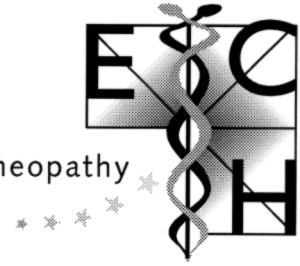


European Committee for Homeopathy



# Data Collection in Homeopathic Practice

A Proposal for

An International Standard

## A. Steinsbekk and the Data Collection Group<sup>1</sup>

### Summary

Even in the early 1990s practice-based clinical research was being seen as a means of promoting scientific acceptance of homeopathy, in addition to the performance of randomized controlled studies. Various prospective documentation projects were therefore started independently of one another, with differing objectives and designs. It became clear that an international standard for data collection in homeopathic practice was needed if possible synergies were to be exploited and valid data were to be accumulated. This concern was addressed by the European Committee for Homeopathy and a special Data Collection Group (DCG) was set up.

This guide begins by explaining the various areas which prospective documentation projects can be used to investigate, then presents possible study types and their advantages and disadvantages. A list is given of the standard parameters which need to be recorded for particular areas (quality assurance, treatment outcome or economic outcome). An overview of outcomes scales, quality of life measures and the coding systems used illustrates the difficulties involved in standardizing the design of prospective documentation projects. General recommendations are also given on practical aspects and data management in a documentation project. Since this is not the easiest of subjects, a survey known as the 10-item data set is recommended as a practical introduction.

### Keywords

Homeopathy, prospective documentation, case documentation, international standard, ECH, DCG, study design, survey, 10-item data set, prospective observational study, clinical practice audit, outcomes research, quality of life, health economy, coding systems.

### 1. Background

A scientific evaluation of complementary and alternative medicine such as homeopathy is urgently required. Although randomised controlled trials are the primary tool for such an evaluation, practice-based research such as prospective data collection is needed in order to evaluate the effectiveness of homeopathy under "real life" circumstances<sup>2</sup>. Prospective data collection in homeopathy has until now been few and far between; most has been retrospective. The first attempts at prospective data collection can be found in a documentation system developed by the Royal London Homoeopathic Hospital with the support of VSM Geneesmiddelen in the Netherlands which incorporates the READ Clinical Classification [Read 1991, Van Haselen et al. 1992, Van Haselen et al. 1994], and a Dutch model using the International Classification of Primary Care (ICPC) [Lamberts et al. 1993, Van Berckel Smit 1993]. At virtually the same time a prospective data collection for patients with gynecological

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<sup>2</sup> For all interested in more in-depth information, please refer to the literature referenced. An overview and introduction into the field of data collection including details on seven projects is given in the article on "Prospective documentation in homeopathic practice – An essential contribution to quality assurance" [Heger 1998]. For further information on health economics in complementary medicine in general and homeopathy in particular, please refer to the article written by Eisebitt [1999]. Information on outcomes research in complementary and alternative medicine is summarised in the article "Clinical outcomes research in CAM: An overview of experimental design and analysis" by Gatcheland and Maddrey [1998].

diseases such as amenorrhea and fertility disorders was developed at the Outpatient Clinic for Naturopathy in Heidelberg [Gerhard et al. 1993, Gerhard et al. 1995, Schmück et al. 1995, Gerhard et al. 1996, Gerhard 1997]. The subject of data collection was also raised at the research meeting of the European Committee for Homoeopathy (ECH) held in London in January 1997 [Steinsbekk et al. 1998]. The first proposal for an international co-operation in terms of data collection was made at the Congress of the Liga Medicorum Homoeopathica Internationalis, Seattle, in April 1997 based on practical experiences in Brazil [Biolchini 1997]. This was taken further at the ECH research meeting held in Brussels in October 1998. It was decided to form a Data Collection Group (DCG) in order to develop an international standard for data collection in homeopathic practice. The Data Collection Group consists of the following members: Aslak Steinsbekk (co-ordinator, Norway), Jorge Biolchini (Brazil), Marianne Heger (Germany), Carlo Rezzani (Italy), Nikos Tsamis (Greece), Robbert van Haselen (UK), Claudia Witt (Germany) and Maike Wittorff (Germany).

Several data collection projects have since been started or are planned world-wide. It is obvious that there is a huge need for co-operation in order to create synergies and gain a valid database. An international standard would make it easier to start new projects, as each researcher would not have to invent the wheel again. The objectives of the DCG were to:

- design a "draft" for an international standard on data collection in homeopathic practice for discussion,
- design a "final" document, and update this, whenever necessary, and to
- act as co-ordinator for new data collection projects, if the resources allow it.

The 1<sup>st</sup> draft compiled by the DCG was mailed in December 1998 to various experts in the field for review. Based on the comments received until 1<sup>st</sup> February 1999 the initial idea of designing a "minimum data set" has been left as the parameters required will depend on the objective of a data collection project. In the 2<sup>nd</sup> draft presented on 15–16 April 1999 in London, a "core data set" was discussed for each of the different objectives of a data collection project: (1) Quality assurance, (2) Treatment outcomes, and (3) Economic outcomes. After including all the comments received, the 3<sup>rd</sup> draft was presented by Heger at the Panel on Clinical at the Congress of the Liga Medicorum Homoeopathica Internationalis, Brazil, in October 1999. The feedback was extremely positive stating that the document clearly defines the methods which are appropriate for practice-based research and that it shows the steps how to design a data collection project depending on the objective defined. In a small working group established besides the congress also a new idea came up. It was decided to design a prospective survey, that means a data collection project at the most basic level. Such a survey will provide basic information on the wide-spread use of homeopathy in daily practice. It serves also as a basis for the planning of more sophisticated data collection projects, e.g. outcomes studies or cost-effectiveness studies. The "final" document presented here includes all the relevant comments and suggestions received so far from researchers and homeopathic experts in Europe, United States and Brazil. In general, it is our goal to create maximum synergy and harmonisation between different data collection projects, while maintaining the flexibility to tailor individual projects to local needs and objectives.

## 2. Objectives of a Data Collection Project

Before starting a data collection project, the researcher has to be very clear about the purpose of undertaking it. A data collection project can have different objectives, which have been categorised in the following three broad categories:

### A. Quality Assurance

Quality assurance is defined as systematically looking at the procedures used for diagnosis, care and treatment, investigating the effect care has on the outcomes as assessed by the practitioner, as well as recording the qualifications and experiences of the practitioner.

### B. Treatment Outcomes

Treatment outcomes includes practitioner-assessed effectiveness, patient-assessed effectiveness, utility and quality of life, as well as the assessment of adverse events (AEs, i.e. adverse drug reactions (ADRs) including initial aggravations).

### C. Economic Outcomes

Economic outcomes most often relate to resource use and the cost of caring for a patient. Cost data can be divided into direct, indirect and intangible costs [Rapier 1996]:

- Direct costs are mainly the costs that fall within the health care system, e.g. costs of hospital care, nurses, physicians, drugs and medical interventions.
- Indirect costs usually fall outside the health care service and relate to changes in productivity, e.g. costs to the patient and his/her employer.
- Intangible costs are difficult to value financially, e.g. pain and suffering associated with an illness.

