secondary data analysis. Furthermore, reference is made to Guideline 4 of GEP and the explanatory comments it contains.

#### Guideline 5: Quality assurance

**In secondary data analysis, associated quality assurance of all relevant instruments and procedures should be undertaken.**

Associated internal quality assurance is an essential part of every secondary data analysis. Because the data sources which potentially form the basis of secondary data analysis vary substantially in terms of original purpose, legal principles, data owners and means of transfer, particular value must be put on transparency in relation to data creation and transfer, in order to create analysis procedures that can be replicated. Quality assurance applies at different points of data creation and transfer to create valid principles of analysis. Specifically, quality assurance includes testing data integrity, plausibility controls and defining staff responsibilities (see Recommendations 6.4, 6.6 and 7.2). In the same way, quality assurance extends to documenting data provision as addressed in Guideline 6.

##### *Recommendation 5.1 – Pretesting*

Prior to data provision, it is important to consider whether it is possible to supply sample data with a reduced number of observations.

##### *Recommendation 5.2 – Adapting the protocol*

If it proves necessary, while conducting a secondary data analysis, to change the procedures laid down in the protocol, the reasons for the changes must be given and the changes documented in a supplement to the protocol.

#### Guideline 6: Data preparation

**A detailed system must be set up in advance for capture and storage of all the data surveyed during the study and for the preparation, plausibility testing, coding and provision of the data.**

The need for documentation extends to all the processes involved in data preparation and testing that precede data analysis during data provision by the data owners and data transfer to secondary users. Documentation in the form of a data preparation protocol should encompass a complete and intelligible description of the data management sys-

tem, transferred data (survey and delivery date, number of data sets, transfer format used, code and reference lists used, pseudo-anonymization and anonymization steps etc.) and subsequent transformations until generation of an analysis data set.

*Recommendation 6.1 – Data survey and transfer*

The data fundamentals and data routes should be presented from primary data acquisition up to the time of provision to secondary data users. This includes an account of the purpose of data collection and of the data acquisition rules and checks to ensure that data acquisition rules are applied consistently (diagnosis and procedure coding for instance) and of the legal framework in place over the data collection periods in question.

*Recommendation 6.2 – Baseline data sets*

The baseline data set transferred by the data owner should be available in unchanged form over the whole period of secondary data analysis. The retention period specified in Guideline 7 applies to the reproducibility of the analyses.

*Recommendation 6.3 – Data description*

The scope and structure of the data provided and used should be documented. References to missing data sets and their frequency and data sets that prove to be redundant should also be documented.

*Recommendation 6.4 – Data quality*

The reliability and validity of the data used should be tested on the basis of available information. It is important to ensure external validation of critical features in the context of primary surveys e.g. for sub-populations.

*Recommendation 6.5 – Plausibility checks*

Plausibility checks should be performed before and during secondary data analysis. In principle, they are performed on the basis of the baseline data set. There should be some discussion with the data owner before carrying out any corrections that may be required. All additions and changes of variable values should be documented in full in writing.

*Recommendation 6.6 – Practicability – derived variables*

As a rule, secondary data analysis includes creating variables and variable categories on the basis of other variables from the baseline data set and their values. The creation of derived features should be intelligibly documented and based on any available standards to facilitate comparison of the results. In the same way, the creation of new variables should be documented in full.

*Recommendation 6.7 – Analysis data sets*

The data set that has been reworked after plausibility testing and data transformation should be designated as the analysis dataset and stored and secured independently of the baseline data set. The retention period specified in Guideline 7 also applies to the reproducibility of the analyses.

## Guideline 7: Data analysis

**Suitable methods should be used to analyse secondary data and analysis should be conducted without unnecessary delay. The data on which the results are based should be held in fully reproducible form for at least 10 years.**

To ensure that study results are verifiable, a fixed retention period for baseline data and analysis data sets as well as the data preparation protocol used by the secondary users should be regulated by contract. The critical time for this requirement of secondary data analysis is not the time when the secondary data were created but the time of transfer to secondary users.

The individual analysis steps should be able to be replicated and should be critically analysed with regard to potential repercussions on the selection of the study population, the feasibility of addressing the research question, the scope of the results and the decision criteria used to test the hypothesis.

Secondary data analysis requires the analysis strategy to be planned in accordance with the available data. It must take the accuracy of measurement and completeness of the data into account (in relation to the variables present as well as to potential confounding variables and interactions). The hypotheses to be tested in the context of secondary data analysis must be formulated before the start of the study, as must the decision criteria to be applied in these tests.

### *Recommendation 7.1 – Analysis plan*

The individual questions raised should be analyzed in accordance with an analysis plan produced in advance, on the basis of the current state of epidemiological, statistical or methodological knowledge. It should be possible to replicate both the general analysis strategy and individual analysis steps. The reasons for any necessary changes in the original analysis plan should be stated and changes should be documented.