The four main types of economic analyses are [Drummond 1995]: (1) Cost-Minimisation Analysis (CMA), (2) Cost-Effectiveness Analysis (CEA), (3) Cost-Utility Analysis (CUA), and (4) Cost-Benefit Analysis (CBA). The decision as to which type of analysis is the most appropriate will depend on the aim of the data collection project, the target audience (patient, practitioner, purchaser) and the availability of outcomes data. Cost-minimisation, cost-effectiveness and cost-utility analyses are the most common types used. In the United Kingdom and Canada, for example, cost-utility analysis is of particular interest to government and health service decision makers, as it allows the costs of different medical interventions to be compared in terms of a common unit (e.g. quality adjusted life years). Although the theory behind preference-based measures remains controversial, there is also growing interest in the United States in using cost-utility analysis to aid decision making.

It should be noted that distinctions are not absolute and that there is often an overlap between the different objectives of a data collection project. Apart from this, other objectives may be applicable, such as for instance the clinical verification of a predefined set of prescribing features for a particular homeopathic medication. However, this could also be regarded as a specific type of study assessing treatment outcomes.

### 3. Choosing the Appropriate Research Method

In general, the research method represents a systematic way of gathering information and reaching an answer based on that information. That means that the research method chosen must be appropriate and powerful enough to answer the research question being asked. In the following, different research methods addressing practice-based research questions are described giving a brief indication of why each type is used [Rapier 1996, Hennekens et al. 1987, Rothman et al. 1998]:.

#### 3.1 Surveys

A survey is a systematic method of gathering data on what is happening [RCCM 1999]. It gives a snapshot of current views or activities and is commonly used to assess, for example, the amount of disease in the community, the patients' use of alternative and complementary therapies or their opinions of the treatment received. Ideally, a survey to give maximum information will be targeted at and designed for a particular group of patients. Its usefulness is limited by the bias of sampling, e.g. low response rates. One of the most famous surveys published recently provides valuable insight information on the use of alternative and complementary medicine in the United States [Eisenberg et al. 1998]. There is a huge lack of such basic information in homeopathy. In the United Kingdom, three research groups have started looking at different aspects of homeopathic treatment in daily practice:

**Ann Clover, Kent & Sussex Weald Homoeopathic Hospital, Church Road, Tunbridge Wells, Kent TN1 1JU, United Kingdom.**

*Research Method:* Survey.

*Design:* Prospective systematic survey.

*Primary Objective:* Patient benefit from homeopathy.

*Main Outcome Measure:* Treatment outcomes assessed by the patient using the Tunbridge Wells Outcome Scale.

*Number of Patients Planned:* 2,000 outpatients.

*Start of the Survey:* NA.

*End of the Survey:* NA.

*Data Collection:* Paper.

**Peter Fisher and Robbert A. Van Haselen, Royal London Homoeopathic Hospital, Great Ormond Street, London WC 1N 3HR, United Kingdom.**

*Research Method:* Survey.

*Design:* Prospective systematic survey.

*Primary Objective:* Patient utility and use of conventional medicine in newly referred patients.

*Main Outcome Measure:* Utility assessed by the patient using the EuroQuol (EQ-5D).

*Number of Patients Planned:* 70 outpatients.

*Start of the Survey:* 1998.

*End of the Survey:* 1999.

*Data Collection:* Paper.

**David Spence, United Bristol Healthcare NHS Trust, Bristol Homoeopathic Hospital, Cotham Hill, Bristol BS6 6JU, United Kingdom.**

*Research Method:* Survey.

*Design:* Prospective systematic survey.

*Primary Objective:* Patient satisfaction with homeopathy.

*Main Outcome Measure:* Satisfaction with treatment and practitioner assessed by the patient.

*Number of Patients Planned:* 100 outpatients.

*Start of Survey:* 1998.

*End of Survey:* 1998 (replication of the survey planned in 2000).

*Data Collection:* Paper.

Surveys that look, for example, at the prevalence of the use of homeopathy within the population and the descriptive characteristics of patients that seek homeopathic treatment are a valuable tool in demonstrating the wide-spread use of homeopathy and what kind of complaints are most often

treated. This information is helpful in discussions about homeopathy and its usefulness in various areas with public officials and health insurance companies. It serves also as a basis for the planning of prospective observational studies, outcomes studies and economic analyses. This provided us with the motivation to design a prospective survey, that means a data collection project at the most basic level. One of the keypoints discussed at the Congress of the Liga Medicorum Homoeopathica Internationalis 1999 in Brazil was to involve as many practitioners as possible. In principle, each practitioner should document his/her new patients and contribute to this basic data collection. As practitioners are usually busy, they should not have to spend more than 2 minutes in addition to their usual habits. Therefore, we defined the following items to be required for a basic data collection project on homeopathy in daily practice:

**Survey on Homeopathy: 10-item Data Set**

1. Patient identification [initials // date of birth // sex]
2. Chief complaint/s [severity of chief complaint/s // onset of chief complaint/s]
3. Clinical diagnosis [acute // chronic // since when?]
4. General well-being<sup>Ⓞ</sup> [how has been your general well-being during the past month?]
5. Health state<sup>Ⓞ</sup> [how is your health state today? 0 = worst imaginable health state, 100 = best imaginable health state]
6. Treatment prescribed [homeopathic treatment (medication // potency) // other treatment // therapeutic placebo // no treatment, why?]
7. Total length of consultation [minutes // hours]
8. Outcome of treatment<sup>Ⓞ</sup>
9. Adverse events<sup>Ⓞ</sup> [no // yes // if yes, observed adverse event // start date // end date or ongoing // relationship with treatment (probable // possible // improbable // unable to evaluate) // initial aggravation]
10. Date of patient contact/consultation

<sup>Ⓞ</sup> All items have to be completed by the practitioner except for those items related to the patient's complaints and quality of life (2, 4, 5). <sup>Ⓞ</sup> Discussions with experts in health economics revealed that questions on the patient's feeling and function should also be included. The question on general well-being was selected from the PGWB and that on health state from the EQ-5D. For both questions validations exist in different languages. The question "affect on daily living" was not used as no validations are available. <sup>Ⓞ</sup> NA at initial patient contact.

This 10-item data set will give an overview of which patients seek homeopathic treatment, with which homeopathic medicines are they treated, which benefit do they have from homeopathic treatment and how safe are these homeopathic medicines. The information on length of consultation which can be easily linked, for example, to the average cost of consultation will help to get an idea on the total cost of homeopathic treatment. However, the most important keypoint is that thousands of patients are documented by the practitioners in a consistent and comprehensive way in order to get a valid and systematic database. Our big idea is to create a multi-national "mega database" with at least 10,000 patients per country treated with homeopathy.

**3.2 Prospective Observational Studies**

Prospective observational studies are an instrument to assess the outcome of a medical intervention in "normal" clinical practice. The main features of prospective observational studies are [Rapier 1996]:

- there is no randomisation to treatment,
- they involve a large, mixed patient population who may undergo a range of tests or procedures, and
- the outcomes reflect compliance in the "real world".

Their usefulness is limited by the lack of a control or concurrent comparative group, i.e. there is no way of knowing whether any changes seen in the condition are due to factors other than the treatment effect. These factors include expectation of the effect by the patient or practitioner, natural change in the course of the disease like spontaneous improvement, effect of the interaction between the patient and practitioner, and a host of other factors, e.g. placebo effect [RCCM 1999]. Adjustment for case mix and severity of illness are important to allow for the potential selection bias that occurs when patients are not randomly assigned to alternative treatments. The validity and accuracy of data generated from observational studies must, therefore, always be questioned [Rapier 1996]. Prospective observational studies can be broadly separated into database studies, clinical practice audits, and Post-Marketing Surveillance studies.

#### *Database Studies*

In the United Kingdom there are several large patient outcomes databases (e.g. EPIC and Mediplus), which look at how primary care patients have been managed for several years. Similarly in the United States there are several large databases that can be used to provide data on treatment patterns (e.g. insurance claims, health maintenance organisations and Medicare). Database studies provide useful data for post-marketing pharmaco-economic evaluations and computer modelling. They can also be used to determine how the treatment of patients in a protocol-driven randomised controlled trial differs from that during routine care.

#### *Clinical Practice Audits*

Clinical practice audit is a process by which the effectiveness of a clinical team is continuously assessed and improved, via the monitoring of patient outcomes and improvement of practice guidelines. The definition used by the British Department of Health is generally accepted [Department of Health 1989]: "Clinical practice audit is the systematic critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources and the resulting outcome and quality of life for the patient". Core reasons for performing an audit are [Earl-Slater et al. 1997]: (1) The issue addressed is a common problem, (2) The problem is significant or serious, (3) The issue addressed is relevant to professional practice or development, (4) There is a realistic potential for improvement, (5) The change following audit is likely to benefit patients, (6) The change is likely to lead to greater effectiveness, and (7) The end result is likely to justify the investment or time and effort involved. Another reason for an audit might be that, whilst in principle few would pay for a service without some understanding of the content and impact of the service being bought, many purchases are based on imperfect and incomplete information. Audit can elevate the understanding of what is being bought. In addition, audit can be used to establish the price of services purchased.

An audit allows, for example, light to be shed on various practical aspects of homeopathy, e.g. (1) What symptoms determine the choice of homeopathic medicines?, (2) Which potencies are prescribed for which patients?, (3) What kind of treatment strategies are applied in acute and chronic illnesses, or (4) What kind of substances really antidote homeopathic medicines? etc. In addition, it can also provide information on the interobserver accuracy of the prescription of a homeopathic medicine, e.g. how accurate and reproducible is the homeopathic case-taking process, that means, will five experienced homeopathic practitioners who have seen the patient prescribe the same medication? In

the following, the completed, ongoing and planned audits conducted in homeopathic practice are presented briefly:

**Cees Baas, Robijnring 51, 562999 Eindhoven, The Netherlands.**

*Project Title:* DELPHI Project  
*Research Method:* Observational study (clinical practice audit).  
*Design:* Multi-centre, prospective case documentation.  
*Primary Objective:* Quality assurance in homeopathy with special focus on less known homeopathic medicines.  
*Main Outcome Measure:* Treatment outcomes assessed by the practitioner.  
*Number of Patients Planned:* Not yet decided.  
*Start of the Study:* 2000.  
*End of the Study:* Open enquiry.  
*Data Collection:* Not yet decided.

**Peter Fisher and Robbert A. Van Haselen, Royal London Homoeopathic Hospital, Great Ormond Street, London WC 1N 3HR, United Kingdom.**

*Research Method:* Observational study (clinical practice audit).  
*Design:* Multi-centre, prospective case documentation.  
*Primary Objective:* Quality assurance in homeopathy.  
*Main Outcome Measure:* Treatment outcomes assessed by the practitioner using a 5-point Rating Scale.  
*Number of Patients Planned:* New outpatients.  
*Start of the Survey:* 1999.  
*End of the Survey:* Open enquiry.  
*Data Collection:* Paper.

**Peter König, Maria Theresienstrasse 9/5, 1090 Wien, Austria.**

*Project Title:* Wisdoc.  
*Research Method:* Observational study (clinical practice audit).  
*Design:* Multi-centre, prospective case documentation.  
*Primary Objective:* Quality assurance in homeopathy.  
*Main Outcome Measure:* Treatment outcomes assessed by the practitioner.  
*Start of the Study:* 1997.  
*End of the Study:* Open enquiry.  
*Data Collection:* Paper or Wisdoc, a data base system provided on Windows. Wisdoc integrates a practice organisation and management programme tailored to the needs of homeopathic practitioners.

**David T. Reilly, AD HOMINEM, Glasgow Homoeopathic Hospital, 1000 Great Western Road, Glasgow G12 0NR, Scotland.**

*Project Title:* IDCCIM.  
*Research Method (1):* Observational study (clinical practice audit).  
*Design:* Multi-centre, prospective case documentation.  
*Primary Objective:* Effectiveness of homeopathy for specific acute illnesses in primary care.  
*Main Outcome Measure:* Treatment outcomes assessed by the patient using the Glasgow Homoeopathic Hospital Outcome Scale (GHHOS).  
*Number of Patients Planned:* 1,000 outpatients.  
*Start of the Study:* 1995.  
*End of the Study:* 1998.  
*Data Collection:* Paper.

*Research Method (2):* Observational study (clinical practice audit).  
*Design:* Prospective case documentation.  
*Primary Objective:* Quality assurance in homeopathy.  
*Main Outcome Measure:* Treatment outcomes assessed by the patient using the Glasgow Homoeopathic Hospital Outcome Scale (GHHOS).  
*Number of Patients Planned:* 200 outpatients (first phase).  
*Start of the Study:* 1995.  
*End of the Study:* 1998.  
*Data Collection:* Paper.

*Research Method (3):* Observational study (clinical practice audit).  
*Design:* Prospective case documentation.  
*Primary Objective:* Effectiveness of an integrative care package for complex cases.  
*Main Outcome Measure:* Treatment outcomes assessed by the patient using the Glasgow Homoeopathic Hospital Outcome Scale (GHHOS).  
*Number of Patients Planned:* 200 inpatients (first phase).  
*Start of the Study:* 1995 and 1998.  
*End of the Study:* 2000.  
*Data Collection:* Paper.

*Research Method (4):* Observational study (clinical practice audit).  
*Design:* Prospective case documentation.  
*Primary Objective:* Quality assurance in homeopathy.  
*Main Outcome Measure:* Treatment outcomes using qualitative methodology.  
*Number of Patients Planned:* 100 outpatients from whom 20 will be selected for in-depth assessment.  
*Start of the Study:* 1999.  
*End of the Study:* 2000.  
*Data Collection:* Paper.

**David Spence, United Bristol Healthcare NHS Trust, Bristol Homoeopathic Hospital, Cotham Hill, Bristol BS6 6JU, United Kingdom.**

*Research Method:* Observational study (clinical practice audit).  
*Design:* Mono-centre, prospective observational study.  
*Primary Objective:* Quality assurance in homeopathy.  
*Main Outcome Measure:* Treatment outcomes assessed by the practitioner using the Bristol Homoeopathic Hospital Outcome Scale.  
*Number of Patients Planned:* 3,000 outpatients.  
*Start of Study:* 1997.  
*End of Study:* 2000.  
*Data collection:* Paper.