### *Recommendation 7.2 – Personal responsibility*

All persons responsible for data analysis must be named before work begins and be briefed about the legal and organisational conditions of data collection. This also applies to any further persons involved in data analysis, if an understanding of data collection is necessary for proper conduct of the analysis.

### *Recommendation 7.3 – Interim analyses*

As is the case with primary data analysis, no interim analyses should be performed as part of secondary data analysis. Exceptions to this are interim analyses performed while the study is in progress, which are used to monitor the study and as such are part of quality assurance.

### *Recommendation 7.4 – Checking the results*

The analyses of the results of secondary data analyses should be counterchecked before publication. The analysis strategy, analyses and their results should be reproducible by third parties. All analyses should be documented in such a way that outsiders, either persons or institutions, can understand and reproduce the actual analyses and their results. The data and programmes on which the analyses are based should then be archived in fully reproducible form.

## Guideline 8: Data protection

**The data protection provisions in force for protecting informational self-determination should be observed when planning and conducting secondary data analyses.**

The data protection provisions in force, including the principle of data avoidance and data scarcity, which requires collecting and storing only those data that are absolutely necessary, (§ 3a of the German federal data protection law [BDSG] refers) and, if applicable, other regulations relevant to the data bodies used must be observed. All persons who deal with personal data in connection with a research project must be informed of the content, scope and capacity of the relevant legal provisions. In research with personal data, both the individual's right to informational self-determination as well as the right to freedom in science and research must be observed.

### *Recommendation 8.1 – Purpose of data provision*

The purpose of data provision (in terms of data protection) is to answer the research questions (see Guideline 2) and must be set down in writing.

### *Recommendation 8.2 – Pseudo-anonymization and anonymization*

Use should be made of the means of pseudo-anonymization and anonymization contained in the German federal law on data protection (§ 3a BDSG data avoidance and data scarcity). The involvement of a data custodian should be considered here.

### *Recommendation 8.3 – Depseudo-anonymization and re-identification*

It is important to stipulate in writing in the general contractual conditions whether depseudo-anonymization is intended, and if so, in which cases. In the analysis, appropriate means (technical and contractual) should be employed to prevent unreliable re-identification

### *Recommendation 8.4 – Transfer of personal data to third parties*

As a rule, any transfer of personal data is done by the data owner only.

### *Recommendation 8.5 – Personal data linkage with external data sources*

All personal data linkages with external data sources that are not explicitly provided for require compliance with data protection provisions.

### *Recommendation 8.6 – Persons responsible for data protection*

In every secondary analysis, national and international standards of data security and data protection should be observed. Within a research division, a person should be appointed as the person responsible for data processing, who monitors compliance with these standards. The person in question must have appropriate qualifications for these duties.

### *Recommendation 8.7 – Deletion deadlines*

If, for reasons of data protection, the data provided for secondary data analysis has to be deleted or anonymized after the purpose of the study has been achieved, this must be done in accordance with the retention requirements for baseline and analysis data sets specified in Recommendations 6.2 and 6.7. Similarly, when setting deletion deadlines, an opportunity to check the results obtained from secondary utilization as specified under Guideline 7 must also be provided.

*Recommendation 8.8 – Co-operation with persons responsible for data protection*

The need to make contact with the legitimate persons responsible for data protection should be borne in mind as early as planning the secondary data analysis.

**Guideline 9: General contractual conditions**

**Defined legal and financial conditions are prerequisites of conducting a secondary analysis. It is important to have legally effective agreements between principal and agent and between partners in research co-operations.**

As a rule, secondary data analyses are based on contractual arrangement between data owner and secondary user. It is important to conclude legally effective agreements between cooperation partners, which set out the legal and financial conditions for the intended secondary data utilization, based on the legal conditions on dealing with social data and other personal data. Incidentally, different contractual forms are possible, given the variety of special constellations and potential sources of data.

*Recommendation 9.1 – Contents of the contract*

Transparent and realistic agreements should be reached with the data owner. The contract should regulate issues such as research independence, the rights and duties associated with research and long-term access to the data.

*Recommendation 9.2 – Using results*

Using of the results of contract research for research and teaching should not be prevented, obstructed or unreasonably delayed. Contractual definition of an appropriate blocking period is permitted.

**Guideline 10: Interpretation**

**Interpretation of the research results of a secondary data analysis is the task of the author(s) of a publication. All interpretation is based on critical discussion of the methods, data and results of the author's own study in the context of the available evidence. All publications should undergo external review.**

Evaluating the results is one of the original tasks of the secondary users. The argumentative process on which an interpretation is based should be presented in written discussion in a way that is transparent and comprehensible. Any limitations on the transferability of the study results to populations or time frames other than those considered should be discussed.