**Aslak Steinsbekk, Kongens gt 22, 7011 Trondheim, Norway.**

*Research Method:* Observational study (clinical practice audit).  
*Design:* Multi-centre, prospective observational study.  
*Primary Objective:* Effectiveness of homeopathy on the complaints the patients seek help for.  
*Main Outcome Measure:* Treatment outcomes assessed by the patient using a Visual Analogue Scale (VAS).  
*Number of Patients Planned:* 1,100 outpatients.  
*Start of the Study:* 1996.  
*End of the Study:* 2000.  
*Data Collection:* Paper.

**Harald Walach, Psychologisches Institut der Universität Freiburg, 79085 Freiburg, Germany.**

*Research Method:* Observational study (clinical practice audit).  
*Design:* Multi-centre, prospective observational study.  
*Primary Objective:* Effectiveness of homeopathy and acupuncture for chronic illnesses.  
*Main Outcome Measure:* Health-related quality of life.  
*Number of Patients Planned:* 5,000 outpatients (homeopathy & acupuncture).  
*Start of the Study:* 1995.  
*End of the Study:* 2001  
*Data Collection:* Paper.

**Stefan N. Willich and Claudia Witt, Institut Arbeits- und Sozialmedizin, Universitätsklinikum Charité, Humboldt-Universität Berlin, Schumannstrasse 20-22, 10098 Berlin, Germany.**

*Research Method (1):* Observational study (clinical practice audit).  
*Design:* Multi-centre, prospective observational study.  
*Primary Objective:* Effectiveness of homeopathy for chronic illnesses.  
*Main Outcome Measure:* Health-related quality of life.  
*Number of Patients Planned:* 4,000 outpatients.  
*Start of the Study:* 1997.  
*End of the Study:* 2001.  
*Data Collection:* Paper or FileMaker Pro, a data base system provided on Windows. FileMaker Pro integrates routine data base functions and an interface to a practice management programme.

*Research Method (2):* Observational study (clinical practice audit).  
*Design:* Multi-centre, prospective, non-randomised, parallel groups observational study.  
*Primary Objective:* Cost-effectiveness of homeopathy for specific chronic illnesses compared to conventional medicine.  
*Main Outcome Measure:* Costs per score point of improvement.  
*Number of Patients Planned:* 1,000 outpatients.  
*Start of the Study:* 1999.  
*End of the Study:* 2001.  
*Data Collection:* Paper.

### *Post-Marketing Surveillance Studies*

Post-Marketing Surveillance (PMS) studies have traditionally been conducted by the pharmaceutical industry as a means of collecting additional safety data for new treatments. Some years ago, binding guidelines on the performance of PMS studies were included in the "Draft notice to applicants for marketing authorisation for medicinal products for human use in the European Community" [Commission of the European Communities 1996]. PMS studies have since then been required by the authorities as the pharmaceutical industry's contribution to pharmacovigilance. The importance of such studies will increase and provide yet another source of outcomes data, particularly if the time-scales over which data are collected are increased.

### **3.3 Cohort Studies**

In a cohort study a properly defined group of patients ("cohort") is followed over a predefined period of time in order to assess the potential benefit of a particular treatment [RCCM 1999]. It is designed usually like a prospective observational study including a control or comparative group. In most cases, cohort studies have been conducted to investigate the incidences or relative risks of adverse drug reactions in users and non-users of particular medical treatments or drugs, e.g. Boston Collaborative Drug Surveillance Program.

### **3.4 Outcomes Research Approach**

Over the last few years there has been increasing interest in measuring the effectiveness of the health care provided to patients, both in terms of clinical benefits and economic costs. This has resulted in the development of the "outcomes research" approach which can also be integrated in a data collection project. Outcomes research uses established methodology from epidemiology, clinical research, psychometrics, health economics and health services research [Rapier 1996]. This multidisciplinary approach aims to improve our understanding of the relationship between medical interventions and health outcomes, as well as how health outcomes relate to cost. The emphasis in outcomes research – in contrast to that in traditional clinical trials – is on the benefits to the patient. These include the influence of the treatment on the patient's quality of life, the functional status of the patient and the patient's satisfaction with his/her treatment. Another major difference between outcomes research and traditional clinical trials is that outcomes research is concerned with "normal" medical practice, i.e. the effectiveness of a medical treatment in patients who are not part of a randomised controlled trial. The use of large sample sizes with adjustments made for individual patients' severity of illness and other risk factors is fundamental to outcomes research. As outcomes research considers the overall management and the effectiveness of the whole treatment process, it is an ideal research method for the evaluation of holistic therapies such as homeopathy. In the following, the data collection projects including the outcomes research approach are presented briefly:

**Max Haidvogel, Ludwig Boltzmann Institut für Homöopathie, Dürergasse 4, 8010 Graz, Austria.**  
**Marianne Heger, Research Center HomInt, P.O. Box 410240, 76202 Karlsruhe, Germany.**  
**Michael Fischer, ClinResearch, Robert-Perthel-Strasse 77a, 50739 Köln, Germany.**  
**David Riley, Integrative Medicine Institute, P.O. Box 4310, Santa Fe, NM 87502, USA.**

*Project Title:* IMDCN.

*Research Method (1):* Observational study including the outcomes research approach (cost-effectiveness analysis).

*Design IMDCN:* International, multi-centre, prospective, non-randomised, parallel groups observational study.

*Primary Objective:* Effectiveness of homeopathy and CAM for acute and chronic illnesses compared to conventional medicine.

*Main Outcome Measure:* Treatment outcomes assessed by the patient using the Integrative Medicine Outcomes Scale (IMOS).

*Number of Patients Planned:* 10,000 outpatients.

*Start of the Study:* 1998.

*End of the Study:* Open enquiry.

*Data Collection:* Remote data entry system provided on the internet. It integrates routine data base functions, a SPSS interface and evaluation tools via the internet.

*Project Title:* IMDCN-1.1.

*Research Method (2):* Observational study including the outcomes research approach (cost-effectiveness analysis).

*Design IMDCN-1.1:* International, multi-centre, prospective, non-randomised, parallel groups observational study.

*Primary Objective:* Effectiveness of homeopathy for specific chronic illnesses compared to conventional medicine.

*Main Outcome Measure:* Treatment outcomes assessed by the patient using the Integrative Medicine Outcomes Scale (IMOS).

*Number of Patients Planned:* 1,000 outpatients.

*Start of the Study:* 1999.

*End of the Study:* 2001.

*Data Collection:* Remote data entry system provided on the internet. It integrates routine data base functions, a SPSS interface and evaluation tools via the internet.

Conceptually, there is a large overlap between outcomes research and disease management. Disease management, like outcomes research, is a relatively new concept that has become important due to the concerns about escalating health care costs [Rapier 1996]. In addition, the recognised variations in medical practice and their associated different outcomes have contributed to the increased interest in introducing disease management programmes. The overall aim of disease management is to improve the way patients are managed in the health care system. Fundamental to this process are a full understanding of the way patients are treated, the quality of the care provided, and the clinical and economic outcomes. The development of practice guidelines based on the results of outcomes research is a central part of the disease management process. Outcomes research therefore provides much of the information needed for disease management programmes.

#### **4. Guide to Core Data Set**

Like in any other research project, the following eight key steps can serve as general guidance for the development of a practice-based data collection project:

- define the study's aims and objectives,
- review the available literature,
- identify the target audience (patients, practitioners, purchasers),
- identify the audience's desired outcomes,
- decide how best to measure the desired outcomes (choosing the appropriate outcomes measures),
- decide how best to collect the data (choosing the appropriate research method),
- identify patient risk factors related to outcomes, and
- carefully plan and monitor the study.

Depending on the objective of the data collection project and the research method chosen, a "core data set" will be generated. The following table lists the indispensable parameters required for a data collection project depending on its objective:

Table 1: Parameters required (x) for the purpose of quality assurance (QA), treatment outcomes (TO), and economic outcomes (EO). Optional parameters (o).

**A. Initial Patient Contact/Consultation**

<b>Demographic Information</b>	<b>QA</b>	<b>TO</b>	<b>EO</b>
Patient identification [initials // date of birth // sex]	x	x	x
Weight // Height	o	o	o
Race // Ethnicity	o	o	o
Smoking, coffee and other possible antidotes per day	x	o	o
Payment source	o	o	x
Patient freedom to choose practitioner	o	o	x
Patient experience with homeopathy	o	o	x
Patient experience with practitioner	o	o	o
Patient preference for homeopathy	o	x	o
Patient confidence that the treatment he/she will receive will solve his/her medical problem	o	o	o
Patient confidence in the practitioner's professional skills	o	o	o
Willingness to pay	o	o	x
Quality of life	o	x	x
<b>Chief Complaint/s</b>			
Chief complaint/s	x	x	x
Severity of chief complaint/s assessed by the patient	o	x	o
Severity of chief complaint/s assessed by the practitioner	o	x	o
Onset of chief complaint/s	x	x	x
Occurrence of chief complaint/s in the past 12 months	o	o	o
Clinical diagnosis [acute // chronic // since when?]	x	x	x
Confidence in diagnosis [which examinations or tests // 0- to 10-point Rating Scale]	x	o	o
<b>Concomitant Medical Problems and Medications</b>			
Concomitant medical problems [yes // no // if yes, which? // onset of concomitant medical problems]	x	x	x
Concomitant medications for concomitant medical problems [drug, therapy or measure // indication // dose // medication form // dosing frequency // start date // stop date or ongoing]	x	x	x
<b>Treatment Prescribed</b>			
Homeopathic treatment // Therapeutic placebo // No treatment, why?	x	x	x
Homeopathic medication	x	x	x
Potency	x	x	x
Medication form	o	o	x
Dosing frequency	x	o	x
Number of days	x	o	x
Manufacturer	x	o	x
Prescribing symptoms	x	o	o
Reason for prescription	x	o	o
Confidence in prescription [0- to 10-point Rating Scale]	x	o	o
Adjunctive therapies prescribed [drug, therapy or measure // indication // dose // medication form // dosing frequency // start date // stop date or ongoing]	x	x	x
<b>Further Information</b>			
Type of consultation	x	o	x
Total length of consultation	x	o	x
Total cost of consultation and treatment	o	o	x
Follow-up recommendation	o	o	o
Date of patient contact/consultation	x	x	x

**B. Follow-up Patient Contact/Consultation**

<b>Effectiveness</b>	<b>QA</b>	<b>TO</b>	<b>EO</b>
Severity of chief complaint/s assessed by the patient	o	x	o
Severity of chief complaint/s assessed by the practitioner	o	x	o
Outcome of treatment assessed by the patient	x	x	x
Outcome of treatment assessed by the practitioner	x	x	x
Quality of life	o	x	x
Patient satisfaction with treatment	x	o	o
Patient satisfaction with practitioner	x	o	o

<b>Further Information</b>			
Patient compliance	x	x	x
Occurrence of adverse events	x	x	x
Visit to other practitioners	o	o	x
Use of or changes in adjunctive therapies and concomitant medications	x	x	x
Days-off work	o	o	x
Stay in hospital	o	o	x
Willingness to choose therapy again	o	o	o
Willingness to choose practitioner again	o	o	o
Date of patient contact/consultation	x	x	x

### C. Information on the Participating Practitioners

	<b>QA</b>	<b>TO</b>	<b>EO</b>
Name // Degree // Address	x	x	x
Education // Training	x	o	o
Years in medical practice	x	x	x
Years in homeopathic practice	x	x	x
Experience in research	o	o	o

As each data collection project demands extra time from usually busy practitioners, only those parameters directly relevant for the specific research question should be recorded. Particular attention should always be paid to find the right balance between what is scientifically desirable and practically feasible.

A pragmatic approach to develop a practice-based data collection project is to start a survey collecting information on the needs of homeopathic practitioners. This was applied by Biolchini [1999] in Brazil with the "Informational Needs Study of the Homeopathic Clinician (INSHC)" where the following information was gathered: (1) Professional profile of clinical practice, (2) Use of the Critical Incident Technique, and (3) Data fields used in daily practice. The analysis provided essential elements for the design of both a clinical case database and a technical-scientific communication network for homeopathic professionals.

## 5. Outcomes Measures

Having identified the outcomes of interest, the next step is to select appropriate ways to measure the desired outcomes, and to identify where new measures are required. A review of the clinical research literature should provide information on the measures that have been used and appear to be generally acceptable. For many diseases, however, relevant measures are still being defined. In addition, evaluating a holistic treatment approach such as homeopathy may require new patient-related outcomes measures including quality of life.

Outcomes measures widely used in conventional research as well as complementary and alternative medicine research are Likert style scales. In the following, the outcomes measures used so far in the data collection projects are described:

### Glasgow Homoeopathic Hospital Outcome Scale (GHHOS)

The GHHOS consists of the following 9 categories:

- 0 No change
- 1/+1 Slight deterioration // Slight improvement not affecting daily living
- 2/+2 Moderate deterioration // Moderate improvement affecting daily living

- 3/+3 Major deterioration // Major improvement
- 4/+4 Disastrous deterioration // Cured, back to normal

Assessment: Patient and/or practitioner.

Original language: English.

Other languages available: German, Russian.

Validation: In progress.

References: Publication in preparation.

#### **Integrative Medicine Outcomes Scale (IMOS)**

The IMOS consists of the following 5 categories:

- Complete recovery
- Major improvement
- Slight to moderate improvement
- No change
- Deterioration

Assessment: Patient and/or practitioner.

Original language: English.

Other languages available: German, Dutch, Spanish, Russian.

Validation: In progress.

References: Publication in preparation.

#### **Tunbridge Wells Outcome Scale**

The Tunbridge Wells Outcome Scale consists of the following 7 categories:

- 0 Unchanged
- 1/+1 Slightly worse // Slightly better
- 2/+2 Moderately worse // Moderately better
- 3/+3 Much worse // Much better

Assessment: Patient.

Original language: English.

Other languages available: No.

Validation: No.

References: No.

#### **Bristol Homoeopathic Hospital Outcome Scale**

The Bristol Homoeopathic Hospital Outcome Scale consists of the following 7 categories:

- 0 Unchanged
- 1/+1 A little worse // A little better not affecting daily life
- 2/+2 Worse // Better affecting daily life
- 3/+3 Much worse // Much better

Assessment: Practitioner and patient.