**Guideline 11: Communication and public health**

**Secondary data analyses, which aim to translate results into effective health measures, should include the population groups affected in an appropriate way and aim to achieve qualified risk communication with interested parties in public life.**

Secondary data analyses may deal with the assessment of health system structures and services or the implementation and evaluation of measures relevant to health. This is even more applicable, because they are frequently based on data from health care practice. If, according to the professional opinion of the secondary users, further action is needed as a result of the secondary data analysis, this can be explicitly stipulated in the form of a recommendation for example. Secondary users should accept responsibility for intelligible communication on this matter with non-specialists. Secondary users can also produce recommendations on a sound professional basis to the data owners for making information available to the public and can contribute to technical implementation.

*Recommendation 11.1 – Independence of the data user*

Independently of their research activities, secondary users should have an opportunity to express themselves in relation to the practical consequences of their analyses for the population directly affected, without the agreement of the data owner. Formal aspects of direct communication with the public on the part of secondary users should be regulated by contract.

*Recommendation 11.2 – Transparency of the methods used*

The methods used in secondary data analysis should be published in an appropriate setting and made accessible to interested persons and institutions in terms of method transparency. Transfer or publication of analysis routines, analytical procedures and reporting formats should be possible independently of the data owner.

*Recommendation 11.3 – External utilization of data*

During every secondary data analysis, data owners and secondary users should check whether and to what extent, the data set is made available to the scientific public for research co-operations. The final decision lies with the data owner.

## Definitions of terms

**Primary data** are data which are prepared and analysed in connection with the purpose for which they were originally intended.

**Secondary data** are data which are provided for analysis *over and above their original primary purpose*. Differences between the primary cause of data collection and their subsequent utilization are critical for classifying secondary data. It is irrelevant for classification whether data are further utilized by the data owners themselves or by third parties. Accordingly, routine data from a health insurance fund for example are not only secondary data when they are utilized for scientific questions but also when the statutory health insurance funds have recourse to them for purposes of health care planning.

**Secondary data analysis** defines the utilization of secondary data. Secondary data analysis includes the survey and preparation steps of the secondary data body that are required for the analysis. Only through these preparation steps are the data accessible for scientific questions. It is not always possible to make an unequivocal theoretical distinction a priori between the concepts of primary and secondary data and thus between secondary analysis and secondary data analysis. In the individual case, therefore, it is the duty of the user of an existing data body to provide reasons which third parties understand as to whether the planned analysis is a secondary data analysis. Whether the Guidelines and Recommendations of Good Epidemiological Practice (GEP) and/or Good Practice in Secondary Data Analysis (GPS) primarily apply, depends on the results of this assessment.

**Data owners:** in the context of GPS, this term includes those institutions which (primarily) survey, store and use the data. Data owners and **primary users** are synonyms. The term data owner, however, also emphasizes that the primary owner also possesses legal power of control over the data. In the area of statutory social insurance, data owners are health insurance funds or pension funds, which store (medical) data relating to the insured for administrative purposes, in the same way as (cancer) registers, occupational medicine study centres or epidemiological institutions.

**Secondary users:** in the context of GPS, this term refers to those centres and persons which obtain data from data owners and prepare and analyse it to process research questions independently of the formal primary aim of the data survey. It expresses the fact that the parties involved are generally persons/institutions other than the data owners/primary users.

**Personal data:** personal data, in epidemiological terms, refer to information that can be assigned to an individual person as unit of observation.

**Social data:** This includes routine data belonging to social insurance providers (including statutory health insurance funds, pension funds and accident insurance funds).

**Register data** are data from disease-related but not necessarily population-related registers.

**Pseudo-anonymization:** *Pseudo-anonymization describes replacing a name and other identifying features by an identifier to preclude identification of the parties involved or to make their identification more difficult (German federal data protection law (BDSG) §3 (6a)). The data that identify a person directly (e.g. surname, first name, telephone number, social insurance number and/or personal identity card number) are removed from the data and replaced by a clear identifier (e.g. an identification number). Pseudo-anonymized data still relate to the persons involved. Pseudo-anonymization is particularly necessary when personal data are to be assigned to data that have already been pseudo-anonymised via a known pseudonym.*

**Anonymization:** defined in accordance with BDSG §3 (6a) BDSG: *Anonymization describes changing personal data in such a way that the particulars can no longer be assigned to a defined or definable natural person or can be thus assigned only after disproportionately high expenditure in terms of time, cost and manpower.*

The term anonymization includes procedures which effectively prevent identification of a person in a data body. As in pseudo-anonymization, this may involve replacing data that identify a person with an identification number. However, the replacement should not be reversible. This can be achieved by destroying the key or the reference list used for anonymization for example. Certain features are often changed by means of classification (forming age groups, abbreviating post codes etc) while unclassified information is simultaneously deleted. Within a fully anonymized data body, reference can be made to different information e.g. longitudinally, to one observation unit (one patient, one insured) by allocating a unique code number, from which it is impossible to trace the natural person. Anonymized data no longer fall under the data protection provisions on dealing with personal data.

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