Original language: English.

Other languages available: No.

Validation: No.

References: No.

The importance of measuring satisfaction with care is gaining increasing recognition, as contradictory views on the success of a treatment may suggest that there have been problems in the care of the patients. Such problems include the possibility that the practitioner has failed to discuss the nature and severity of the condition adequately, or to explain the objectives of the intervention and any associated side effects. Patient satisfaction may also be affected by the quality of care provided, the ease of access (e.g. waiting times) and the convenience of the medical services. Recent studies in complementary and alternative medicine, e.g. homeopathy, have shown that patient satisfaction with treatment is an important issue, especially when compared with conventional medicine.

#### **Integrative Medicine Patient Satisfaction Scale (IMPSS)**

The IMPSS consists of the following 5 categories:

- Very satisfied
- Satisfied
- Neutral
- Dissatisfied
- Very dissatisfied

Assessment: Patient.

Original language: English.

Other languages available: German, Dutch, Spanish, Russian.

Validation: In progress.

References: Publication in preparation.

#### **Measure Yourself Medical Outcome Profile (MYMOP)**

MYMOP is a brief patient-generated, problem specific outcome questionnaire assessed by the patient. At the first consultation the patient chooses one or two symptoms, and one activity of daily living which he/she considers the most important. The items must all relate, in the patient's opinion, to the same problem. These choices are written down in the patients own words and are then scored on a seven point scale. The patient also scores general well-being. At the next follow-up the wording of the previously chosen items remain unchanged but

there is an optional fifth item for a new symptom. Follow-up questionnaires can be administered postally or during subsequent consultations.  
Original language: English.  
Other languages available: No.  
Validation: Yes (English).  
References: Paterson, C. Measuring outcome in primary care: A patient-generated measure, MYMOP, compared to the SF-36 health survey. *British Medical Journal* 312: 1016–1020 (1996).

#### **Visual Analogue Scale (VAS)**

Instead of verbal rating scales, a Visual Analogue Scale (VAS) can be used. A VAS is a 10 cm long line on which the patient rates how he/she is feeling. Only the endpoints are described, e.g. "No pain" up to "Worst thinkable pain".  
Assessment: Patient.  
Original language: English.  
Other languages available: No.  
Validation: Yes (pain).  
References: No.

As different outcomes measures are used in data collection projects having similar objectives, it will be difficult to compare the data, particularly with small sample sizes. For future projects, the DCG will offer advice how best to measure the desired outcomes depending on the research question being asked. In general, outcomes measures need to be reliable, valid and responsive to clinical changes. In multi-national studies, only validated translations of accepted outcomes measures should be used.

## **6. Quality of Life**

Quality of life is a term used to describe how a person feels and functions in his/her everyday life [Spilker 1996]. The measurement of a patient's quality of life is an important part of outcomes research as it focuses on the effectiveness of a medical intervention from the patient's perspective. One of the advantages is that it provides "additional information" about the clinical effectiveness of a treatment. For example, many interventions do not actually cure a disease or extend life expectancy, but they may significantly improve patient's quality of life or his/her ability to function. Quality of life measurements are therefore particularly useful when comparing treatments for chronic diseases. A range of questionnaires and rating scales have been developed to enable researchers to measure quality of life. Each instrument has its own main purpose. There are a variety of ways of categorising the instruments, but basically there are three main types each of which has advantages and disadvantages:

### *Preference-based measures*

Preference-based measures (also known as utility measures) can be used to assess the preferences of individuals for alternative health states or outcomes. They attempt to put a value on the patient's quality of life and measure how this is affected by a medical intervention. This approach is favoured by some health economists as the results can be used to influence public policy and resource allocation decisions.

### *General health profiles*

Like preference-based measures, general health profiles are generic in nature in that they can be used to measure the quality of life of patients with a range of diseases. If reference values are available, comparisons can also be made across diseases. A range of scales has been developed which cover many of the important areas (domains) of quality of life, such as physical, psychological, social, role functioning, ability for self-care, pain and general well-being. Examples of some general

health profiles include the Short Form 12 and 36 (SF-12, SF-36), the EQ-5D, the Sickness Impact Profile, the Nottingham Health Profile, and the Psychological General Well-Being Index (PGWB).

#### *Disease-specific measures*

Over the last few years, many different measures have been developed to assess a patient's quality of life for a specific disease or condition. The main advantage of these instruments over generic measures is that they are more sensitive to changes in the disease, and hence the chances of observing change is greater. Disease-specific measures are probably more acceptable to patients as they only ask questions relevant to the patient's condition.

Choosing a quality of life measure is not an easy task. There is no single, perfect instrument available for all situations. It is therefore advisable to seek expert advice in order to make sure that the most appropriate instruments are used based on the objectives of the data collection project and the desired outcomes. For example, if a value is required for a subsequent economic analysis, it may be necessary to include a preference-based measure. If quality of life data are primarily being collected as an additional measure of effectiveness, a general health profile and/or a disease-specific measure may be more appropriate. Indeed, as general health profiles and disease-specific measures both provide important, yet different information, it is becoming common to include both types of instruments. The choice of instrument will also be influenced by who is going to complete the questionnaire. In general, any measure needs to be reliable, valid and responsive to clinical changes, as well as acceptable to patients. It should always be used in its original, complete form and changes should not be made. In multi-national studies, only validated translations of accepted instruments should be used. Furthermore, some instruments are country specific and cannot be used elsewhere. If no appropriate measure appears to exist, the development of a new instrument may seem attractive. However, this is expensive and time-consuming, particularly if the instrument is needed in different languages.

## **7. Coding Systems**

In the data collection projects listed in section 3 different coding systems have been used for clinical diagnosis and concomitant medical problems. This makes it difficult to compare the data. The best solution would be to reach consensus on a single coding system. However, this is very difficult. In the following, the different coding systems used so far are described briefly giving some examples:

#### *International Classification of Diseases (ICD-10)*

The "International Statistical Classification of Diseases and Related Health Problems", published by the World Health Organisation (WHO) in 1989 has a 100-year-old history on its origins. Since 1986, the hospitals have implemented the prescribed diagnostic encoding with the ICD-9, which was published by the WHO in 1976 and is meanwhile obsolete. In 1997, the intended replacement of the ICD-9 through ICD-10 on January 1<sup>st</sup> 1998 was postponed by the Federal Ministry of Health due to temporal delay of translation of the ICD-10 as well as manifold difficulties with the transition of the ICD-9 into the ICD-10. In 1998, there was merely a modification of the encoding of certificates of deaths, changing from ICD-9 to ICD-10. The consequence is that different diagnostic classifications

are registered concerning morbidity and mortality which are only restrictedly comparable. In its current version, ICD-10 is the only accepted standard for the classification of diagnoses, symptoms and other medical treatment reasons world-wide. In the following, two examples of coding according to ICD-9 and -10 are given:

1. Acute respiratory syncytial virus bronchitis

ICD-9: Bronchitis, acute or subacute 466.0  
ICD-10: Bronchitis, acute or subacute  
Acute respiratory syncytial virus bronchitis J20.5

2. Migraine (idiopathic) with aura

ICD-9: Migraine (idiopathic)  
Migraine (idiopathic) with aura 346.0  
ICD-10: Migraine (idiopathic)  
Migraine (idiopathic) with aura G43.1

*International Classification of Primary Care (ICPC)*

In 1987, the World Organisation of National Colleges, Academies, and Academic Associations of General Practitioners/Family Practitioners (WONCA) published the first edition of the International Classification of Primary Care (ICPC). This is a tool for general practitioners and family doctors. The second edition of ICPC has been prepared for two main reasons: (1) To relate it to the ICD-10, and (2) To add inclusion criteria and cross referencing for many of the rubrics. ICPC-2 has been mapped to ICD-10 so that conversion systems can be used. Four general categories of diagnosis are used in primary care: Etiological, pathological, pathophysiological and nosological symptoms. There are 15 body or somatic systems, one psychological and one social chapter. The axis of the 17 chapters is characterised by a one-character alphanumeric code. The separation in three component groups, 1 for symptoms and complaints, 2 to 6 for procedures (2: Diagnostic, screening and preventive, 3: Medication, treatment, 4: Test results, 5: Administrative, 6: Referrals and other reasons for encounter), and 7 for diagnoses/diseases, corresponds to the general structure of the ICPC. The axis of the 7 components is represented by a two-figure numerical code. Both combined form a three-character global code. In the following, two examples of the coding according to ICPC are given:

1. Acute respiratory syncytial virus bronchitis

Chapter R – Respiratory  
Component 7 – Diagnosis/Diseases  
Acute bronchitis, bronchiolitis R78

Additional possible classifications:

Chapter R – Respiratory  
Component 1 – Symptoms and complaints  
Pain, respiratory system R01  
Cough R05

Chapter P – Psychological  
Component 1 – Symptoms and complaints  
Sleep disturbance P06

Chapter Z – Social problems  
Component 1 – Symptoms and complaints  
Compliance/being ill problem Z11

## 2. Migraine (idiopathic) with aura

Chapter N – Neurological  
Component 7 – Diagnosis/Diseases  
Migraine *N89*

Additional possible classification:

Chapter N – Neurological  
Component 1 – Symptoms and complaints  
Headache *N01*  
Pain, face *N03*  
Vertigo/dizziness *N17*

Chapter P – Psychological  
Component 1 – Symptoms and complaints  
Memory disturbance *P20*

Chapter Z – Social problems  
Component 1 – Symptoms and complaints  
Partner illness problem *Z14*

### *READ Clinical Classification*

The READ Clinical Classification began in 1982 when Dr James Read, a full time general practitioner, developed a simple set of mnemonic codes for his first computer to record conditions presented commonly in his practice. Over the next few years the number of codes and the sophistication of the file structure increased to produce one of the leading coding systems for the recording of clinical care. The READ Clinical Classification is a comprehensive list of terms intended for use by all health care professionals to describe the care and treatment of their patients. It is at least as detailed as, mapped to, and compatible with the most widely used standard statistical national and international classifications such as ICD-9, ICD-9-CM diagnoses and procedures, or ICPC. The READ Clinical Classification contains, at present, a nomenclature of 100.000 terms and a list of 150.000 synonymous terms. Synonyms are linked to their "preferred" term by a unique secondary or synonym code. Each term in the nomenclature has a definable load of lexical knowledge – i.e. knowledge "arcs" link each term to many related terms – and this represents our current knowledge about the term. The nomenclature uses alpha-numeric codes: 0-9, A-Z, a-z. The hierarchy is produced by partitioning the nomenclature into classes by the selected attribute, separating the classes into sub-classes with stepwise ranking of the concept until "terminal" terms are reached. The main chapters of the READ Clinical Classification covers: Clinical findings, operations, procedures and interventions, causes of injury and poisoning, administration, occupations, drugs or medical interventions, as well as appliances and equipment. Two examples of coding according to the READ Clinical Classification are listed below:

### 1. Acute respiratory syncytial virus bronchitis

Clinical findings  
Disorders  
Respiratory disorder  
Respiratory tract infection  
Infection of lower respiratory tract  
Acute lower respiratory tract infection  
Acute infective bronchitis  
Acute viral bronchitis  
Acute respiratory syncytial virus bronchitis *H060D*

Other coding options:

Clinical findings

- History and observations
  - Functional observations of respiratory tract
    - Observation of cough *Xa7n8*
  - General observation of patient
    - Temperature-associated observation
      - Shivering *XM00f*
  - Personal history observations *XaB3C*
  - Temporal observations
    - Date of onset *Xa6p0*
  - Family history observations
    - Family health history *Xa07V*

- Anatomical concepts
  - Human body structure
    - Bronchial structure
      - Bronchus
        - Lobar bronchus
          - Right lobar bronchus
            - Right superior lobar bronchus *X757J*

## 2. Migraine (idiopathic) with aura

- Clinical findings
  - Disorders
    - Neurological disorder
      - Headache disorder
        - Migraine
          - Migraine with aura
            - Migraine with typical aura *X007J*

Other coding options:

- Clinical findings
  - History and observations
    - Clinical history and observations
      - Neurological observations
        - CNS symptom *X75Z*
          - Observation of sensation
            - Observation of pain tolerance *Xa7MC*
  - Family history observations
    - Family health history *Xa07V*

The READ Clinical Classification, by its very nature dynamic system, has been developed further constantly by primary care practitioners. It is the commonly used computer coding system in the United Kingdom. It is also used by nurses, and non-medical staff can also be taught to code diagnoses. Although the READ Clinical Classification is based on orthodox medical diagnoses, it offers also codes for presenting complaints and many administrative aspects of primary care as well as links to the homeopathic case taking including the symptom pictures. As it is a complex scheme one problem is that different people choose different codes for the same problem, i.e. there is almost too much flexibility and there are too many options.

### *WISDOC Coding*

The WISDOC Coding has been developed by Peter König and Guy Sermeus. They decided not to use the ICD code as they felt that this does not meet the interests and philosophy of homeopathic practitioners. WISDOC Coding provides a long list of capital abbreviations which have been constructed in a logical fashion. It only takes a short amount of time to learn them and they can be written immediately, e.g. on the right-hand margin of the consultation notes and/or in a different colour for easier accessibility. The abbreviations of the indications are designed in such a way that the greatest possible clarity and distinctiveness is given by using Latin-Greek or English sources.

Users speaking different languages should be provided with much comprehensibility as possible. A small search index, which has been integrated into the system, can be used to simplify the translation of everyday homeopathic language into WISDOC Coding language. Particularly, whilst familiarising oneself with the system, creating individual abbreviations (and consequently individual access options) can be done at any time and is easy, however, at the cost of the new data's compatibility with the other data. It is important to find both clinical terms (e.g. HR-UR = haemorrhage/urinary) and homeopathic items (e.g. JEAL = jealousy) as well as to be able to build up groups of coding-items (e.g. "addiction"). There is a search-system integrated being capable of looking for the different possibilities of abbreviations ("indications") using one word to be searched for (e.g. "mamma"). It is possible (for those colleagues who type their patients' notes straight into the computer) to link up to and access a data processing programme with recorded data. In principle, it is assumed that the majority of practitioners using the system have hand-written notes, and that not only patients' cases that have been repertorised ought to be documented, or, to be precise, that rubrics selected for repertorisation contain only a portion of the information which would be useful for documentation. Out of a large amount of recorded data related to patients, i.e. consultation notes, it should be possible within a short time to establish the most important access criteria (terms which are appropriate for documentation, indications).

As a result, the question which coding system should be recommended is still open. An answer may be that everybody uses a coding system that he/she feels appropriate for his/her purpose. When someone has time and money, he/she can develop a computer programme translating the different coding systems. However, translations between READ, ICPC and ICD-9/-10 already exist.

## **8. Conduct and Management of a Data Collection Project**

### **8.1 Basic Principles**

The design and performance of the data collection project must be clearly formulated in an experimental protocol (study protocol). An outline of a protocol for a data collection project will be published in one of the next editions of the HomInt R&D NewsLetters. The protocol should be submitted to an ethics committee or institutional review board for approval. Like in any other research on human beings, each patient must be adequately informed about the aims, methods, anticipated benefits and potential hazards of the data collection project, and the discomfort it may entail. He/she should be informed that he/she is at liberty to abstain from participating in the project and that he/she is free to withdraw his/her consent to participation at any time. The practitioner should then obtain the patient's freely-given informed consent in writing.

In general, all parties involved in the data collection project should share the responsibility of accepting and working according to the standards of Good Clinical Practice (GCP) in mutual trust and confidence. Pre-established, systematic written procedures for the organisation, conduct, data collection, documentation and verification of the data collection project are necessary to ensure that the rights and integrity of the patients are thoroughly protected, to establish the credibility of data, and to improve the ethical, scientific and technical quality of the project. These procedures include

also good statistical design as an essential prerequisite for credibility of data. In order to ensure the best possible way of management according to good clinical practice detailed written instructions are applied: Standard Operating Procedures (SOPs). They provide a general framework enabling the efficient implementation and performance of all the functions and activities for a data collection project, e.g. identification and training of the investigators, study initiation visits, monitoring visits at the investigational site, reporting of adverse events, study termination visits etc.

## 8.2 Data Management

The Standard Operating Procedures used for data processing have also to be described in detail in the protocol. In the following, the requirements for data management using traditional paper case report forms (CRFs) are listed depending on the objective of the data collection project:

Table 2: Requirements for data management (x) using traditional paper case report forms (CRFs): Quality assurance (QA), treatment outcomes (TO), and economic outcomes (EO). Optional requirements (o).

	QA	TO	EO
Use validated data base system only. Each patient in the data base must be identified by an unambiguous unique code.	x	x	x
Ensure that all observations and findings are recorded <b>correctly and completely</b> in the CRFs and signed, according to the study protocol.	x	x	x
Corrections on the CRFs must not obscure the original entry. Corrected data must be inserted with reason, date, and signature of the investigator.	o	x	x
Confidential records must be retained by the investigator to allow the unambiguous identification of each patient.	x	x	x
Use double data entry technique (appropriate working instructions must be in place).	o	x	x
Appropriate measures (e.g. validated data base retrievals and/or monitor checks) should be taken to avoid overlooking of missing data and inconsistencies.	o	x	x
Appropriate measures must be taken to ensure the greatest possible accuracy when transforming data.	x	x	x
If data must be transferred into another system (e.g. statistical analysis package) during data processing, this must be documented and validated.	x	x	x
The sponsor must protect data against illegal data access.	x	x	x
The original CRFs as well as electronic records of the data (especially on adverse events) must be held as required according to Good Clinical Practice.	o	x	x

In the future, the increased use of information technology and computerised systems will no doubt increase our knowledge of patient outcomes. For example, in the United States many health care companies are already developing information systems to track patient outcomes over time and to analyse the data. The results are then used to change the way health care is delivered, with the overall aim of improving the effectiveness and quality of care provided to patients. In Europe, however, although there is a lot of discussion about the use of data networks and several pilot projects are underway, it will take many years before the health service is fully computerised in such a way that the patient management is improved. In an "ideal" world, practitioners, would enter the patient's details directly into a computerised system for data entry (remote data entry system). Such a system should fulfil the same requirements as listed in Table 2. In the following, additional requirements for data management using a remote data entry system are listed depending on the objective of the data collection project:

Table 3: Requirements for data management (x) using a remote data entry system: Quality assurance (QA), treatment outcomes (TO), and economic outcomes (EO). Optional requirements (o).

	QA	TO	EO
The remote data entry system must be validated. A detailed description of its use must be available and kept up-to-date.	x	x	x
Paper print-outs and electronic back-up records must be available in principle at every time during data processing.	o	x	x
Only authorised persons should have access to the system (e.g. electronic permit, passwords). Different access levels (e.g. data review, data entry) should be assigned to each person who has access to the system.	x	x	x
The remote data entry system should allow for corrections of the data after initial entry.	x	x	x
Working instructions must be in place for all personnel who have access to the system.	x	x	x
A record of all changes and corrections along with reason, date, and initials of the investigator must be available (audit file).	o	x	x
If data are transferred via telephone lines or the internet every effort should be made to protect data against illegal access (e.g. data encryption).	x	x	x
The remote data entry system needs to be user friendly and of clinical value.	x	x	x

## 9. Conclusion

There are different research methods available, from simple surveys to carefully planned prospective observational studies. It should be noted that the validity of the data, i.e. of the results, is closely linked to the research method chosen for a data collection project. Choosing the appropriate research method is not an easy task. In general, the research method must be appropriate and powerful enough to answer the research question. An important point which has to be addressed in each research project is that it is practically feasible. Particular attention should always be paid to find the right balance between what is scientifically desirable and practically feasible.

Including the outcomes research approach in a data collection project presents a major challenge: Public and private payers, hospitals and health organisations, practitioners, patients and the general public all have a stake in outcomes research. Outcomes research has come a long way, but it has a long way still to go. Considerable further research is required: Definitions of desired outcomes are needed in most disease areas, there is the necessity for agreement about the most appropriate ways of generating outcomes data, and better ways must be developed for measuring and valuing outcomes. Other areas of debate are the transformation of efficacy to effectiveness data, the implementation of practice guidelines for disease management and statistical issues. Even if the outcomes research approach is still in its infancy, it presents an ideal tool for the evaluation of homeopathy as a holistic therapy compared to conventional medicine. In addition, outcomes research also provides much of the information needed for disease management programmes.

This does not mean that we need only highly sophisticated research methods such as the outcomes research approach. We need all of them. Each method provides information at a specific level, however, we have to keep in mind that each method has its limitations. Another problem which occurs especially in practice-based research is the lack of time at the investigational site. Given the fact that each research project demands extra time from usually busy practitioners, each practitioner interested in research should carefully evaluate how much time he/she will be able to spend. As a first, humble step into the direction of research we recommend to start with the survey on homeopathy using the 10-item data set outlined in section 3.

Hopefully, this document creates a platform for discussions on practice-based research in homeopathy and stimulates further developments in this field. It is planned to update this document in regular intervals. It will also serve as a tool for data collection in homeopathic practice and future research in homeopathy.

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